

PROGENICS PHARMACEUTICALS INC  
Form 10-K/A  
October 22, 2003

[Click Here for Contents](#)

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

**FORM 10-K/A  
AMENDMENT NO. 1**

**(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, 2002  
or**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**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, zip code)

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

**Securities Registered pursuant to Section 12(b) of the Act: None**

**Securities Registered pursuant to Section 12(g) of the Act:**

Common Stock, par value \$0.0013 per share

(Title of Class)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). 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.

The aggregate market value of the voting stock held by non-affiliates of the registrant on March 26, 2003, based upon the closing price of the Common Stock on the Nasdaq National Market of \$4.64 per share, was approximately \$25,707,000.(1) As of March 26, 2003, 12,742,450 shares of Common Stock, par value \$.0013 per share, were outstanding.

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**DOCUMENTS INCORPORATED BY REFERENCE**

Part III □ Portions of the Registrant's definitive Proxy Statement with respect to the Registrant's Annual Meeting of Stockholders, to be filed not later than 120 days after the close of the Registrant's fiscal year.

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(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.

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[Back to Contents](#)

**TABLE OF CONTENTS**

PART I	1
Item 1. Business	1
PART II	40
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	40
Item 8. Financial Statements and Supplementary Data	46
PART IV	46
Item 15. Exhibits, Financial Statement Schedule and Reports on Form 8-K	46
INDEX TO FINANCIAL STATEMENTS	F-1
SIGNATURES	S-1
EXHIBIT INDEX	E-1

**Explanatory Note**

This Amendment No. 1 on Form 10-K/A (the "Amended 10-K") is being filed to reflect certain revisions and clarifications in Items 1, 7, 8 and 15 of our Form 10-K for the fiscal year ended December 31, 2002, filed on March 31, 2003 (the "Original 10-K"). The Amended 10-K speaks as of the filing date of the Original 10-K, except for the certifications which speak as of their respective dates and the filing date of the Amended 10-K. Except as specifically indicated, the Amended 10-K has not been updated to reflect events occurring subsequently to the filing of the Original 10-K.

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[Back to Contents](#)

## PART I

This Annual Report on Form 10-K/A contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include, but are not limited to, the uncertainties associated with product development, the risk that clinical trials will not commence or be completed when planned, the risks and uncertainties associated with dependence upon the actions of our corporate, academic and other collaborators, and of government regulatory agencies, the risk that products that appeared promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials and the other risks described in this report, including those described under the caption "Item 1. Business" Risk Factors.

### Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, or the Exchange Act. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, 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. The public can obtain any documents that we file with the SEC at <http://www.sec.gov>.

We also make available, free of charge, on or through our Internet website (<http://www.Progenics.com>) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

### Item 1. Business

#### GENERAL

##### Overview

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. We apply our expertise in immunology and molecular biology to develop biopharmaceuticals to fight viral diseases, such as human immunodeficiency virus ("HIV") infection, and cancers, including malignant melanoma and prostate cancer. In symptom management and supportive care, we are developing therapies to provide patients with an improved quality of life. Progenics' most clinically advanced product is methylnaltrexone ("MNTX"), a compound in phase 3 clinical testing that is designed to block the debilitating side effects of opioid analgesics without interfering with pain palliation. The Company is conducting multi-dose phase 2 clinical trials with its lead HIV product, PRO 542, a viral-entry inhibitor, and is in preclinical development with PRO 140 and other follow-on product candidates in HIV infection. The Company is developing cancer immunotherapies based on prostate-specific membrane antigen ("PSMA") technology and currently is conducting phase 1 clinical studies of a therapeutic prostate cancer vaccine. GMK is a cancer vaccine in phase 3 clinical trials for the treatment of malignant melanoma.

##### Product Development

We apply our expertise in clinical medicine, immunology, and molecular biology to develop novel therapeutics to meet unmet medical needs. Our principal programs are directed toward symptom management and supportive care, HIV infection, and cancer. In the symptom management and supportive care area, we have initiated a late-stage clinical development program for methylnaltrexone. MNTX is being tested in the clinic for the prevention or reversal of the debilitating side effects of opioid analgesics, and we expect to begin testing MNTX soon for treating post-operative bowel dysfunction. In the area of HIV infection, we are

[Back to Contents](#)

developing viral-entry inhibitors, molecules that inhibit the virus's ability to attach, bind or enter certain immune system cells. Our most advanced therapeutic product in this area is a genetically engineered molecule that functions as an antibody and selectively targets HIV for neutralization. We are also actively engaged in research, discovery, and preclinical development of compounds based on the primary HIV receptor, CD4, and the HIV co-receptor CCR5, and their roles in viral attachment, fusion and entry. In the case of cancer, we are developing monoclonal antibodies as well as therapeutic vaccines that are designed to induce specific immune responses to cancer antigens. Through our joint venture with Cytogen Corporation, PSMA Development Company LLC, we are pursuing in parallel programs for the development of monoclonal antibodies directed against PSMA and the development of vaccines designed to stimulate an immune response to PSMA.

We are actively seeking out other promising products and technologies around which to build development programs. Our in-licensing strategy has been the basis for our clinical development programs for MNTX, novel HIV therapeutics, and cancer immunotherapies. Except with respect to our development programs targeting PSMA, which are being conducted through our joint venture with Cytogen, we own the worldwide commercialization rights to each of our product candidates.

The following table summarizes the current status of our principal development programs and product candidates:

<b>Program/Product</b>	<b>Indication/Use</b>	<b>Status(1)</b>
<i>Symptom Management and Supportive Care</i>		
Methylnaltrexone	Reversing opioid side effects in patients with advanced medical illness	Phase 3; second phase 3 study expected to begin in 2003
	Treating post-operative bowel dysfunction	Phase 2 expected to begin in the first half of 2003
	Reversing opioid side effects in patients with chronic pain	Phase 1 expected to begin in the second half of 2003
<i>HIV Therapeutics</i>		
PRO 542 PRO 140	HIV therapy HIV therapy	Phase 2 multi-dose Preclinical; phase 1 expected to begin in 2004
CD4 attachment inhibitors and gp41 fusion inhibition ProVax	HIV therapy	Research
	HIV vaccine	Research
<i>Cancer Immunotherapeutics</i>		
GMK	Vaccine for melanoma	Phase 3 (Stages IIb and III disease) Phase 3 (Stage II disease)
PSMA(2): Vaccines	Immunotherapy for prostate cancer	rsPSMA vaccine in phase 1
	Immunotherapy for prostate cancer	Viral vector vaccine phase 1 expected to begin in 2004
Monoclonal antibody	Immunotherapy for prostate cancer	Phase 1 expected to begin in 2004

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

[Back to Contents](#)

□Preclinical□ means that a lead compound is undergoing toxicology, formulation and other testing in preparation for clinical trials. Testing in the research and preclinical phases is often referred to as *in vitro*, *in vivo* or *ex vivo*. *In vitro* refers to tests conducted in an artificial environment, such as a test tube or culture media, as opposed to *in vivo*, which refers to tests in animals or otherwise in a living body, or *ex vivo*, which refers to tests conducted outside the body on samples of blood or other tissue that have been removed from the patient.

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

□Phase 1□: Evaluation of safety.

□Phase 1/2□: Evaluation of safety with some measure of activity.

□Phase 2□: Evaluation of safety, dosing and activity or efficacy.

□Phase 3□: Larger scale evaluation of safety and efficacy.

See □Business□Government Regulation.□ The actual timing of events can vary dramatically relative to the expected timing described in the table above due to a variety of factors. See □□Risk Factors□Our clinical trials could take longer to complete than we expect.□

(2) Programs conducted through our joint venture with Cytogen Corporation.

### **Symptom Management and Supportive Care**

Opioids are the mainstay in controlling severe pain, with approximately 190 million prescriptions written annually in the U.S. To relieve pain, narcotic medications such as morphine, codeine, and other opioid derivatives interact with receptors that are located in the brain and spinal cord. Opioids also activate receptors outside the central nervous system resulting, in many cases, in undesirable side effects, including constipation, delayed gastric emptying, nausea and vomiting, pruritis (itching) and urinary retention. Reversing the peripheral side effects of opioid pain therapy, while maintaining pain relief, represents a major treatment dilemma and a large, unmet medical need.

#### *Methylnaltrexone*

In October 2001, we entered into an agreement with UR Labs, Inc. to obtain the worldwide exclusive rights to MNTX, an investigational drug in late-stage clinical development. MNTX is designed to reverse certain side effects of opioid pain medications and to treat post-operative bowel dysfunction. UR Labs licensed MNTX from the University of Chicago, where it was discovered. MNTX is designed to block opioids from activating the peripheral receptors in the body that cause side effects. As MNTX does not cross the blood-brain barrier in humans, it does not interfere with brain-centered pain relief.

MNTX has been studied in approximately 400 patients and volunteers in 15 clinical trials. Published studies and clinical trials to date have demonstrated that the compound was well tolerated and highly active in blocking opioid-associated side effects without interfering with analgesia.

In October 2001, we announced statistically significant positive results from a phase 2 clinical study of MNTX. Clinicians at the University of Chicago reported that administration of MNTX prevented morphine-induced bowel paralysis and reduced, in the aggregate, 12 common side effects of morphine. Investigators further reported that subcutaneous administration of MNTX produced clinical activity similar to that of intravenous or oral administration of the drug.

There are an estimated 1.2 million deaths in the U.S. each year associated with advanced medical illness, and the vast majority are treated with opioids for moderate-to-severe pain. Most of these patients experience constipation and other side effects. Laxatives and stool softeners have significant limitations in this setting.

In December 2002, we reported preliminary results from a phase 2b clinical trial of subcutaneous MNTX directed to the reversal of opioid-induced constipation in patients with advanced medical illness, particularly cancer. An analysis of the open-label portion of this multi-center study showed that patients were 2.6 times as likely to have a bowel movement within four hours after receiving the highest MNTX dose versus the lowest





[Back to Contents](#)

dose analyzed (67% versus 26%). There was also a significant dose-dependent laxation response to the four doses of MNTX used in the open-label portion of the study. Patients entering the clinical trial averaged 1.7 bowel movements per week, which increased to more than three laxations per week during the MNTX treatment phase. The preliminary results from the open-label portion of the phase 2b methylnaltrexone study confirmed and extended the findings obtained from 14 previous clinical studies. The complete results from the phase 2b study are scheduled to be fully analyzed and announced in the first half of 2003.

There have been no serious adverse events reported to date related to MNTX in the phase 2b trial. The most common side effects were flatulence and abdominal cramping, necessary physiological prerequisites to a bowel movement in patients with significant constipation. As in previous trials, no evidence of opioid withdrawal was observed in the phase 2b trial, and there was no increase in analgesic requirements.

Based upon the positive preliminary results of the open-label portion of the phase 2b study and the findings of prior clinical trials, we initiated a placebo-controlled phase 3 clinical study in December 2002 to evaluate the ability of single subcutaneous doses of MNTX to induce laxation within four hours. This clinical trial also includes a four-week open label phase wherein patients receive MNTX as requested. We also plan to expand the phase 3 program to include additional randomized, multi-dose trials of MNTX in 2003.

We also believe that preclinical studies and clinical results support expanded clinical testing of MNTX as a potential treatment for post-surgical bowel dysfunction, a paralysis of the gastrointestinal tract that frequently occurs after surgery and is accompanied by nausea, vomiting, and urinary retention. An estimated four million patients annually in the U.S. are at high risk for developing post-operative bowel dysfunction. We intend to initiate in the first half of 2003 a phase 2 clinical study of intravenous MNTX in post-operative bowel dysfunction.

We plan to pursue further the use of MNTX in the reversal of opioid-induced bowel dysfunction in ambulatory patients with chronic pain, including those suffering from headaches, arthritis, lower-back pain, sickle-cell disease, fibromyalgia, and other disorders. According to a national survey conducted for the American Pain Society and American Academy of Pain Medicine, approximately four million patients take opioids for chronic pain relief associated with various diseases and conditions. We expect to initiate in the second half of 2003 a phase 1 clinical trial with oral MNTX for bowel dysfunction in patients who must take opioids for chronic pain.

Given the extent of MNTX clinical testing completed or planned to date, we believe that we will be able to chart a development path that is designed for timely submission of this compound for regulatory consideration. Pending successful completion of clinical trials and medical and regulatory reviews, we believe that MNTX may be the first product candidate in our pipeline to be approved for marketing, which may occur as early as 2005. Furthermore, with our MNTX phase 3 clinical program well underway, we have recently initiated early stage discussions with a number of pharmaceutical companies concerning strategic partnering opportunities for MNTX. We have requested and expect to receive and review proposals in the first half of 2003, however no assurances can be given with respect to the nature of these proposals or whether any such proposal will result in a strategic partnership.

### **The Human Immune System**

The human immune system protects the body from disease by specifically recognizing and destroying invading viruses, bacteria and other pathogens. In addition, the immune system is capable of recognizing and eliminating from the body abnormal cells, such as cells infected with viruses and bacteria, and cancer cells. This recognition function relies on the immune system's ability to identify as foreign specific molecular configurations which are generically called antigens. White blood cells, particularly B and T lymphocytes, have the ability to recognize antigens made by infectious agents and abnormal cells and react to them. For example, B lymphocytes produce antibodies that recognize specific antigens. Antibodies are complex protein molecules that can bind to these antigens and neutralize or eliminate infectious agents and cancer cells.

Vaccines are designed to induce the production of antibodies against specific antigens on infectious agents and abnormal cells and thereby protect the body from illness. Although vaccines have historically been used prophylactically to prevent the contraction of an infectious disease, more recently vaccines are being



[Back to Contents](#)

developed as therapeutic agents to fight ongoing diseases. In addition, genetic engineering techniques have enabled the production of antibodies or antibody-like molecules in the laboratory. These genetically designed molecules are intended to mimic the body's own immune response and are administered in situations where the immune response has been suppressed or is otherwise inadequate.

### **HIV Therapeutics**

HIV infection causes a slowly progressive deterioration of the immune system which results in Acquired Immune Deficiency Syndrome or AIDS. HIV specifically infects cells that have the CD4 receptor on their surface. Cells with the CD4 receptor are critical components of the immune system and include T lymphocytes, monocytes, macrophages and dendritic cells. The devastating effects of HIV are largely due to the multiplication of the virus in these cells resulting in their dysfunction and destruction.

Viral infection occurs when the virus binds to a host cell, enters the cell, and by commandeering the cell's own reproductive machinery, creates thousands of copies of itself within the host cell. This process is called viral replication. Our scientists and their collaborators have made important discoveries in understanding how HIV enters human cells and initiates viral replication.

In the 1980s, our scientists demonstrated that the initial step of HIV infection involves the specific attachment of the virus to the CD4 receptor on the surface of human immune system cells. These researchers also showed that a specific glycoprotein, gp120, located on the surface of the virus, binds with high affinity to the CD4 receptor. Although these researchers demonstrated that binding to CD4 was necessary for HIV attachment, further discoveries have shown that attachment alone is not sufficient to enable the virus to enter the cell and initiate viral replication.

Subsequently, our scientists, in collaboration with researchers at the Aaron Diamond AIDS Research Center (ADARC), described in an article in *Nature* the discovery of a co-receptor for HIV on the surface of human immune system cells. This co-receptor, CCR5, enables fusion of HIV with the cell membrane after binding of the virus to the CD4 receptor. This fusion step results in entry of the viral genetic information into the cell and subsequent viral replication. These scientists further determined that the gp120 binding site on CCR5 is a discrete region at one end of the CCR5 molecule. Further work by other scientists has established the existence of a second co-receptor, CXCR4.

We have a letter agreement with ADARC 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. In addition, we previously had an arrangement with ADARC, not subject to a written agreement, pursuant to which ADARC provided services to us, including assistance with tests and studies of some of our leading HIV product candidates.

The HIV therapy research and development programs we are pursuing, alone and in collaboration with our academic and commercial partners, have been awarded \$3.6 million in National Institutes of Health grants and research contracts during 2002.

#### *Progenics' HIV Receptor Technologies*

Based on our participation in the discoveries of CD4 and CCR5, we are pursuing several approaches in the research and development of products designed to block entry of HIV into human immune system cells. Our PRO 542 product candidate and our viral-entry inhibition programs are based on the CD4 receptor, and our PRO 140 and HIV co-receptor/fusion programs are based on the CCR5 co-receptor.

Because HIV must first attach to the CD4 receptor to infect human cells, we believe that the part of the HIV gp120 glycoprotein that attaches to the CD4 receptor on immune system cells must remain constant across all strains of the virus. The gp120 glycoprotein is located on the exterior of HIV. PRO 542 incorporates a part of the CD4 receptor into genetically engineered molecules that function like antibodies and are designed to bind specifically to the gp120 glycoprotein of HIV. In *in vitro* tests, these molecules have demonstrated the ability to bind with high affinity to gp120 glycoproteins from a wide range of HIV strains, including the most prevalent strains. Our technology is targeted to a part of HIV that is believed to be necessary for the virus to enter cells. Mutation at this site would likely render the virus non-infectious, as it



[Back to Contents](#)

would be unable to attach and infect immune system cells. By targeting this attachment site of the virus, we believe that our technology may address the viral resistance seen with other HIV therapeutics caused by the high mutation rate of the virus.

In another program, we have developed a panel of monoclonal antibodies against CCR5 that have been shown to block the ability of HIV to infect cells isolated from healthy individuals by inhibiting virus-to-cell fusion. One of these monoclonal antibodies, which we have designated PRO 140, has been shown to inhibit HIV fusion *in vitro* at concentrations that have no apparent effect on the normal function of CCR5.

### *Target Market*

UNAIDS estimated that, as of the end of 2002, 42 million people worldwide were living with HIV. In high-income countries, 1.6 million people are infected and approximately 75,500 people were newly infected with HIV during 2002. Furthermore, reports from the National AIDS Programs stated that, as of June 2002, approximately 1.2 million people in North and South America were living with HIV. Since the late 1990s, many HIV patients have benefited from combination therapy of protease and reverse transcriptase inhibitors. Increasingly, after years of HAART (highly active anti-retroviral therapy), patients begin to develop resistance to these drugs. Our viral-entry inhibitors represent a potential new class of drugs for such patients.

### *Current Therapies*

At present, three classes of products have received marketing approval from the U.S. Food and Drug Administration (FDA), the agency that regulates new drug approvals in the United States, for the treatment of HIV infection and AIDS: reverse transcriptase inhibitors, protease inhibitors and entry inhibitors. Both reverse transcriptase and protease inhibitors block viral enzymes and have shown efficacy in reducing the concentration of HIV in the blood and prolonging asymptomatic periods in HIV-positive individuals, especially when administered in multi-drug combination.

While combination therapy slows the progression of disease, it is not a cure. HIV's rapid mutation rate results in the development of viral strains that are resistant to reverse transcriptase and protease inhibitors. The potential for resistance is exacerbated by interruptions in dosing which lead to lower drug levels and permit increased viral replication. Non-compliance is common in patients on combination therapies, since these drug regimens often require more than a dozen tablets to be taken at specific times each day. An additional problem is that many currently approved drugs produce toxic side effects in many patients, affecting a variety of organs and tissues, including the peripheral nervous system and gastrointestinal tract. These side effects may result in patients interrupting or discontinuing therapy.

### *Viral Entry Inhibitors*

Based on our pioneering research, we believe we are a leader in the discovery of viral entry inhibitors, a promising new class of HIV therapeutics. For the large number of patients who are failing conventional antiretroviral or combination therapy, viral entry inhibitors will likely become the next generation of therapy. Fuzeon (formerly referred to as T-20) is an entry inhibitor developed by Trimeris, Inc. in collaboration with F. Hoffmann-La Roche Ltd that was approved for marketing by the FDA in March 2003. PRO 542, PRO 140 and Fuzeon inhibit different steps in the sequence of events leading to the entry of HIV into target cells, and therefore may act synergistically in their ability to block HIV infection of healthy cells.

### *PRO 542: HIV Therapy*

We are developing PRO 542 for the treatment of HIV infection. PRO 542 is a proprietary antibody-like product with four binding sites for the gp120 glycoprotein on HIV. PRO 542 is designed to neutralize HIV through one of two mechanisms: (i) binding to the gp120 glycoprotein and thereby preventing infection of healthy cells; or (ii) binding to and detaching the gp120 glycoprotein from the virus.

In *in vitro* and *ex vivo* tests that we conducted in collaboration with scientists at the Aaron Diamond AIDS Research Center (ADARC) and the Centers for Disease Control and Prevention, PRO 542 neutralized a wide variety of clinical strains of HIV as well as viruses from the blood of HIV-positive individuals. In studies at

ADARC, PRO 542 protected severe-combined-immune-deficient mice transplanted

[Back to Contents](#)

with human peripheral blood lymphocytes against infection by the three HIV strains tested, including strains of the virus isolated from HIV-positive individuals.

We completed two dose-escalation phase 1/2 clinical trials of PRO 542 which were designed to measure the safety, pharmacokinetics, immunogenicity, and antiviral activity of PRO 542. Pharmacokinetic studies analyze how the body acts on a drug once the drug is administered and will determine, for example, how long the drug persists in the body. Immunogenicity studies analyze to what extent a patient's immune system mounts a response to the drug, which could impair the drug's ability to have its desired therapeutic effect and could, in some cases, have serious health consequences to the patient. Immunogenicity can be a serious problem, particularly for antibody-based drugs.

Our first dose-escalation clinical trial of PRO 542 was conducted in 15 HIV-positive adult patients at Mount Sinai Medical Center in New York City. Findings indicated peak and one-week serum concentrations of PRO 542 compared favorably with preclinical models, approximating drug levels previously shown to neutralize clinical HIV strains *in vitro*. Data from this trial demonstrated that in patients receiving the highest dosage of PRO 542, infectious HIV was reduced to undetectable levels for prolonged periods following treatment. Results from this trial also indicated that administration of a single dose of PRO 542 was able to produce a statistically significant reduction in viral load in patients treated with the highest dose. Viral load is the concentration of virus nucleic acid, or genetic material, in the blood and is a widely used indicator of infection levels. PRO 542 serum concentrations remained above HIV inhibitory levels for greater than one week. In addition, PRO 542 was well tolerated and non-immunogenic in all patients treated. We believe that these results support expanded clinical testing of this agent as a potentially non-toxic therapy for HIV infection.

The second dose-escalation phase 1/2 clinical trial was conducted in HIV-positive children at Baylor College of Medicine in Houston, the University of California at San Francisco, and the University of Pennsylvania by the AIDS Clinical Trials Group, a leading cooperative HIV research group supported by the National Institute of Allergy and Infectious Diseases. This trial was the first time PRO 542 was tested on children or in multiple doses. All patients treated demonstrated a decrease in viral load. Additionally, the drug was well tolerated by all patients tested. During 2000 we initiated, in cooperation with the Pediatric AIDS Clinical Trial Group (PACTG) of the National Institutes of Health, a new phase 2 trial to define the dose and frequency of administration of PRO 542 for HIV-infected children, including those resistant to available antiviral therapies.

We also determined in preclinical *in vitro* testing that the combination of PRO 542 and Fuzeon<sup>®</sup> demonstrated significantly enhanced anti-HIV activity in blocking the entry of HIV into healthy cells. In further preclinical *in vitro* studies, it was also shown that a "triple cocktail" of PRO 542, PRO 140 and Fuzeon, each of which inhibits a different step in the sequence of events leading to the entry of HIV into targeted cells, acted synergistically to block HIV infection of healthy cells. A scientific article regarding this research subsequently appeared in the *Journal of Infectious Diseases*.

In October 2001, we announced the results of preclinical studies that demonstrated that PRO 542 possesses potent antiviral activity when given by multiple routes of administration, including subcutaneous injection. The studies demonstrated that PRO 542 reduced viral load to undetectable levels in a well-recognized animal model of HIV infection and may point the way towards simplified dosing regimens in man.

In June 2001, we entered into an agreement with Formatech, Inc., to assist in the development of improved product formulations for subcutaneous and intramuscular delivery of PRO 542. This agreement is subject to expansion based on the results and successful completion of the first phase of the product formulation work.

During 2002, two major milestones in the PRO 542 clinical program were achieved. We identified a target population of patients who are most likely to benefit from PRO 542, those with advanced disease, and we established clinical proof-of-concept that infrequent dosing with PRO 542 yielded prolonged viral-load reduction. In September 2002, we reported final results from a phase 2 clinical trial of PRO 542, which showed that this monoclonal antibody-like molecule reduced plasma concentrations of HIV in infected





[Back to Contents](#)

individuals who were no longer responding to currently available antiretroviral medications. In these treatment-experienced patients, a single dose of PRO 542 reduced viral concentrations in the blood by 60% to 80% on average. The viral-load reductions were sustained throughout the six-week follow-up period, and no serious side effects were observed. Additional findings from this phase 2 clinical trial of PRO 542, announced in February 2003, indicate that the magnitude of viral load reductions were correlated strongly with viral susceptibility to PRO 542 prior to drug treatment, as measured by the PhenoSense<sup>®</sup> HIV Entry assay from ViroLogic, Inc. We believe that viral-resistance testing may identify patients who will derive the greatest benefit from therapy with HIV entry inhibitors. In addition, patient viruses collected six weeks after treatment initiation showed no evidence of having developed resistance to PRO 542.

Achieving sufficient supplies of PRO 542 has been an on-going challenge. In February 2000, we entered into a development and supply agreement with Genzyme Transgenics Corporation, continuing the collaboration we commenced in September 1997. The objective of this program was to develop a transgenic source of PRO 542 using Genzyme Transgenics<sup>®</sup> proprietary technology. This collaboration was designed to result in commercial-scale manufacture by producing PRO 542 in the milk of transgenic goats. The expanded agreement was entered into upon the completion of transgenic feasibility studies conducted by Genzyme Transgenics. During 2001, the first transgenic goats containing the PRO 542 gene were born. However, the development of transgenic animals that express adequate concentrations of PRO 542 in their milk in sufficient volumes to make it commercially viable has continued to take longer than expected. We are conducting an ongoing examination of the merits of this project and the results achieved to date and expect to make a determination of its future viability in 2003.

During the course of 2002, we devoted concentrated efforts both internally and with third-party collaborators to enhance our ability to supply adequate quantities of PRO 542 for our clinical program through the creation a high-producing genetically engineered PRO 542 cell line and to expanding our internal manufacturing capabilities. In March 2003, we entered into an agreement with Gala Design, Inc. to create a high-producing genetically engineered cell line that expresses PRO 542. Additionally, we are preparing to install a 1,000-liter bioreactor that will utilize the new cell line to increase productivity. This facility, which we expect will be operational during 2004, is designed to provide us with an additional source of PRO 542 in support of our clinical program. The investment in cell-line development provides us with a viable strategic alternative to our reliance on transgenic goats as a source of PRO 542.

We are presently conducting a multi-dose open-label phase 2 clinical study of PRO 542 in the advanced disease setting in patients who are no longer responding to currently available anti-retroviral medications. Patients are receiving three intravenous doses of PRO 542 per week for three weeks. The goal of the study is to determine if repeat dosing can induce sustained viral load reductions beyond the 60% to 80% range seen in the single-dose phase 2 study. Sustained reduction in viral load is a primary goal of HIV therapy. Results from this study are expected in early 2004.

Our phase 2 clinical program also includes studies that employ repeated subcutaneous dosing of PRO 542. In these studies, we intend to use the PhenoSense<sup>®</sup> HIV Entry assay to select for those patients harboring the most sensitive viruses to PRO 542 neutralization. In July 2002, we announced an agreement with ViroLogic, Inc., to use their proprietary HIV resistance-testing technology, the PhenoSense<sup>®</sup> HIV Entry assay, in the development of PRO 542 and PRO 140, our second experimental viral entry inhibitor.

Additional clinical trials may include treating patients with PRO 542 in combination with Fuzeon<sup>®</sup>. The initiation of such studies will depend on the commercial availability of supplies of Fuzeon for use in clinical trials. In preclinical studies, PRO 542 and Fuzeon were shown to be synergistic in inhibiting HIV, as each drug was designed to block the virus in a different manner before it enters the human immune cells.

#### *PRO 140: HIV Therapy*

In May 1999, we announced the development of a panel of proprietary anti-CCR5 monoclonal antibodies created at Progenics and evaluated in collaboration with the Aaron Diamond AIDS Research Center. These antibodies are designed to block the ability of HIV to infect cells isolated from healthy individuals by inhibiting virus-cell fusion, an approach not targeted by current HIV therapies. One murine monoclonal antibody, which we have designated PRO 140, inhibited HIV infection at concentrations that had no apparent



[Back to Contents](#)

effect on the normal function of CCR5. We believe that these properties were correlated with PRO 140's ability to bind to a distinct site on CCR5 that does not interfere with the normal receptor function of CCR5. Effective April 1999, we entered into a development and license agreement with Protein Design Labs, Inc. (PDL), for the development of a humanized version of PRO 140 that retains the antibody's antiviral activity but is more suitable for chronic use in humans.

We subsequently announced in 2000 the findings from a preclinical study carried out in collaboration with ADARC in which PRO 140 potently blocked each of 17 primary HIV isolates that use CCR5 as a fusion co-receptor. These viruses are typical of those associated with person-to-person transmission of HIV and predominate during the early stages of infection, when antiviral therapies have proven to be most effective. PRO 140 was shown in these *in vitro* models to be effective at protecting both primary T-cells and macrophages, immune system cells that provide the major targets for HIV infection *in vivo*. We also announced in 2000 the results of preclinical *in vitro* studies where it was shown that a "triple cocktail" of PRO 542, PRO 140 and Fuzeon, each of which inhibits a different step in the sequence of events leading to the entry of HIV into targeted cells, acted synergistically to potently block HIV infection of healthy cells.

We achieved further advancements in the development of PRO 140, which were announced during the course of 2001. In January 2001, the publication of a scientific article in the *Journal of Virology* described how PRO 140 demonstrated potent, broad-spectrum antiviral activity against more than 40 genetically diverse "primary" HIV viruses isolated directly from infected individuals *in vitro*. In April 2001, we announced that single doses of a murine-based PRO 140 reduced viral burdens to undetectable levels in a well-recognized animal model of HIV infection. In mice treated with PRO 140, initially high HIV concentrations became undetectable for up to nine days after a dose of the experimental drug.

Later in 2001, we also reported that we had elucidated the molecular basis for the synergistic antiviral activity observed for HIV entry inhibitors PRO 542, PRO 140 and the fusion inhibitor Fuzeon. The multi-step nature of HIV entry into cells — attachment, co-receptor binding and fusion — may leave the virus susceptible to inhibition by combinations of drugs that act at different stages of the process. In laboratory studies, the drug combinations provided a synergistic activity whereby actions of the first drug (PRO 542 or PRO 140) temporarily immobilizes the virus and "holds" it in a way that makes it more susceptible to the second drug (PRO 140 or Fuzeon). Preclinical studies also demonstrated that HIV failed to develop resistance to PRO 140 despite 40 weeks of continued exposure to the drug. This period is considerably longer than that required for HIV to develop resistance to other classes of antiviral agents in similar laboratory studies.

Additionally, in December 2001, we further reported that multiple doses of PRO 140 reduced and then maintained viral loads at undetectable levels for the duration of therapy in an animal model of HIV infection. Sustaining undetectably low levels of virus in the blood is a primary goal of HIV therapy.

In February 2002, we announced that we had selected a humanized form of the PRO 140 antibody for clinical testing. Unlike its mouse-based predecessor, humanized PRO 140 is designed to be suitable for repeat dosing in humans. Humanization of the PRO 140 monoclonal antibody was accomplished under our collaborative agreement with Protein Design Labs, Inc. entered in April 1999. We expect to file an Investigational New Drug Application with the FDA for humanized PRO 140 in early 2004. We plan to use ViroLogic's PhenoSense HIV Entry assay to select for patients harboring the most sensitive viruses to PRO 140 inhibition.

## **Small-Molecule Drugs**

### *Co-Receptor/Fusion: HIV Therapy*

Our HIV co-receptor programs are based on the CCR5 co-receptor and the important role the molecule plays in virus-to-cell fusion and subsequent viral replication. CCR5 belongs to a larger family of cellular receptors, known as seven-transmembrane G-protein-coupled receptors. These receptors have been successfully exploited as targets by commercialized therapeutic drugs addressing a wide range of human diseases. Additionally, studies have indicated that a naturally occurring genetic mutation that disables the CCR5 co-receptor prevents HIV infection without compromising immune function. For these reasons, we believe that our co-receptor/fusion technology offers significant commercial opportunities.



[Back to Contents](#)

We have developed proprietary fusion assays based on our HIV co-receptor technology. These assays model fusion of HIV with human cells rapidly, automatically, sensitively and without the use of infectious virus. In December 1997, we entered into a collaboration with the Roche Group of Basel, Switzerland to use these assays to discover and develop small-molecule HIV therapeutics that target the fusion co-receptors, including CCR5 and CXCR4.

Subsequently we reported, in February 2002, the identification of small-molecule CCR5 inhibitors with novel antiviral properties, which were identified under this collaboration with the Roche Group, using our proprietary approach to identifying CCR5 inhibitors. The compounds potently and specifically blocked HIV entry in multiple laboratory studies. In addition, these compounds had little or no effect on the normal function of CCR5.

In March 2002, Roche exercised its right to discontinue funding of the research being conducted under this agreement. Discussions conducted with Roche subsequent to this decision resulted in an agreement by which we gained the exclusive rights to continue the research and development of these small molecule CCR5 inhibitors identified during our collaborative effort and to their commercialization, subject to certain reservations of rights in favor of Roche. (*See Corporate Collaborations*)

In March 2000, we entered into a research and license agreement with Pharmacoepia, Inc. to discover small molecule HIV therapeutics that block the attachment of the virus to its primary cellular receptor, CD4. This agreement expanded on a collaboration with Pharmacoepia commenced in September 1997. Under the terms of this agreement, we have provided proprietary CD4 attachment assays and expertise related to the interaction between HIV and CD4, and Pharmacoepia is engaging in a screening program of its internal compound library. In August 2000, we expanded our collaboration with Pharmacoepia to add two additional programs, including one program directed to the HIV envelope glycoprotein gp41. Under the terms of the Agreement we are entitled to an exclusive, royalty-bearing license to active compounds identified in these programs.

In November 2001, we were awarded approximately \$600,000 from the National Institutes of Health (NIH) for the development of novel inhibitors of HIV entry and infection. Entry inhibitors are a promising new class of HIV drugs that may offer significant benefits in both safety and efficacy over currently available HIV therapies. The grant supports an ongoing collaboration between Progenics and Pharmacoepia, Inc. to develop orally available small-molecule inhibitors of the HIV envelope glycoprotein gp41, which mediates fusion and entry of HIV into cells of the human immune system. The project combines Pharmacoepia's proprietary, high-throughput assays with screening technologies developed at Progenics for identifying fusion inhibitors. Pharmacoepia has utilized these technologies to screen its libraries of several million novel, drug-like compounds, and screening of other libraries is underway for other undisclosed targets. We continue to assess the results of this collaboration as they become available.

#### *Sulfated Peptides*

In collaboration with ADARC, we have identified specific naturally-occurring chemical modifications to CCR5 that govern its binding to HIV. Synthetic peptides incorporating these modifications potently blocked the binding of HIV to CCR5 on the cell surface. The modified CCR5 co-receptor peptides also inhibited certain HIV strains from entering target cells *in vitro*. The modified CCR5 co-receptor peptides may constitute a new class of HIV fusion inhibitors and also may provide a tool for identifying small-molecule drugs that target CCR5. Our subsequent preclinical work on these modified CCR5 peptides with our academic collaborators at Albert Einstein College of Medicine, resulted in the identification of the specific binding site for HIV on CCR5, the selection of a lead therapeutic sulfated CCR5 peptide and the identification of a sulfated CCR5 peptide that was only nine amino acids long yet was the core structure recognized by HIV in its bid to gain entry into a cell. Scientists from Progenics and the Albert Einstein College of Medicine reported these later findings in the *Journal of Virology*.

Given the focus of our efforts on our other more advanced programs, we have at this time scaled back our internal work directed to the development of sulfated peptides and are currently examining strategic alternatives relating to our progress achieved in such program to date.



[Back to Contents](#)

### *ProVax: HIV Vaccine*

We are conducting research with respect to our ProVax vaccine, a vaccine candidate which we believe may be useful as a prophylactic for uninfected individuals and/or as a therapeutic treatment for HIV-positive individuals. We are currently performing government-funded research and development of the ProVax vaccine in collaboration with the Weill/Cornell Medical College.

Prophylactic HIV vaccines, which are under development by companies and academic laboratories worldwide, are designed to work by eliciting antibodies that target viral surface proteins and neutralize the virus. The surface of HIV is studded with envelope spikes that consist of three copies each of the gp120 and gp41 glycoproteins in a trimeric configuration. These envelope trimers mediate entry of the virus into immune system cells. Blocking this viral-entry process thus impedes infection. However, the instability of the natural form of the trimer complex in the laboratory has been a major obstacle to the creation of a vaccine, as the dissociated components, monomeric gp120 and gp41, do not reliably elicit antibodies that neutralize circulating strains of HIV.

We are developing two novel strategies for producing the stabilized gp120/gp41 proteins in their native trimeric form. The first approach involved modifying the gp120 glycoprotein to enhance trimer stability, whereas the second method employed modifications to gp41. Importantly, the trimers can be isolated in homogenous form, as required for use in a vaccine. A vaccine containing the trimeric structure of HIV surface proteins may be crucial to eliciting an immune response able to neutralize the virus in humans.

In 2002, we announced the development of vaccine candidates that contain critical surface proteins whose form closely mimics the structures found on the virus. The findings were described in articles in the *Journal of Virology*.

### **Cancer Immunotherapy**

Cancer is a category of diseases, each of which is characterized by aberrations in cell growth and differentiation. The establishment and spread of a tumor is a function of its growth characteristics and its ability to suppress or evade the body's normal defenses, including surveillance and the elimination of cancer cells by the immune system. Eradication of malignant cells that can metastasize, or spread, to vital organs, leading to death, is central to the effective treatment of cancer.

Despite recent advances in treatment, therapies for many types of cancer suffer from serious limitations. The principal therapies for cancer have historically been surgery, radiation and chemotherapy. A significant drawback to conventional anti-cancer therapy is that both occult, or hidden, and residual disease is difficult or impossible to eliminate fully, which can lead to relapse.

### *GMK: Therapeutic Vaccine for Malignant Melanoma*

GMK is a proprietary therapeutic vaccine for melanoma that is currently in two pivotal phase 3 clinical trials. GMK, which is the first cancer vaccine based on a defined cancer antigen to enter phase 3 clinical trials, is designed to prevent recurrence of melanoma in patients who are at risk of relapse after surgery. GMK is composed of the ganglioside GM2 conjugated to the carrier protein keyhole limpet hemocyanin, or KLH, and combined with the adjuvant QS-21. QS-21 is a compound in the Stimulon family of adjuvants developed and owned by Aquila Biopharmaceuticals, Inc., a wholly owned subsidiary of Antigenics, Inc. GMK is designed to stimulate the immune system to produce specific antibodies to the ganglioside antigens. These antibodies have been shown *in vitro* to recognize and destroy cancer cells. Based on the *in vitro* results and the clinical trial results described below, we believe that vaccination of cancer patients with ganglioside conjugate vaccines may delay or prevent recurrence of cancer and prolong overall survival.

### *Target Market*

Melanoma is a highly lethal cancer of the skin cells that produce the pigment melanin. In early stages, melanoma is limited to the skin, but in later stages it can spread to the lungs, liver, brain and other organs. The National Cancer Institute (NCI) estimated that in 1999 there were 480,000 melanoma patients in the U.S. The American Cancer Society estimates that there were 53,600 new cases of melanoma diagnosed in the





[Back to Contents](#)

U.S. during 2002. Melanoma accounts for 4% of skin cancer cases, but 79% of skin cancer deaths. Melanoma has one of the fastest growing incidence rates of any cancer in the U.S. Increased exposure to the ultraviolet rays of the sun may be an important factor contributing to the increase in new cases of melanoma.

GMK is being developed for the treatment of patients with Stage II or Stage III melanoma. The American Cancer Society estimates that approximately 50% of new melanoma patients are diagnosed with Stage II or Stage III melanoma and that approximately half of all Stage III melanoma patients will experience recurrence of their cancer and die within five years after surgery.

### *Current Therapies*

Standard treatment for melanoma patients includes surgical removal of the cancer. Thereafter, therapy varies depending on the stage of the disease. For Stage I and II melanoma patients, treatment generally consists of close monitoring for recurrence. The only approved treatment for Stage III melanoma patients is high-dose alpha-interferon. However, treatment with high-dose alpha-interferon causes substantial toxicities, requires an intensive treatment over twelve months (intravenous administration five-days-a-week for the first month followed by subcutaneous injections three-days-a-week for the remaining eleven months).

Other approaches for treatment of Stage II or III melanoma patients are currently under investigation, but none has been approved for marketing in the U.S. These experimental therapies include chemotherapy, low-dose alpha-interferon, and other vaccines.

### *Clinical Trials*

GMK entered a pivotal phase 3 clinical trial in the United States in August 1996. A pivotal clinical trial is one that is designed to produce results sufficient to support regulatory approval. GMK was administered in this study on an out-patient basis by 12 subcutaneous injections over a two-year period.

This ongoing U.S. phase 3 clinical trial compares GMK with high-dose alpha-interferon in Stage IIb (advanced Stage II) and Stage III melanoma patients who have undergone surgery but are at high risk for recurrence. This randomized trial, which exceeded its targeted enrollment of 851 patients by September 1999, has been conducted nationally by the Eastern Cooperative Oncology Group (ECOG) in conjunction with the Southwest Oncology Group (SWOG) and other major cancer centers, cooperative cancer research groups, hospitals and clinics. ECOG and SWOG are leading cooperative cancer research groups supported by the National Cancer Institute and are comprised of several hundred participating hospitals and clinics, primarily in the United States. The primary endpoint of the U.S. trial is a comparison of the recurrence of melanoma in patients receiving GMK versus patients receiving high-dose alpha-interferon. Additionally, the study is designed to compare quality of life and overall survival of patients in both groups.

In May 2000, as a result of an unplanned early analysis of a subset of the 880 patients enrolled in the trial, ECOG recommended to clinical investigators participating in the trial that they discontinue administering GMK. ECOG's decision was based on its early analysis of data from the subset group which, according to ECOG, showed that the relapse-free and overall survival rates for patients receiving the GMK vaccine were lower than for patients receiving high-dose alpha-interferon.

As a result of the actions of ECOG, the trial did not complete patient dosing as contemplated by the initial trial protocol. Despite ECOG's action, we extended our clinical trial to allow those patients who so elected, with the advice of their treating physicians, to complete the full dosing protocol. We continue to monitor all patients in the trial until its scheduled completion as contemplated by the initial trial protocol. This action has been taken with the knowledge of the FDA and the various institutional review boards at the clinical sites affected. We refer to [extending] the trial in this manner as an [extension study.] ECOG is assisting us in continued patient follow-up and data compilation. We are planning to meet with the FDA in 2004 to finalize the method of analysis for this study. Given recent FDA actions on similar product candidates, we are considering amending our statistical plan for this study to compare median 5.5 year survival between the two treatment groups. We anticipate reaching median 5.5 year survival in late 2003 and would plan to perform the final analysis in 2004.

While all patients received at least a portion of the planned dosing, only about one-half of the patients received the full number of doses of GMK. We believe that the likely potential outcomes of the ECOG trial



[Back to Contents](#)

as supplemented by the extension study are as follows: if the data are good, the data could support a filing with the FDA for marketing approval; if the data are not good or inconclusive, they would not support a marketing approval and further studies would be required.

In May 2001, we initiated a large international phase 3 clinical trial of the GMK vaccine to prevent the relapse of malignant melanoma, the deadliest form of skin cancer. The study is being conducted with the EORTC (European Organization for Research and Treatment of Cancer), Europe's leading cancer cooperative group. The EORTC phase 3 trial expects to enroll 1,300 patients who are at intermediate risk for recurrence of the disease. The study is recruiting patients from Europe, as well as Australia. EORTC will randomize patients after surgery to receive either GMK or the current standard of care, which is no treatment but close monitoring. Patients on the vaccine arm of the study will receive 14 doses of GMK over three years, with an estimated two years of additional follow-up. The primary endpoint of this trial is to compare the recurrence of melanoma in patients receiving GMK versus in patients receiving observation with no treatment. The study will also compare overall survival of patients in both groups. Patient accrual for this study has proceeded more slowly than anticipated due to regulatory delays, however, at present we expect to enroll all 1,300 patients by mid-2005.

#### *MGV: Therapeutic Vaccine for Certain Cancers*

MGV is a proprietary therapeutic vaccine for cancers which express GD2 or GM2 gangliosides. These cancers include colorectal cancer, lymphoma, small cell lung cancer, sarcoma, gastric cancer and neuroblastoma. MGV has three components: (i) GM2-KLH, or GM2 ganglioside conjugated to KLH; (ii) GD2-KLH, or GD2 ganglioside conjugated to KLH; and (iii) QS-21 adjuvant. MGV is designed to prevent recurrence of cancer and prolong overall survival of patients after their cancer has been removed by surgery or reduced by chemotherapy or radiation therapy.

MGV completed a phase 1/2 clinical trial in 2000 under an institutional IND at Memorial Sloan-Kettering Cancer Center (MSKCC). This study, which had as its primary objectives the establishment of the safety of MGV and the ability of the vaccine to induce specific immune responses to both GD2 and GM2, showed that the combination of GM2-KLH/GD2-KLH/QS-21 could produce antibodies to GM2 and GD2 and was well tolerated. We announced, in January 2001, the publication of MGV clinical trial results in the journal *Clinical Cancer Research*. Specifically, MGV induced antibodies to the GM2 ganglioside in 97% of patients. In addition, 91% of patients who received an optimal dose of the vaccine also developed antibodies to GD2. The study demonstrated that for the first time in cancer patients that it is possible to induce antibody responses to two gangliosides using a bivalent vaccine.

Due to our increased focus on its more advanced programs, internal work directed to the development of MGV has been scaled back at this time. However, with our support our collaborators at MSKCC continue to evaluate an optimized GD2 vaccine component through additional phase 1/2 studies.

#### *PSMA*

Prostate cancer is the most common form of cancer affecting U.S. males and is the second leading cause of cancer deaths in men each year. The American Cancer Society estimates that 30,200 men will die from prostate cancer, and 189,000 new cases were diagnosed, in 2002. Conventional therapies include radical prostatectomy, in which the prostate gland is surgically removed, radiation and hormone therapies, chemotherapy and "watchful waiting." Surgery and radiation therapy are associated with urinary incontinence and impotence. Hormone therapy and chemotherapy are generally not intended to be curative and are not actively used to treat localized, early-stage prostate cancer.

Through PSMA Development Company LLC (the "Joint Venture"), our joint venture with Cytogen Corporation, we are engaged in a research and development program relating to vaccine and antibody immunotherapeutics based on Prostate Specific Membrane Antigen ("PSMA"). PSMA is a protein that is abundantly expressed on the surface of prostate cancer cells, but not normal cells. We believe this antigen may have applications in immunotherapeutics for prostate cancer and potentially for other types of cancer. In December 2001, the Joint Venture announced that it had characterized the native molecular structure of

[Back to Contents](#)

PSMA, a finding that may have fundamental implications for development of prostate cancer immunotherapies.

In December 2002, the Joint Venture announced the initiation of a phase 1 clinical trial with its novel therapeutic recombinant soluble PSMA (rsPSMA) vaccine, which is designed to stimulate a patient's immune response system to recognize and destroy prostate cancer cells. The vaccine combines the PSMA cancer antigen with an immune stimulant to induce an immune response against prostate cancer cells as foreign and to eliminate them. The genetically engineered PSMA vaccine generated potent immune responses in preclinical animal testing. This clinical trial is the first of a series designed to elicit potent and durable immune responses to PSMA. The clinical trial is designed to evaluate the safety and immune-stimulating properties of the vaccine in patients with either newly diagnosed or recurrent prostate cancer.

In October 2002, the Joint Venture also announced that it had been awarded approximately \$1 million from the National Cancer Institute of the National Institutes of Health ("NIH") for the development of novel immunotherapies for prostate cancer. The funding comes from four Phase I Small Business Innovation Research ("SBIR") grants for therapies that use components of the immune system to target cancer cells for destruction. Funding is intended to support development of monoclonal antibodies and therapeutic vaccines directed against PSMA.

Two of the grants will support production and preclinical development of lead vaccine candidates, a purified protein vaccine and a viral-vector vaccine. The projects seek to optimize two vaccines, first individually and then eventually in novel "prime-boost" combinations. In these latter studies, the immune system is "primed" with a first vaccine and then "boosted" with a second vaccine in a manner that induces an optimal balance of killer T cells and antibodies capable of eliminating PSMA-expressing prostate cancer cells. The two additional grant awards will support the preclinical development of anti-PSMA monoclonal antibodies for the treatment of prostate cancer. The projects will explore the development of the antibodies both in unlabeled form and labeled with alpha- and beta-emitting radioisotopes.

We are also pursuing, in parallel, a vaccine program that utilizes novel and proprietary viral vectors designed to deliver the PSMA gene to the immune system in order to generate potent and specific immune responses to the prostate cancer cells. PSMA-based immunotherapy is designed to destroy cancer cells while sparing healthy tissue. In September 2001, the Joint Venture entered into a worldwide exclusive licensing agreement with AlphaVax Human Vaccines, Inc., to use the AlphaVax Replicon Vector ("ArV") system to create a therapeutic prostate cancer vaccine incorporating the PSMA antigen. Preclinical studies of this viral-vector prostate cancer vaccine generated a potent dual-immune response against PSMA, yielding both antibodies and killer T cells, the two principal mechanisms used by the immune system to eliminate abnormal cells. We are completing our preclinical development activities on the PSMA ArV vaccine in anticipation of phase 1 clinical studies in 2004.

The Joint Venture has also developed a new generation of novel murine monoclonal antibodies which identify and bind to the three-dimensional structure of PSMA as presented on cancer cells. These antibodies represent potentially excellent candidates for therapy development since they possess a higher affinity and specificity for PSMA than antibodies that do not recognize the physical structure of the target antigen. The Joint Venture entered a collaboration with Abgenix, Inc. in March 2001 to use the company's XenoMouse technology for generating fully human antibodies to PSMA and subsequently announced the successful creation of these human antibodies to PSMA. Subsequently in May 2002, we announced that we had selected a monoclonal antibody that targets PSMA as a clinical candidate for development as a novel therapy for prostate cancer. The high-affinity antibody was produced under our collaboration with Abgenix. Clinical trials in prostate cancer patients of a human monoclonal antibody to PSMA are expected to begin in 2004.

In November 2002, we reported that fully human monoclonal antibodies substantially reduced tumor growth in an animal model of human prostate cancer. These antibodies demonstrated the ability to selectively deliver a lethal payload to cells that expressed PSMA on their surface. We are in the process of selecting the optimal toxin and radioactive payloads in parallel with producing clinical-grade antibodies. We expect to begin phase 1 clinical studies with this antibody in 2005.

[Back to Contents](#)

### **Stroke: DHA**

We licensed from Memorial Sloan-Kettering Cancer Center patent rights and technology relating to a derivative of vitamin C called dehydroascorbic acid, or DHA. We have obtained exclusive worldwide rights to use DHA for treatment of disease involving oxidative damage to tissue, including tissues of the central nervous system. In preclinical studies conducted in an animal model of human stroke, DHA demonstrated significant dose-dependent decreases in brain damage, neurological deficits, and death caused by stroke when administered as long as three hours after a stroke.

While we continue with certain preclinical research and activities in conjunction with our academic collaborators at Columbia University, we are also examining our overall strategic alternatives in the DHA program to date.

### **Corporate Collaborations**

#### ***Roche Group***

In December 1997, we entered into a collaboration agreement with the Roche Group of Basel, Switzerland to discover and develop novel HIV therapeutics that target the fusion co-receptors CCR5 and CXCR4. This collaboration, among other things, provided for Roche to apply its library of small-molecule compounds to our original screening assays in order to identify inhibitors of the interaction between HIV co-receptors and HIV.

Subsequently, in March 2002, Roche exercised its right to discontinue funding of the research being conducted under this agreement. Discussions conducted with Roche during the course of 2002 resulted in a successive agreement by which we gained the exclusive rights to continue the research and development of the small-molecule CCR5 inhibitors identified during our collaborative effort and to their commercialization, subject to certain reservations of rights in favor of Roche. Under the terms of the new agreement, Roche retains an option to resume joint development and commercialization of these compounds at defined intervals in their development. We are currently optimizing compounds in order to select a clinical development candidate. If Roche does not exercise the option described above and we achieve specified milestones, we will be obligated to pay Roche approximately \$9.1 million. In addition, we are required to pay Roche royalties on the sale of any licensed products. As of December 31, 2002, we have paid \$0 to Roche under this agreement.

#### ***Cytogen Corporation***

In June 1999, we and Cytogen Corporation formed a joint venture in the form of a limited liability company for the purposes of conducting research, development, manufacturing and marketing of products related to PSMA. All patents and know how owned by us or Cytogen and used or useful in the development of PSMA-based antibody or vaccine immunotherapeutics have been licensed to the joint venture. The principal intellectual property licensed initially are several patents and patent applications owned by Sloan-Kettering that relate to PSMA. We and Cytogen must also offer to license to the joint venture patents, patent applications and technical information used or useful in the joint venture's field to which we or Cytogen acquire licensable rights. By the terms of the joint venture, Cytogen is principally responsible for product marketing and we have co-promotion rights. To date, we have been principally responsible for preclinical and clinical development.

Each member of the joint venture currently owns 50% of the joint venture. Each member made an initial capital contribution of \$100,000. In general, each member has equal representation on the joint venture's management committee, equal voting rights and equal rights to profits and losses of the joint venture. Pursuant to the joint venture agreement, a member's voting and ownership interest will be diluted if it fails to make required capital contributions. Under specified circumstances, a change in control of one of the members will result in that member's loss of voting, management and marketing rights.

In general, the amount of funds that we and Cytogen must pay to the joint venture to fund the operations of the joint venture is based on a budget that is required to be approved by both parties and updated periodically. We are required to fund that portion of the budget equal to our percentage interest in the joint

[Back to Contents](#)

venture. We were required to fund the initial cost of research up to \$3.0 million. As of December 31, 2001, we had surpassed the \$3.0 million in funding for research costs, and funding obligations were thereafter shared equally by Cytogen and us.

Under the joint venture agreement, we were required to pay to the joint venture \$2.0 million in supplemental capital contributions, which was used by the joint venture to pay a \$2.0 million non-refundable licensing fee to Cytogen.

We provide research and development services to the joint venture and are compensated for our services based on agreed upon terms which approximate our cost. All inventions made by us in connection with our research and development services to the joint venture are required to be assigned to the joint venture for its use and benefit.

The joint venture agreements generally terminate upon the last to expire of the patents licensed by the members to the joint venture or upon a breach by either member, that is not cured within 60 days of written notice. Of the patents and patent applications that are the subject of the joint venture, the issued patents expire on dates ranging from 2014 and 2016. Patent term extensions and pending patent applications may extend the period of patent protection and thus the term of the joint venture agreements, when and if such patent applications are allowed and issued.

#### ***Genzyme Transgenics Corporation***

We have entered into a collaboration with Genzyme Transgenics to develop a transgenic source of the PRO 542 molecule. Under this agreement, Genzyme Transgenics has engaged in a program designed to result in the establishment of a line of transgenic goats capable of expressing the molecule in lactation milk. We are obligated to pay Genzyme Transgenics certain fees to conduct the program as well as additional fees upon the achievement of specified milestones. As of December 31, 2002, we have paid to Genzyme \$1.0 million under this agreement. If Genzyme achieves certain milestones specified under the agreement, we will be obligated to pay Genzyme an additional approximately \$2.625 million during the term of the agreement. If the program is successful, we may elect to enter into a further agreement for production by Genzyme Transgenics of commercial-scale quantities of the molecule, the principle terms of which have been agreed upon. However, the development of transgenic animals that express adequate concentrations of PRO 542 in their milk in sufficient volumes to make it commercially viable has continued to take longer than expected. We are conducting an ongoing examination of the merits of this project and the results achieved to date and expect to make a determination of its future viability in 2003. See also [\[HIV Therapeutics\]](#) [\[PRO 542: HIV Therapy\]](#).

#### ***Formatech, Inc.***

In June 2001, we entered into a collaborative agreement with Formatech, Inc. to develop improved product formulations for PRO 542. We are obligated to pay Formatech certain fees for the conduct of its activities under the program, which is subject to expansion based on the results of the first phase of the work. The Formatech agreement may be terminated by us upon 30 days prior written notice. As of December 31, 2003, we paid Formatech \$223,000 under this agreement.

#### ***Pharmacopeia, Inc.***

In March 2000, we entered into a research and license agreement with Pharmacopeia, Inc. to discover small molecule HIV therapeutics that block the attachment of the virus to its primary cellular receptor, CD4. This agreement expanded a collaboration with Pharmacopeia commenced in September 1997. Under the terms of the agreement, we have provided proprietary CD4 attachment assays and expertise related to the interaction between HIV and CD4 and Pharmacopeia is engaging in a screening program of its internal compound library. In August 2000, we expanded our collaboration with Pharmacopeia further to add two additional programs, including one program directed to the HIV envelope glycoprotein gp41. Pharmacopeia has utilized these technologies to screen its libraries of several million novel, drug-like compounds, and screening of other libraries is underway for other undisclosed targets. We will be granted a license to active compounds identified in the program. We are obligated to pay Pharmacopeia fees for its screening programs as well as additional amounts upon the achievement of specified milestones, annual maintenance fees until



[Back to Contents](#)

commencement of a clinical trial of a licensed product and royalties on any sales of therapeutics marketed as a result of the collaboration. As of December 31, 2002, we have paid to Pharmacoepia \$500,000 under this agreement. If certain milestones specified under the agreement are achieved, we will be obligated to pay Pharmacoepia an additional approximately \$4.25 million.

***ViroLogic, Inc.***

In May 2002 we entered into a fee-for-service agreement with ViroLogic, Inc. under which ViroLogic has agreed to perform clinical laboratory tests using ViroLogic's HIV resistance-testing technology on samples we provide. Services under the contract are performed upon our submission of a work order setting forth an agreed-upon scope of clinical laboratory tests and services to be performed by ViroLogic, as well as a fee schedule. We are not obligated to submit any work orders and can terminate any work order with or without cause upon 30 days written notice, with the obligation to pay for work performed under the work order. As of December 31, 2002, we have paid to ViroLogic \$35,000 under this agreement.

**Licenses**

We are a party to license agreements under which we have obtained rights to use certain technologies in our cancer and HIV programs, as well as certain other human therapeutics. Set forth below is a summary of each of these licenses.

***Sloan-Kettering.*** We are party to a license agreement with Sloan-Kettering under which we obtained the worldwide, exclusive rights to certain technology relating to ganglioside conjugate vaccines, including GMK and MGV, and their use to treat or prevent cancer. In general, the Sloan-Kettering license agreement terminates upon the later to occur of the expiration of the last to expire of the licensed patents or 15 years from the date of the first commercial sale of a licensed product pursuant to the agreement, unless sooner terminated. Patents that are presently issued expire in 2014; however, pending patent applications that we have also licensed and patent term extensions may extend the license period, when and if the patent applications are allowed and issued or patent term extensions are granted. In addition to the patents and patent applications, we have also licensed from Sloan-Kettering the exclusive rights to use relevant technical information and know-how. A number of Sloan-Kettering physician-scientists also serve as consultants to Progenics.

Our license agreement requires us to achieve development milestones. The agreement states that we are required to have filed for marketing approval of a drug by 2000 and to commence manufacturing and distribution of the drug by 2002. We have not achieved these milestones due to delays that we believe could not have been reasonably avoided. The agreement provides that Sloan-Kettering shall not unreasonably withhold consent to a revision of the milestone dates under specified circumstances, and we believe that the delays referred to above satisfy the criteria for a revision of the milestone dates. Sloan-Kettering has not consented to a revision of the milestone dates; however, we are in discussions with them in this regard.

As of December 31, 2002 we have paid to Sloan-Kettering \$1.0 million under this agreement. In addition, we are obligated to pay royalties based on the sales of products under the license. We have a \$200,000 minimum royalty payment obligation in any given calendar year, which is fully creditable against currently earned royalties payable by us to Sloan-Kettering in such year based on sales of licensed products.

We are also a party to a license agreement with Sloan-Kettering under which we obtained an exclusive, worldwide license to certain patent rights relating to DHA. The license continues for 20 years or to the end of the term for which the patent rights are granted. The presently issued patents expire in 2019; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted. As of December 31, 2002, we have paid to Sloan-Kettering \$100,000. If we achieve certain milestones under the agreement, we will be obligated to pay Sloan-Kettering an additional \$3.25 million. We are also required to pay royalties based on the sale of products we develop under the license.



[Back to Contents](#)

**Columbia University.** We are party to a license agreement with Columbia University under which we obtained exclusive, worldwide rights to certain technology and materials relating to CD4. In general, the license agreement terminates (unless sooner terminated) upon the expiration of the last to expire of the licensed patents, which is presently 2020; however, patent applications that we have also licensed and patent term extensions may extend the period of our license rights, when and if the patent applications are allowed and issued or patent term extensions are granted.

Our license agreement requires us to achieve development milestones. Among others, the agreement states that we are required to have filed for marketing approval of a drug by 2001. We have not achieved this milestone due to delays that we believe could not have been reasonably avoided. The agreement provides that Columbia shall not unreasonably withhold consent to a revision of the milestone dates under specified circumstances, and we believe that the delays referred to above satisfy the criteria for a revision of the milestone dates. Columbia has not consented to a revision of the milestone dates; however, we are in discussions with them in this regard.

As of December 31, 2002, we have paid to Columbia \$800,000 under this agreement. In addition, we are obligated to pay Columbia \$225,000 upon the earlier to occur of June 1, 2004 or our achievement of our final milestone under the agreement. We are also required to pay annual maintenance fees of \$50,000 and royalties based on the sale of products we develop under the license.

**Aquila Biopharmaceuticals.** We have entered into a license and supply agreement with Aquila Biopharmaceuticals, Inc., a wholly owned subsidiary of Antigenics, Inc., pursuant to which Aquila agreed to supply us with all of our requirements for the QS-21 adjuvant for use in certain ganglioside-based cancer vaccines, including GMK and MG. QS-21 is the lead compound in the Stimulon family of adjuvants developed and owned by Aquila. In general, the license agreement terminates upon the expiration of the last to expire of the licensed patents, unless sooner terminated. In the United States the licensed patent will expire in 2008.

Our license agreement requires us to achieve development milestones. The agreement states that we are required to have filed for marketing approval of a drug by 2001 and to commence the manufacture and distribution of a drug by 2003. We have not achieved these milestones due to delays that we believe could not have been reasonably avoided. The agreement provides that Aquila shall not unreasonably withhold consent to a reasonable revision of the milestone dates under specified circumstances, and we believe that the delays referred to above satisfy the criteria for a revision of the milestone dates. Aquila has not consented to a revision of the milestone dates.

As of December 31, 2002, we have paid to Aquila \$758,000 under this agreement. We have no future cash payment obligations relating to milestones under the agreement, although we are required to pay Aquila royalties on the sale of products we develop under the license.

**Protein Design Labs.** We have entered into a development and license agreement with PDL for the humanization by PDL of PRO 140. Pursuant to the agreement, PDL granted us certain exclusive and nonexclusive worldwide licenses under patents, patent applications and know-how relating to the humanized PRO 140. In general, the license agreement terminates on the later of ten years from the first commercial sale of a product developed under the agreement or the last date on which there is an unexpired patent or a patent application that has been pending for less than ten years, unless sooner terminated. Thereafter the license is fully paid. The last of the presently issued patents expires in 2014; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted. As of December 31, 2002, we have paid to PDL approximately \$1.72 million under this agreement. If all milestones specified under the agreement are achieved, we will be obligated to pay PDL an additional approximately \$4.5 million. We are also required to pay annual maintenance fees of \$150,000 and royalties based on the sale of products we develop under the license.

**UR Labs.** We have entered into an agreement with UR Labs, Inc. (the "UR Labs Agreement") to obtain worldwide exclusive rights to intellectual property rights related to methylnaltrexone. UR Labs has exclusively licensed MNTX from the University of Chicago, where it was discovered. In consideration for the license, we paid a nonrefundable, noncreditable license fee and are obligated to pay additional payments upon



[Back to Contents](#)

the occurrence of certain defined milestones associated with the MNTX product development and commercialization program. As of December 31, 2002, we have paid to UR Labs \$400,000 under this agreement. If we satisfy all future development milestones specified in the agreement, we will be obligated to pay UR Labs an additional \$1.2 million. Furthermore, we are required to pay royalties based upon net sales of any licensed products (but at a rate of not less than \$100,000 per year after product approval in the United States). The UR Labs Agreement may be terminated under specified circumstances that include our failure to achieve specified development milestones; however, the consent of UR Labs to appropriate revisions to the development milestones shall not be unreasonably withheld under specified circumstances. If not terminated early, the agreement continues so long as we are obligated to pay royalties on the sale of a licensed product (including MNTX). If there is a valid patent relating to a licensed product in a particular country on the date of the first commercial sale in that country, we are obligated to pay royalties until the later of the expiration of the last to expire licensed patent or five years from the date of that sale. If a valid licensed patent does not exist in a particular country on the date of the first commercial sale of a licensed product in that country, we are obligated to pay royalties until seven years from the date of that sale. The last of the presently issued patents expire in 2017; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted.

**Abgenix, Inc.** In February 2001, our joint venture with Cytogen entered into a worldwide exclusive licensing agreement with Abgenix, Inc. to use Abgenix's XenoMouse technology for generating fully human antibodies to the joint venture's proprietary PSMA antigen. In consideration for the license, the joint venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments 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, 2002, the joint venture had paid to Abgenix \$200,000 under this agreement. If the joint venture achieves certain milestones specified under the agreement, it will be obligated to pay Abgenix an additional approximately \$6.9 million. Furthermore, the joint venture is required to pay royalties based upon net sales of any antibody products. This agreement may be terminated, after an opportunity to cure, by Abgenix for cause upon 30 days prior written notice. The joint venture 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.

**AlphaVax Human Vaccines, Inc.** In September 2001, the joint venture entered into a worldwide exclusive license agreement with AlphaVax Human Vaccines, Inc., to use the AlphaVax Replicon Vector system to create a therapeutic prostate cancer vaccine incorporating the joint venture's proprietary PSMA antigen. In consideration for the license, the joint venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating AlphaVax's system. As of December 31, 2002, the joint venture has paid to AlphaVax \$400,000 under this agreement. If the joint venture achieves certain milestones specified under the agreement, it will be obligated to pay AlphaVax an additional approximately \$5.4 million. Furthermore, the joint venture is required to pay royalties based upon net sales of any products developed using AlphaVax's system. This agreement may be terminated, after an opportunity to cure, by AlphaVax under specified circumstances that include the joint venture's failure to achieve certain milestones; however the consent of AlphaVax to revisions to the due dates for the milestones shall not be unreasonably withheld. The joint venture 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 AlphaVax's system. The last of the presently issued patents expire in 2015; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted.

**Rights and Obligations.** We have the right generally to defend and enforce patents licensed by us, either in the first instance or if the licensor chooses not to do so. In addition, our license agreement with UR

[Back to Contents](#)

Labs regarding MNTX gives us the right to prosecute and maintain the licensed patents. We bear the cost of engaging in all of these activities with respect to our license agreements with Sloan- Kettering for GMK, Columbia for our HIV product candidates subject to the Columbia license and UR Labs for MNTX. With most of our other license agreements, the licensor bears the cost of engaging in all of the activities, although we may share in those costs under specified circumstances. Historically, our costs of defending patent rights, both our own and those we license, have not been material.

The licenses to which we are party impose various milestone, commercialization, sublicensing, royalty and other payment, insurance, indemnification and other obligations on us and are subject to certain reservations of rights. Failure to comply with these requirements could result in the termination of the applicable agreement, which would likely cause us to terminate the related development program and cause a complete loss of our investment in that program.

### **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, Western European countries 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 United States are effective for:

- the longer of 17 years from the date of issue or 20 years from the earliest effective filing date of the corresponding patent application, if the patent application was filed prior to June 8, 1995; and

- 20 years from the earliest filing date for patent applications filed on or after June 8, 1995.

In addition, in certain instances, the patent term can be extended to recapture a portion of the term lost during the FDA regulatory review period. The duration of foreign patents varies in accordance with the provisions of applicable local law.

We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position in our product areas. We require our employees, consultants and corporate partners who have access to our proprietary information to sign confidentiality agreements.

Currently our patent portfolio relating to our proprietary technologies in the HIV, cancer and symptom management areas is comprised, on a worldwide basis, of 90 patents that are issued or allowed and 128 pending patent applications, which we either own directly or of which we are the exclusive licensee. The issued patents that we own expire on dates ranging from 2012 through 2021. However, we have filed a number of United States and foreign patent applications related to MNTX, our HIV attachment assay technology, our technology directed to PRO 542 and PRO 140, our ProVax technology and clinical uses of these technologies. We have also filed a number of United States and foreign patent applications, one of which is owned jointly with the Aaron Diamond AIDS Research Center, relating to the discovery of an HIV co-receptor, CCR5. These pending patent applications may extend the period of patent protection afforded our products in development, when and if such patent applications are allowed and issued.

Our patent portfolio includes United States and foreign patents and pending patent applications that relate to our products in development in the HIV, cancer, symptom management and supportive care areas and of which we are the exclusive licensee. This portion of our patent portfolio is described in more detail below.

Under a license agreement with UR Labs, Inc., we obtained worldwide exclusive rights to certain technology relating to MNTX. This technology is the subject of issued U.S. and European patents and several related U.S. and foreign patent applications filed by the University of Chicago relating to certain compositions, formulations and uses of MNTX. The last of the presently issued patents expire in 2017; however, patent applications that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted. Furthermore, we have continued to expand the patent coverage relating to MNTX with the filing of



[Back to Contents](#)

new patent applications that may extend the patent protection period for MNTX when and if such patent applications are allowed and issued.

Under a license agreement with Sloan-Kettering, we obtained worldwide exclusive rights to certain technology relating to ganglioside conjugate vaccines, including GMK and MGV, and their use to treat or prevent cancer. This technology is the subject of a patent filed by Sloan-Kettering in the United States and 25 foreign countries claiming composition of matter and methods of production and use of certain ganglioside conjugate vaccines for the treatment or prevention of human cancer. The currently issued patents expire in 2014. However, pending patent applications that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted.

Under a license agreement with Columbia University, we obtained worldwide, exclusive rights to certain technology relating to CD4. This technology is the subject of issued U.S. and European patents and several related U.S. and foreign patent applications filed by Columbia University. The issued patents and the patent applications claim composition of matter and methods of production and use of certain CD4-based products for the treatment or prevention of HIV infection. The issued patents covered by this license agreement expire on dates ranging from 2007 to 2020; however, patent applications that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted.

Under a license agreement with Sloan-Kettering, we obtained worldwide exclusive rights to certain technology relating to dehydroascorbic acid and its use to increase the concentration of vitamin C in tissues, including the brain, for treating neurodegenerative and neurovascular diseases. This technology is the subject of issued U.S. patents claiming methods for increasing the vitamin C concentration in the cells of a patient by administering dehydroascorbic acid to the patient. The issued patents expire in 2019; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted.

The research, development and commercialization of a biopharmaceutical often involves 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 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 products we will need to obtain a license to a patent, which 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.

### **Government Regulation**

Progenics and our products are subject to comprehensive regulation by the Food and Drug Administration in the United States and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the preclinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, record keeping, advertising and promotion of our products. None of our product candidates has received marketing or other approval from the FDA or any other similar regulatory authority.

FDA approval of our products, including a review of the manufacturing processes and facilities used to produce such products, will be required before such products may be marketed in the United States. The process of obtaining approvals from the FDA can be costly, time consuming and subject to unanticipated delays. We cannot assure you that approvals of our proposed products, processes, or facilities will be granted on a timely basis, or at all. If we experience delays in obtaining, or do not obtain, approvals for our products, commercialization of our products would be slowed or stopped. Moreover, 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.

[Back to Contents](#)

The process required by the FDA before our products may be approved for marketing in the United States generally involves:

- preclinical laboratory and animal tests;
- submission to the FDA of an investigational new drug application, or IND, which must become effective 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;
- 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. Preclinical tests include laboratory evaluation of product chemistry and animal studies to gain preliminary information about a product's pharmacology and toxicology and to identify any safety problems that would preclude testing in humans. Products must generally be manufactured according to current Good Manufacturing Practices, and preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practices. The results of the preclinical tests are submitted to the FDA as part of an IND (Investigational New Drug) application. An IND is a submission which the sponsor of a clinical trial of an investigational new drug must make to the FDA and 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, the IND will become effective 30 days following its receipt by the FDA, and initial clinical studies may begin, although companies often obtain affirmative FDA approval before beginning such studies. We cannot assure you that submission of an IND will result in FDA authorization to commence clinical trials.

A New Drug Application, or NDA, is an application to the FDA to market a new drug. 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 new drug may not be marketed in the United States until the FDA has approved the NDA.

A Biologic License Application, or BLA, is an application to the FDA to market a biological product. 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. The biological product may not be marketed in the United States until a biologic license is issued.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients 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 that detail, among other things, the objectives of the study, the parameters to be used to monitor safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study





[Back to Contents](#)

must be conducted under the auspices of an Institutional Review Board. The Institutional Review Board will consider, among other things, ethical factors, the safety of human subjects, the possible liability of the institution and the informed consent disclosure which must be made to participants in the clinical trial.

Clinical trials are typically conducted in three sequential phases, although the phases 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 patient 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 new product is found to have an effect and to have an acceptable safety profile in phase 2 evaluation, phase 3 trials are undertaken in order to further evaluate clinical efficacy and to further test for safety within an expanded patient population. 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.

The results of the preclinical 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, approval of which must be obtained prior to commencement of commercial sales. 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. Moreover, 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 preclinical and clinical testing process, the approval process, or thereafter, may result in various adverse consequences, including FDA delay in approving or refusal to approve a product, withdrawal of an approved product from the market or the imposition of criminal penalties against the manufacturer or sponsor. In addition, later discovery of previously unknown problems may result in restrictions on such product, manufacturer, or sponsor, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

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 such product in such countries. The approval procedure varies from country to country, and the time required may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filing for certain European countries, in general, each country has its own procedures and requirements. We do not currently have any facilities or personnel outside of the United States.

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,



[Back to Contents](#)

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**

We currently manufacture PRO 542, PRO 140, GMK and PSMA protein vaccines in our two pilot production facilities in Tarrytown, New York. One of these facilities is for the production of vaccines and the other is for the production of recombinant proteins. We are preparing to install a 1,000-liter bioreactor that will utilize a new cell line. This facility, which we expect will be operational during 2004, is designed to provide us with an additional source of clinical supplies of PRO 542 in support of our clinical program. We believe that our existing production facilities will be sufficient to meet our initial needs for clinical trials for these product candidates. However, these facilities may be insufficient for all of our late-stage clinical trials for these product candidates and would be insufficient for commercial-scale requirements. We may be required to further expand our manufacturing staff and facilities, obtain new facilities or contract with third parties or corporate collaborators to assist with production.

We currently rely on single-source third party manufacturers for the supply of both bulk and finished form methylglucuronide. While we believe that our existing arrangements with such single-source third party manufacturers are stable, reliable and adequate for the balance of our clinical trial and initial commercial supply requirements, we are actively engaged in a program to further expand such relationships, as well as to identify additional manufacturers for bulk and finished form MNTX as supplements and backup to our current arrangements.

In the event we decide to establish a full-scale commercial manufacturing facility for any or all of our products, we would need to spend substantial additional funds and will be required to 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 organization to perform the marketing function for our products. We believe that our current approach allows us maximum flexibility of selecting the marketing method that will both increase market penetration and commercial acceptance of our products and enable us to avoid expending significant funds to develop a large sales and marketing organization. Cytogen has certain marketing rights with respect to the products covered by the Joint Venture Agreement.

### **Competition**

Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. We face competition from many companies and major universities and research institutions in the United States 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 preclinical 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. We cannot assure you that our products under development will compete successfully with existing products or products under development by other companies, universities and other institutions. Our competitors may succeed in obtaining FDA 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, the speed with which we can develop products, complete the clinical trials and approval

[Back to Contents](#)

processes and ultimately supply commercial quantities of the products to the market is expected to be an important competitive factor.

With respect to methylnaltrexone, there are currently no FDA approved products for reversing the debilitating side effects of opioid pain therapy or for the treatment of post-operative bowel dysfunction. We are, however, aware of a product candidate in advanced clinical development that targets these therapeutic indications, but its effects are limited solely to the lumen of the gastrointestinal tract, whereas methylnaltrexone is available systemically.

With respect to our products for the treatment of HIV infection, three classes of products made by our competitors have been approved for marketing by the FDA for the treatment of HIV infection and AIDS: reverse transcriptase inhibitors, protease inhibitors and entry inhibitors. These drugs have shown efficacy in reducing the concentration of HIV in the blood and prolonging asymptomatic periods in HIV-positive individuals, especially when administered in combination.

With respect to GMK, the FDA and certain other regulatory authorities have approved high-dose alpha-interferon for marketing as a treatment for patients with high-risk melanoma. High-dose alpha interferon has demonstrated efficacy for this indication.

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 product candidates is and will be based, among other things, on:

- efficacy and safety of our products;
- timing and scope of regulatory approval;
- product reliability and availability;
- marketing and sales capabilities;
- capabilities of our collaborators;
- reimbursement coverage from insurance companies and others;
- degree of clinical benefits of our product candidates relative to their costs;
- method of administering a product;
- price; and
- patent protection.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and to secure sufficient capital resources for the often substantial period between technological conception and commercial sales. Competitive disadvantages in any of these factors could materially harm our business and financial condition.

## **Product Liability**

The testing, manufacturing and marketing of our 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 products independently, we will bear the risk of product liability directly. We have obtained product

[Back to Contents](#)

liability insurance coverage in the amount of \$5.0 million per occurrence, subject to a deductible and a \$5.0 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, 2002, we had 100 full-time employees, 17 of whom, including Dr Maddon, hold Ph.D. degrees or foreign equivalents and four of whom, including Dr. Maddon, hold M.D. degrees. At such date, 71 employees were engaged in research and development, medical and regulatory affairs and manufacturing activities and 29 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.

### Executive Officers and Key Management

Our executive officers and key management are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Paul J. Maddon, M.D., Ph.D.	43	Chairman of the Board, Chief Executive Officer and Chief Science Officer
Ronald J. Prentki, M.B.A.	45	President and Director
Robert J. Israel, M.D.	46	Senior Vice President, Medical Affairs
Robert A. McKinney, CPA	46	Vice President, Finance & Operations and Treasurer
Philip K. Yachmetz, J.D.	46	Vice President, General Counsel and Secretary
Richard W. Krawiec, Ph.D.	55	Vice President, Investor Relations & Corporate Communications
William C. Olson, Ph.D.	40	Vice President, Research & Development
Kenneth G. Surowitz, Ph.D.	44	Vice President, Regulatory Affairs & Quality
Thomas A. Boyd, Ph.D.	51	Vice President, Preclinical Development and Project Management
James H. Conover, Ph.D.	60	Vice President, Regulatory Affairs

**Paul J. Maddon, M.D., Ph.D.** is our founder and has served in various capacities since our inception, including as our Chairman of the Board of Directors, Chief Executive Officer, President and Chief Science Officer. From 1981 to 1988, Dr. Maddon performed research at the Howard Hughes Medical Institute at Columbia University in the laboratory of Dr. Richard Axel. Dr. Maddon serves on two NIH review committees and is a member of the Board of Directors of the New York Biotechnology Association. Dr. Maddon also serves on the board of directors of Epixis SA, a French biotechnology company. He received a B.A. in biochemistry and mathematics and a M.D. and a Ph.D. in biochemistry and molecular biophysics from Columbia University. Dr. Maddon has been an Adjunct Assistant Professor of Medicine at Columbia University since 1989.

**Ronald J. Prentki, M.B.A.** joined us as our President in July 1998 and became a director in September 1998. Prior to joining Progenics, Mr. Prentki had been Vice President of Business Development and Strategic Planning at Hoffmann-La Roche Inc. from 1996 to 1998. Mr. Prentki spent from 1990 to 1996 at Sterling Winthrop (subsequently acquired by Sanofi Pharmaceuticals), most recently serving as Vice President of Business Development. From 1985 to 1990, Mr. Prentki was with Bristol-Myers Squibb International Division, initially supporting the marketing of that company's oncology products and later as Director of Cardiovascular Products. Mr. Prentki started his career in 1979 in the Ames Diagnostic Division of Miles Laboratories holding a series of sales, marketing and product development positions before leaving Miles Laboratories in 1985. Mr. Prentki received a B.S. in Microbiology and Public Health from Michigan State University and an M.B.A. from the University of Detroit.

**Robert J. Israel, M.D.** joined us as Vice President, Medical Affairs in October 1994 and was promoted to Senior Vice President, Medical Affairs in 2002. From 1991 to 1994, Dr. Israel was Director, Clinical Research-Oncology and Immunohematology at Sandoz Pharmaceuticals Corporation. From 1988 to 1991, he was Associate Director, Oncology Clinical Research at Schering-Plough Corporation. Dr. Israel is a licensed physician and is board certified in both internal medicine and medical oncology. He received a B.A. in



[Back to Contents](#)

physics from Rutgers University and a M.D. from the University of Pennsylvania and completed an oncology fellowship at Sloan-Kettering. Dr. Israel has been a consultant to the Solid Tumor Service at Sloan-Kettering since 1987.

**Robert A. McKinney, CPA** joined us in September 1992. Mr. McKinney served as Director, Finance and Operations and Treasurer from 1992 to January 1993, when he was appointed Vice President, Finance and Operations and Treasurer of Progenics. From 1991 to 1992, he was Corporate Controller at VIMRx Pharmaceuticals, Inc., a biotechnology research company. From 1990 to 1991, Mr. McKinney was Manager, General Accounting at Micrognosis, Inc., a software integration company. From 1985 to 1990, he was an audit supervisor at Coopers & Lybrand LLP, an international accounting firm. Mr. McKinney studied finance at the University of Michigan, received a B.B.A. in accounting from Western Connecticut State University, and is a Certified Public Accountant.

**Philip K. Yachmetz, J.D.** joined us in September 2000 as General Counsel and Secretary and was promoted to Vice President in January 2002. Prior to joining Progenics, Mr. Yachmetz had been Senior Vice President, Business Development, General Counsel and Secretary of CytoTherapeutics, Inc from 1998 to 1999, where he also was Acting Chief Financial Officer and Treasurer during 1999. From 1997 to 1998, Mr. Yachmetz was a Principal and Managing Director of Millennium Venture Management LLC a business consulting group servicing the healthcare and high technology industries. Mr. Yachmetz was, from 1996 to 1997, Director, Legal & Corporate Affairs and Secretary of PlayNet Technologies, Inc. an Internet based entertainment company. From January 1989 to October 1996, Mr. Yachmetz served as Senior Counsel of Hoffmann-La Roche Inc. Mr. Yachmetz received a B.A. in Political Science from George Washington University and a J.D. from California Western School of Law and is admitted to practice law in New York and New Jersey.

**Richard W. Krawiec, Ph.D.** joined us in February 2001 as Vice President, Investor Relations and Corporate Communications. Prior to joining Progenics, Dr. Krawiec served as Vice President of Investor Relations and Corporate Communications of CytoGen Corporation from 2000 to 2001. Prior to CytoGen, Dr. Krawiec headed these departments at La Jolla Pharmaceuticals, Inc. during 1999, at Amylin Pharmaceuticals, Inc. from 1993 to 1998 and IDEC Pharmaceuticals, Inc. previously thereto. Previously, Dr. Krawiec was the founder and Editor-In-Chief of *Biotechnology Week* magazine and the Managing Editor and founder of *Biotechnology Newswatch*. Dr. Krawiec received a B.S. in Biology from Boston University and a Ph.D. in Biological Sciences from the University of Rhode Island.

**William C. Olson, Ph.D.** joined us in May 1994 serving in various roles of increasing responsibility through his promotion to Vice President, Research and Development in January 2001. From 1989 to 1992, Dr. Olson served as a Research Scientist at Johnson & Johnson, and from 1992 until 1994 he was a Development Scientist at MicroGeneSys, Inc., a biotechnology company. Dr. Olson received a Ph.D. from the Massachusetts Institute of Technology and a B.S. from the University of North Dakota. Both degrees were awarded in the field of chemical engineering.

**Kenneth G. Surowitz, Ph.D.** joined us in January 1999. Dr. Surowitz served as Senior Director, Quality & Regulatory Affairs from January 1999 to January 2000, when he was appointed Vice President, Quality & Regulatory Affairs of Progenics. From 1988 to 1999, Dr. Surowitz was employed at the Wyeth-Lederle Vaccines and Pediatrics unit of American Home Products Corp. in a number of positions within the organization, most recently as Director of Global Regulatory Affairs. From 1985 to 1988, he was employed as a Product Development Microbiologist at Procter and Gamble. Dr. Surowitz received Ph.D. and M.S. degrees from Ohio State University in the field of microbiology and an A.B. degree from Lafayette College in biology.

**Thomas A. Boyd, Ph.D.** joined us in January 2000 as Senior Director, Project Management and was promoted to Vice President, Preclinical Development and Project Management in January 2002. From 1996 through 2000, Dr. Boyd was Associate Director, R&D Project Management at Boehringer Ingelheim Pharmaceuticals, Inc. and held various positions with Wyeth-Ayerst Research and Alteon, Inc. prior thereto. He received his Ph.D. from Brown University in physiology and biophysics and an A.B. degree from the College of Arts and Sciences, Cornell University.





[Back to Contents](#)

**James H. Conover, Ph.D.** joined us in July 2002 as Vice President, Regulatory Affairs. Previously he was at Endo Pharmaceuticals, Inc., where he was Vice President of Regulatory Affairs. He has held senior regulatory affairs positions at The Purdue Frederick Company, Parke-Davis and Lederle Laboratories. He earned a Ph.D. in Biochemistry and Human Genetics and a M.S. in Biology from New York University, and an undergraduate degree in Biology from Siena College.

### **Scientific Advisory Boards and Consultants**

An important component of our scientific strategy is our collaborative relationship with leading researchers in cancer and virology. Certain of these researchers are members of our two Scientific Advisory Boards, one in cancer and one in virology. The members of each SAB attend periodic meetings and provide us with specific expertise in both research and clinical development. In addition, we have collaborative research relationships with certain individual SAB members. All members of the SABs are employed by employers other than us and may have commitments to or consulting or advisory agreements with other entities that may limit their availability to us. These companies may also compete with us. Several members of the SABs have, from time to time, devoted significant time and energy to our affairs. However, no member is regularly expected to devote more than a small portion of time to Progenics. In general, our scientific advisors are granted stock options in Progenics and receive financial remuneration for their services.

The following table sets forth information with respect to our Scientific Advisory Boards.

#### **Cancer Scientific Advisory Board**

Alan N. Houghton, M.D. (Chairman)	Chairman, Immunology Program, Sloan-Kettering and Professor, Weill/Cornell Medical college (WCMC)
Angus G. Dalglish, M.D., Ph.D.	Chairman and Professor of Medical Oncology, St. George's Hospital, London
Samuel J. Danishefsky, Ph.D.	Kettering Professor and Head, Bioorganic Chemistry, Sloan-Kettering Institute and Professor of Chemistry, Columbia University
Philip O. Livingston, M.D. John Mendelsohn, M.D.	Member, Sloan-Kettering and Professor, WCMC President, The University of Texas M. D. Anderson Cancer Center
David A. Scheinberg, M.D., Ph.D.	Vincent Astor Chair and Chairman, Molecular Pharmacology and Chemistry Program, Sloan-Kettering and Professor, WCMC
David B. Agus, M.D.	Research Director, Prostate Cancer Institute, Cedars-Sinai Medical Center

#### **Virology Scientific Advisory Board**

Stephen P. Goff, Ph.D. (Chairman)	Professor of Biochemistry, Columbia University
Lawrence A. Chasin, Ph.D.	Professor of Biological Sciences, Columbia University
Leonard Chess, M.D.	Professor of Medicine, Columbia University
Wayne A. Hendrickson, Ph.D.	Professor of Biochemistry, Columbia University
J. Steven McDougal, M.D.	Chief, Immunology Branch, CDC, Atlanta
Sherie L. Morrison, Ph.D.	Professor of Microbiology, UCLA
Robin A. Weiss, Ph.D.	Professor and Director of Research, ICR, Royal Cancer Hospital, London

#### **Other Scientific Consultants**

David W. Golde, M.D.	Member, Sloan-Kettering and Professor, WCMC
Jonathan Moss, M.D., Ph.D.	Professor, Department of Anesthesia and Critical Care, and Vice Chairman for Research, University of Chicago Medical Center
Thomas P. Sakmar, M.D.	Acting President and Professor, The Rockefeller University



[Back to Contents](#)

## RISK FACTORS

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

### **Our product development programs are novel and, consequently, inherently risky.**

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include, but are not limited to, the possibility that:

- the technologies we use will not be effective;
- our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals;
- our product candidates will be hard to manufacture on a large scale or will be uneconomical to market; or
- we do not successfully overcome technological challenges presented by our products.

To our knowledge, other than Trimeris' Fuzeon product, no drug designed to treat HIV infection by blocking viral entry and no cancer therapeutic vaccine has been approved for marketing in the U.S. Our other research and development programs involve similarly novel approaches to human therapeutics. Consequently, there is little precedent for the successful commercialization of products based on our technologies. We cannot assure you that any of our products will be successfully developed.

### **If we cannot advance our products beyond the early stages of product development or demonstrate clinical efficacy, we will never commercialize a product.**

Many of our products are at an early stage of development. The successful commercialization of our products will require significant further research, development, testing and regulatory approvals and additional investment. If we cannot advance our products beyond the early stages of product development or demonstrate clinical efficacy, we will never commercialize a product. There are a number of technological challenges that we must successfully address to complete most of our development efforts. We cannot assure you that any of our products in the research or preclinical development stage will yield results that would permit or justify clinical testing or that products that advance to clinical testing will be commercialized.

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

We have two ongoing phase 3 clinical trials for GMK and expect to conclude and analyze the data from one of them in the first half of 2004. Both of these trials are designed to be pivotal, which means that they are designed to produce results sufficient to support regulatory approval. In addition we have on-going and planned phase 2 studies for PRO 542, expect to commence studies for PRO 140, and also have on-going and planned phase 1 studies for our PSMA vaccine and antibody candidates, respectively.

If the results of either of the GMK trials are not satisfactory, we may need to conduct additional clinical trials or abandon our GMK program. Additionally, if the results of our early stage studies with PRO 542, PRO 140 or our PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or in the worst case abandon the program involved.

In May 2000, our collaborating research cooperative in one of our ongoing phase 3 GMK trials, ECOG, recommended to clinical investigators participating in the trial that they discontinue administering GMK. See the discussion of GMK clinical trial results under "Business" above for more information. We are continuing to follow-up patients who were enrolled in that trial. However, we cannot predict how long this will take or what the results will show, and we do not expect to know the results much before the first half of 2004 or later.

If the results of any of these trials are not satisfactory, the clinical development program involved can be adversely affected, resulting in the need to reconfigure such clinical development program and delayed

[Back to Contents](#)

timelines to the commencement of planned trials and of our regulatory filing strategy. A setback of this nature could have a material adverse effect on our business.

**A setback in our methylnaltrexone clinical program could adversely affect us.**

We have an ongoing phase 3 clinical trial for MNTX and expect to commence additional phase 3 clinical trials designed to produce results and data sufficient to support timely regulatory submissions. We are also planning to commence a series of additional phase 2 clinical trials involving MNTX before the end of 2003. We are dependent on single source third party suppliers for our supplies of bulk and finished form clinical trial materials. If the results of any of these trials are not satisfactory, or if we encounter clinical trial supply issues, our MNTX development program can be adversely affected resulting in delays in the commencement of planned trials and our regulatory filing. The need to conduct additional clinical trials or significant revisions to our clinical development plan would lead to delays in our filing for and obtaining the regulatory approvals necessary to market MNTX. Since MNTX is our most clinically advanced product, a setback of this nature could have a material adverse effect on our business.

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

Although for planning purposes we forecast the commencement and completion of clinical trials, and have included some of those forecasts herein, the actual timing of these events can vary dramatically due to factors such as delays, scheduling conflicts with participating clinicians and clinical institutions and the rate of patient accruals. For example, GMK is intended for treating patients with relatively early stage cancer and to delay or prevent the recurrence of disease. As a consequence, clinical trials involving these product candidates are likely to take longer to complete than clinical trials involving other types of therapeutics. We cannot assure you that clinical trials involving our product candidates will commence or be completed as forecasted.

We have limited experience in conducting clinical trials. In certain circumstances we rely on corporate collaborators, academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our products. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and consequently will be dependent on governmental participation and funding. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. We cannot assure you that these trials will commence or be completed as we expect or that they will be conducted successfully. Failure to commence or complete, or delays in, any of our planned clinical trials could unsettle investors' confidence in our ability to develop products, which would likely cause our stock price to decrease.

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

To achieve the results we need to obtain regulatory approval, we or our collaborators must demonstrate a product's safety and efficacy in humans through extensive preclinical and clinical testing. Numerous unforeseen events may arise during, or as a result of, the testing process, including the following:

- the results of preclinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- potential products may not have the desired effect or may have undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
- results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;
- after reviewing test results, we or our collaborators may abandon projects which we might previously have believed to be promising, some of which may be described herein; and
- we, our collaborators or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks.

[Back to Contents](#)

Clinical testing is very expensive and can take many years. The failure to adequately demonstrate the safety and efficacy of a therapeutic product under development would delay or prevent regulatory approval of the product, which could adversely affect our profitability and credibility.

**Even if we get our products approved, 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. Even if our products obtain regulatory approval, we cannot assure you that they will achieve market acceptance of any significance. 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 achieve market acceptance will depend on competitive factors. Competition in our industry is intense, and it is accentuated by the rapid pace of technological development. Products currently exist in the market that will compete with certain of the products that we are developing. Many of our competitors have substantially greater research and development capabilities and experience and greater manufacturing, marketing, financial and managerial resources than do we. 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 profitability and financial position would suffer.

**A competitor developing an opioid antagonist may reach the market ahead of us.**

We are aware that Adolor Corporation, in partnership with GlaxoSmithKline plc, is developing an opioid antagonist, alvimopan, for chronic opioid-induced bowel dysfunction and post-operative ileus (both of which indications for this drug are currently in phase 3 trials), as well as for acute opioid-induced bowel dysfunction (currently in phase 2 trials). Alvimopan is only administered orally and its activity is restricted to the lumen of the gastrointestinal tract. As alvimopan is not available systemically, it does not deactivate opioid receptors found in the bladder or skin. Opioid-induced activation of these receptors may induce urinary retention and pruritis. We believe that MNTX may have certain advantages over Alvimopan in terms of dosing flexibility, rapidity of onset of action, and systemic availability. However, alvimopan appears to be further along in the clinical development process than MNTX. If alvimopan reaches the market before MNTX, the considerable marketing and sales capabilities of GlaxoSmithKline may affect our ability to penetrate the market if we obtain regulatory approval of MNTX.

**If we lose our collaborative partners, or if they do not apply adequate resources to our collaborations, our product development and profitability may suffer.**

Our business strategy includes entering into collaborations with corporate partners, primarily pharmaceutical and other biotechnology companies, for one or more of the research, development, manufacturing, marketing and other commercialization activities relating to certain of our product candidates. If we lose our collaborative partners, or if they do not apply adequate resources to our collaborations, our product development and profitability may suffer.

The amount and timing of resources dedicated by our collaborators to their collaborations with us is not within our control. If any collaborator breaches or terminates its agreements with us, or fails to conduct its collaborative activities in a timely manner, the commercialization of our product candidates could be slowed down or blocked completely. We cannot assure you that our collaborative partners will not change their strategic focus or pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by these collaborative programs. Our revenues and earnings also will be affected by the effectiveness of our corporate partners in marketing any successfully developed products.

We cannot assure you that our collaborations will continue or be successful or that we will receive any further research funding or milestone or royalty payments. If our partners do not develop products under these collaborations, we cannot assure you that we would be able to do so on our own. Disputes may arise between

[Back to Contents](#)

us and our collaborators as to a variety of matters, including financial or other obligations under our contracts, the most promising scientific or regulatory route to pursue or ownership of intellectual property rights. These disputes may be both expensive and time-consuming and may result in delays in the development and commercialization of product candidates.

**We may not be able to negotiate additional collaborative agreements, which could increase our internal cash burn rate or reduce our rate of product development.**

We intend to continue to pursue and enter into new collaborative agreements in the future. For instance, we are currently in active discussions with potential strategic partners for MNTX. However, we cannot assure you that we will be successful in identifying or negotiating any additional collaborative arrangements, or that any of these relationships, if established, will be scientifically or commercially successful. Any additional collaborations would likely subject us to some or all of the risks described above with respect to our current collaborations. Furthermore, if we do not enter into new collaborative arrangements, it is likely that our internal cash burn rate would increase or that we would need to take steps to reduce our rate of product development.

**If we do not remedy our current failure to achieve milestones or satisfy certain conditions regarding some of our product candidates, we may not maintain our rights under our licenses relating to these product candidates.**

We are required to make substantial cash payments, achieve specified milestones and satisfy other conditions, including filing for and obtaining product approvals and introducing products, to maintain our rights under our licenses, including our licenses from UR Labs, Inc., Sloan-Kettering Institute for Cancer Research and Columbia University. We may not be able to maintain our rights under these licenses. Under our license agreements relating to GMK and our HIV product candidates, including PRO 542, we are required, among other things, to have filed for marketing approval for a drug by 2000 and to commence commercialization of the drug by 2002 (for GMK) and to file for marketing approval by 2001 (for the HIV products). We have not achieved these milestones and are unlikely to achieve them soon. If we can establish that our failure to achieve these milestones was as a result of technical issues beyond our control or delays in clinical studies that could not have been reasonably avoided, we may be entitled under these license agreements to a revision of these milestone dates. Although we believe that we satisfy one or more of these conditions, we may become involved in disputes with our licensors as to our continued right to a license. If we do not comply with our obligations under our license agreements, the licensors may terminate them. Termination of any of our licenses could result in our losing our rights to, and therefore being unable to commercialize, any related product.

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

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, 2002, we had an accumulated deficit of approximately \$46.3 million. These losses have resulted principally from costs incurred in our research and development programs and from our general and administrative costs. We have derived no significant revenues from product sales or royalties, and we do not expect to 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 development and clinical trial efforts.

Our ability to achieve long-term profitability is dependent in part on obtaining regulatory approvals for products and entering into agreements for commercialization of our products. However, we cannot assure you that our operations will be profitable even if any of our products under development are commercialized.

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

Our current and anticipated development projects require substantial capital. We are likely to need substantial additional funds to conduct product development activities. However, our access to capital funding is uncertain. We do not have committed external sources of funding for most of our drug discovery and

[Back to Contents](#)

development projects, and we cannot assure you that we will be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, we may be required to:

- delay, reduce the scope of or eliminate one or more of our programs;
- obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves; or
- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

If we raise additional funds by issuing equity securities, further dilution to stockholders may result, and new investors could have rights superior to existing stockholders.

**We have limited manufacturing capabilities, which could adversely impact 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. The manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up when large-scale production is required and subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our product candidates or related materials become unavailable to us on a timely basis or at all or are contaminated or otherwise lost, 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 have constructed two pilot-scale manufacturing facilities, one for the production of vaccines and one for the production of recombinant proteins. We believe that, for these types of product candidates, these facilities will be sufficient to meet our initial needs for clinical trials. However, these facilities may be insufficient for late-stage clinical trials for these types of product candidates and would be insufficient for commercial-scale manufacturing requirements. 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 cannot assure you that we will be able to develop a manufacturing facility that both meets regulatory requirements and is sufficient for all clinical trials or commercial-scale manufacturing.

We have entered into arrangements with third parties for the manufacture of certain of our products. We cannot assure you that this strategy will result in a cost-effective means for manufacturing products. In employing third-party manufacturers, we will not control many aspects of the manufacturing process. We cannot assure you that we will be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes or that commercial quantities of products will be available from contract manufacturers at acceptable costs.

**Manufacturing PRO 542 in amounts sufficient to support large-scale clinical trials has proven particularly difficult, which could delay clinical development.**

PRO 542 is a recombinant protein, which generally involves more complex production methods than small-molecule drugs. We are pursuing alternative, potentially redundant manufacturing strategies, including expanding our internal manufacturing through mammalian cell-line fermentation, a standard recombinant manufacturing process, and more sophisticated methods, such as transgenics. Nevertheless manufacturing





[Back to Contents](#)

PRO 542 is challenging, and these challenges could increase the cost of production, delay product development or commercialization or otherwise adversely impact our ability to commercialize PRO 542.

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

We and our products are subject to comprehensive regulation by the Food and Drug Administration in the United States and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the preclinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, record keeping, advertising and promotion of pharmaceutical products. Violations of regulatory requirements at any stage, whether before or after marketing approval is obtained, may result in fines, forced removal of a product from the market and other adverse consequences.

**We do not yet have, and may never obtain, the regulatory approvals we need to successfully market our products.**

Our products have not yet been approved by applicable regulatory authorities for commercialization. The process of obtaining FDA and other required regulatory approvals, including foreign 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 necessary to gain regulatory approvals. We cannot guarantee that any of our products under development will be approved for marketing by the FDA. Even if regulatory approval of a product is granted, we cannot be certain that we will be able to obtain the labeling claims necessary or desirable for the promotion of such products. Even if we obtain regulatory approval, we may be required to undertake post-marketing trials to verify a product's efficacy or safety. In addition, identification of side effects after a drug is on the market or the occurrence of manufacturing problems could result in subsequent withdrawal of approval, reformulation of the drug, additional preclinical testing or clinical trials, changes in labeling of the product, and additional marketing applications. If we receive regulatory approval, we will also be subject to ongoing FDA obligations and continued regulatory review. Delays in receipt of or failure to receive regulatory approvals, or the loss of previously received approvals, would delay or prevent product commercialization, which would adversely affect our financial results.

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

Our success is dependent in part on obtaining, maintaining and enforcing patent and other proprietary 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 in such cases, or the degree of protection afforded under such patents. Accordingly, we cannot assure you that patent applications owned by or licensed to us will result in patents being issued or that, if issued, the patents will give us an advantage over competitors with similar technology.

We own or have licenses to certain issued patents. However, the issuance of a patent is not conclusive as to its validity or enforceability. The validity or enforceability of a patent after its issuance by the patent office can be challenged in litigation. We cannot assure you that our patents will not be successfully challenged. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, we cannot assure you that our patents will not be infringed or successfully avoided through design innovation.

Generally, we 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. In addition, our license agreement with UR Labs regarding MNTX gives us the right to prosecute and maintain the licensed patents. We bear the cost of engaging in some or all of these activities with respect to our license agreements with Sloan-Kettering for GMK, Columbia for our HIV product candidates subject to the Columbia license and UR Labs for MNTX. With most of our other license

[Back to Contents](#)

agreements, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under specified circumstances. Historically, our costs of defending patent rights, both our own and those we license, have not been material.

We are required to make substantial cash payments and achieve certain milestones and satisfy certain conditions, including filing investigational new drug applications, obtaining product approvals and introducing products, to maintain our rights under our licenses, including our licenses from UR Labs, Inc., Memorial Sloan-Kettering Cancer Center and Columbia University. We cannot assure you that we will be able to maintain our rights under these licenses. Termination of any of these licenses could result in our being unable to commercialize any related product.

In addition to the intellectual property rights described above, we also rely on unpatented technology, trade secrets and confidential information. We cannot assure you that others will not independently develop substantially equivalent information and techniques or otherwise gain access to our technology or disclose such technology, or that we can 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. We cannot assure you, however, that these agreements will provide effective protection in the event of unauthorized use or disclosure of this confidential information.

**If we infringe third-party patents, we could need to alter or terminate a product development program.**

There may be patent rights belonging to others that require us to alter our products, pay licensing fees or cease certain activities. If our products conflict with patent rights of others, they 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 cannot assure you that we would prevail in any such action or that any license required under any such patent would be made available on acceptable terms or at all. For example, we have filed a number of U.S. and foreign patent applications, one of which is owned jointly with the Aaron Diamond AIDS Research Center, relating to the discovery of the HIV co-receptor CCR5. We are aware that other groups have claimed discoveries similar to those covered by our patent applications. We do not expect to know for several years the relative strength of our patent position as compared to these other groups.

The research, development and commercialization of a biopharmaceutical often involves 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 it is possible that to pursue the preferred development route of one or more of our products we will need to obtain a license to a patent, which 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 on third parties for a variety of functions; we cannot assure you that these arrangements will provide us with the benefits we expect.**

In addition to our reliance on collaborators, we rely in part on third parties to perform a variety of functions. As of December 31, 2002, we had only 100 full-time employees. We are party to several agreements which place substantial responsibility on third parties for portions of the development of our products. We also in-license technology from medical and academic institutions in order to minimize investments in early research, and we enter into collaborative arrangements with certain of these entities with respect to clinical trials of product candidates. We cannot assure you that we will be able to maintain any of these relationships or establish new ones on beneficial terms, that we can enter into these arrangements without undue delays or expenditures or that these arrangements will allow us to compete successfully.

[Back to Contents](#)

**We lack sales and marketing experience, which makes us dependent on third parties for their expertise in this area.**

We have no experience in sales, marketing or distribution. Assuming receipt of required regulatory approvals, we expect to market and sell our products principally 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. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of our products, any revenues we receive will depend primarily on the efforts of these third parties. We will not control the amount and timing of marketing resources such third parties devote to our products. In addition, if we market products directly, significant additional expenditures and management resources would be required to develop an internal sales force. We cannot assure you that we would be able to establish a successful sales force should we choose to do so.

**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, our Chairman, Chief Executive Officer and Chief Science Officer, or Mr. Prentki, our President, could cause our management and operations to suffer unless a qualified replacement could be found. We maintain key man life insurance on Dr. Maddon in the amount of \$2.5 million. By mutual agreement of Dr. Maddon and the Company, Dr. Maddon's employment agreement was allowed to expire effective as of December 22, 2002. Dr. Maddon continues in his capacities as Chairman, Chief Executive Officer and Chief Scientific Officer as an at-will employee while the parties continue discussions directed to reaching mutually acceptable terms for a new employment agreement between the Company and Dr. Maddon.

We also have an employment agreement with Mr. Prentki the initial term of which runs through March 2004, subject to automatic annual extensions unless either party provides six-months prior notice of termination.

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 cannot assure you that we will be successful in hiring or retaining qualified personnel.

**If sufficient quantities of the raw and bulk materials needed to make our products are not available, product development and commercialization could be slowed or stopped.**

We cannot assure you that sufficient quantities of the raw materials needed to make our products will be available to support continued research, development or commercial manufacture of our products. We currently obtain supplies of critical raw materials used in production of GMK and methylnaltrexone from single sources. In particular, we rely on single source third party manufacturers for the supply of both bulk and finished form methylnaltrexone. In addition, commercialization of GMK requires an adjuvant, QS-21, available only from Antigenics, Inc. We have entered into a license and supply agreement with a subsidiary of Antigenics pursuant to which they agreed to supply us with all of our QS-21 requirements for use in certain ganglioside-based cancer vaccines, including GMK. We also have supply arrangements in place with our single source methylnaltrexone suppliers. However, we cannot assure you that the existing arrangements will result in the supply of sufficient quantities of methylnaltrexone and QS-21 needed to accomplish our clinical development programs or that we will 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 could slow or stop product development and commercialization of the relevant product.

[Back to Contents](#)

**A substantial portion of our funding comes from federal government grants; we cannot rely on these grants as a continuing source of funds.**

A substantial portion of our revenues to date has been derived from federal grants and research contracts. In addition to previous years' awards, in 2002 we were awarded, in the aggregate, approximately \$5.6 million in National Institute of Health grants and research contracts. We cannot rely on these grants as a continuing source of funds. The government's obligation to make payments under these grants is subject to appropriation by the United States Congress for funding in each year. Moreover, 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. Consequently, we cannot assure you that we will be awarded research grants in the future or that any amounts derived from them will not be less than those received to date.

**We are subject to the uncertainty related to health care reform measures and reimbursement policies.**

In recent years, there have been numerous proposals to change the health care system in the United States. Some of these proposals have included measures that would limit or eliminate payments for medical procedures and treatments or subject the pricing of pharmaceuticals to government control. In addition, as a result of the trend towards managed health care in the United States, 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 succeeds in bringing one or more of our products to market, we cannot assure you that third-party payors will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. Significant changes in the health care system in the United States or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our profitability. Such changes also could have a material adverse effect on our ability to raise capital. Furthermore, our ability to commercialize products may be adversely affected to the extent that these proposals affect our collaborators.

**We are exposed to product liability claims, and it is uncertain that in the future insurance against these claims will be available to us at a reasonable rate.**

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We cannot assure you that we will be able to avoid product liability exposure. Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all. We have obtained product liability insurance coverage in the amount of \$5.0 million per occurrence, subject to a \$5.0 million aggregate limitation. However, we cannot assure you that our present insurance coverage is now or will continue to be adequate. In addition, some of our license and collaborative agreements require us to obtain product liability insurance. We cannot assure you that adequate insurance coverage will be available to us at a reasonable cost in the future or that a product liability claim or recall would not have a material adverse effect on our financial position.

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

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 precautionary procedures that we implement for handling and disposing of these materials, the risk of accidental contamination or injury cannot be eliminated. In the event of a hazardous waste spill or other accident, we could also be liable for damages, penalties or other forms of censure. Although we believe that we are in compliance in all material respects with applicable environmental laws and regulations, we cannot assure you that we will not be required to incur significant costs to comply with environmental laws and regulations in the future or that we will not be materially and adversely affected by current or future environmental laws or regulations.

[Back to Contents](#)

**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. At times, our stock price has been volatile even in the absence of significant news or developments relating to Progenics. Moreover, the stocks of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years. Factors that may have a significant impact on the market price of our common stock include:

- the results of preclinical studies and clinical trials by us, our collaborators or our competitors;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
- developments in our relationships with collaborative partners;
- developments in patent or other proprietary rights;
- governmental regulation;
- changes in reimbursement policies;
- health care legislation;
- public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
- fluctuations in our operating results; and
- general market conditions.

In addition, the market prices of equity securities generally have experienced significant volatility in the recent past, with the stock of small capitalization companies, like us, experiencing the greatest volatility. These price swings, as to our stock, as to our industry, as well as to the stock market generally, may continue. Moreover, the experiences of other companies would lead us to expect a severe decline in our stock price if we experience an adverse development in our business. As described above, our business plan is risky, and so there is a very real possibility that we will not succeed in achieving our goals.

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

Dr. Maddon and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately 35% of our outstanding shares of common stock. These persons, 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 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.

**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



[Back to Contents](#)

- otherwise dilute the rights of holders of common stock and depress the market price of our common stock.

**Sales of common stock may have an adverse impact on the market price of our common stock.**

A substantial number of outstanding shares of common stock and shares of common stock issuable upon exercise of outstanding options and warrants are eligible for sale in the public market. Sales of substantial numbers of shares of common stock could adversely affect prevailing market prices. Some of our stockholders are entitled to require us to register their shares of common stock for offer or sale to the public. We have filed a Form S-8 registration statement registering shares issuable pursuant to our stock option plans. Any sales by existing stockholders or holders of options or warrants may have an adverse effect on our ability to raise capital and may adversely affect the market price of the common stock.



[Back to Contents](#)

## PART II

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

#### Overview

Progenics is a biopharmaceutical company focusing on the development and commercialization of innovative products to address the unmet medical needs of patients with debilitating conditions and life-threatening diseases. We commenced principal operations in late 1988 and since that time have been engaged primarily in research and development efforts, development of our manufacturing capabilities, establishment of corporate collaborations and raising capital. In order to commercialize the principal products that we have under development, we will need to address a number of technological challenges and comply with comprehensive regulatory requirements. Accordingly, it is not possible to predict the amount of funds that will be required or the length of time that will pass before we receive revenues from sales of any of these products. To date, 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. Our other sources of revenues through December 31, 2002 have been payments received under our collaboration agreements, research grants and contracts related to our cancer and HIV programs and interest income.

To date, a majority of our expenditures have been for research and development activities. We expect that our research and development expenses will increase significantly as our programs progress and we make filings for related regulatory approvals. With the exception of the years ended December 31, 1997 and 1998, we have had recurring losses and had, at December 31, 2002, an accumulated deficit of approximately \$46,308,000. We will require additional funds to complete the development of our products, to fund the cost of clinical trials and to fund operating losses that are expected to continue for the foreseeable future. We do not expect our products under development to be commercialized in the near future.

#### Results of Operations

*Years Ended December 31, 2001 and 2002*

#### Revenues:

We recognized \$5,298,000 and \$199,000 of revenue for research and development services performed for the PSMA Development Company, LLC, our joint venture with Cytogen Corporation, (the "JV") during 2002 and 2001, respectively. We have a 50% interest in the JV. We were required to fund the first \$3.0 million of research and development costs and such amounts were recorded as capital contributions to the JV. During the fourth quarter of 2001, we surpassed the \$3.0 million threshold, at which time we began recognizing revenue for services and costs being provided to and paid by the JV. The level of future revenues from the JV will be dependent upon the extent of research and development services requested by the JV and the future financial position of the JV. We provide services to the JV under a Services Agreement. As of March 31, 2002, and through December 31, 2002, the Company was performing services for the JV under a month-to-month extension of the Services Agreement. At December 31, 2002, and through March 28, 2003, the Members were negotiating the terms of a new Services Agreement. Accordingly, future revenue will also be dependent upon the extension, if any, and terms of an amended Services Agreement. The level of commitment by Progenics and Cytogen (collectively, the "Members") to fund the JV is based on an annual budget that is approved by both of the Members. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002.

Other contract research and development revenue declined from \$4,916,000 in 2001 to \$194,000 in 2002 primarily due to a decrease in funding received from Bristol-Myers Squibb Company ("BMS") after we and BMS mutually terminated our collaboration agreement in May 2001. We received \$3,673,000 from BMS in 2001 under the agreement and \$0 in 2002. Revenues from contract research and development performed for other collaborators decreased from \$1,243,000 in 2001 to \$194,000 in 2002 as our commitments for such work were completed.



[Back to Contents](#)

Revenues from research grants increased from \$3,725,000 in 2001 to \$4,544,000 in 2002. The increase resulted from the funding of a greater number of grants in 2002. Sales of research reagents increased from \$43,000 in 2001 to \$49,000 in 2002 resulting from increased orders for such reagents during 2002.

**Expenses:**

Research and development expenses include scientific labor, supplies, facility costs, clinical trial costs, patent costs, and product manufacturing costs. In late 2001, we in-licensed MNTX, an investigational drug in late-stage clinical development designed to reverse certain side effects of opioid pain medications. The product has entered phase 3 clinical trials and has become our lead product candidate. A major portion of our spending has been and will continue to be concentrated on this product candidate. Research and development expenses increased from \$14,501,000 in 2001 to \$23,761,000 in 2002. The increase was principally due to (i) an increase of \$2,292,000 related to an increase in headcount from 50 in 2001 to 70 in 2002 in the research and development, manufacturing and medical departments, (ii) an increase of \$2,537,000 in manufacturing supplies (particularly for MNTX), (iii) additional rent of \$303,000 for new laboratory space as we expanded our programs to include MNTX, and (iv) an increase of \$4,033,000 in spending on the PSMA and HIV research programs.

General and administrative expenses include executive and administrative labor, professional fees, office rent and supplies. General and administrative expenses remained unchanged at \$6,499,000 in 2001 and \$6,484,000 in 2002. The minimal decrease was principally due to a decrease of \$180,000 in professional fees offset by an increase of \$371,000 in operating expenses such as rent.

Loss in joint venture increased from \$2,225,000 in 2001 to \$2,886,000 in 2002. The increase was primarily due to the growth and acceleration of the joint venture's development programs to develop in vivo immunotherapies for prostate cancer and the costs of licensing transactions. We recognize our share of the JV's loss under the terms of the JV with Cytogen Corporation. The increase in the JV loss was due to an increase in the headcount assigned to the PSMA project and the related cost of supplies. Additionally, prior to reaching the \$3.0 million threshold, we recognized 100% of the joint venture's research and development losses; that percentage was reduced to 50% subsequent to reaching that threshold in December 2001. The level of future losses from the JV will be dependent upon the extent of research and development costs expended by the JV, the future financial position of the JV and the extension, if any, and terms of an amended Services Agreement. The level of commitment by Progenics and Cytogen to fund the JV is based on an annual budget that is approved by the Members. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002.

Depreciation and amortization increased from \$707,000 in 2001 to \$1,049,000 in 2002 as we purchased capital assets and made leasehold improvements in 2002 to accommodate expansion.

Other income (expense):

Interest income decreased from \$3,348,000 in 2001 to \$1,708,000 in 2002 as cash available for investing decreased and interest rates declined year over year. During 2001, we received a non-recurring payment of \$9,852,000 from BMS in connection with the termination of the BMS Agreement (see above). As a result of the termination of the BMS Agreement, we will receive no additional payments from BMS. During 2002, we received a \$1,600,000 payment from an insurance settlement related to a heat excursion in our storage facility.

Our net loss was \$1,898,000 in 2001 compared to a net loss of \$20,789,000 in 2002.

*Years Ended December 31, 2000 and 2001*

**Revenues:**

We recognized \$0 of revenue for research and development services performed for the PSMA Development Company, LLC, our joint venture with Cytogen Corporation, (the "JV") during 2000 and \$199,000 in 2001. We were required to fund the first \$3.0 million of research and development costs and



[Back to Contents](#)

such amounts were recorded as capital contributions to the JV. That \$3.0 million threshold was reached in the fourth quarter of 2001. Other contract research and development revenue declined from \$7,941,000 in 2000 to \$4,916,000 in 2001 including funding received from Bristol-Myers Squibb Company (□BMS□) after the Company and BMS mutually terminated their collaboration agreement in May 2001. The Company received \$6,213,000 from BMS in 2000 under the agreement and \$3,673,000 in 2001.

#### **Expenses:**

Research and development expenses increased from \$13,075,000 in 2000 to \$14,501,000 in 2001. The increase was principally due to increases of \$774,000 related to increased headcount, \$342,000 for additional rent for new laboratory space as we expanded our research and development programs to include MNTX in October 2001 and \$148,000 for related laboratory supplies.

General and administrative expenses increased from \$5,042,000 in 2000 to \$6,499,000 in 2001. The increase was principally due to \$795,000 related to increased headcount, an increase of \$243,000 in legal expenses related to our intellectual property filings and prosecutions and \$103,000 of additional rent for new office space to accommodate growth.

Loss in joint venture increased from \$945,000 in 2000 to \$2,225,000 in 2001. The increase was primarily due to the growth and acceleration of the joint venture's development programs to develop in vivo immunotherapies for prostate cancer and the costs of licensing transactions.

Other income (expense):

Interest income decreased from \$4,127,000 in 2000 to \$3,348,000 in 2001 as cash available for investing remained relatively constant and interest rates decreased year over year.

Interest expense decreased from \$95,000 in 2000 to \$49,000 in 2001. The decrease was principally due to the recognition of interest expense as we discounted future capital contributions to the joint venture that decreased in 2001 and reduced capital lease obligations in 2001. We also received a non-recurring payment of approximately \$9,852,000 from BMS in connection with the termination of the BMS Agreement. As a result of the termination of the BMS Agreement, we will receive no additional payments from BMS.

Our net loss was \$5,917,000 in 2000 compared to a net loss of \$1,898,000 in 2001.

#### **Liquidity and Capital Resources**

We have funded our operations since inception primarily through private placements of equity securities, loans that were subsequently converted into equity securities, a line of credit that was repaid and terminated, payments received under collaboration agreements, such as those with BMS and Roche, two public offerings of common stock, funding under government research grants and contracts, interest on investments, and the proceeds from the exercise of outstanding options and warrants. In May 2001, we and BMS mutually agreed to terminate our cancer vaccine collaborative development agreement, pursuant to which we regained all rights to the products and received a non-recurring payment of approximately \$9,852,000 from BMS. As a result of the termination of the BMS Agreement, we will receive no additional payments from BMS. In 2002, we received \$1,600,000 in full settlement of an insurance claim.

At December 31, 2002, we had cash, cash equivalents and marketable securities, including non-current portion, totaling approximately \$42.4 million compared with approximately \$61.9 million at December 31, 2001. The cash used in operations for the year ended December 31, 2002 was \$17.3 million compared with \$2.1 million of cash provided by operations for the same period in 2001. The cash used in operations for the year ended December 31, 2002 resulted primarily from a net loss of \$20.8 million partially offset by depreciation and amortization of \$2.3 million.

The cash provided by investing activities for the year ended December 31, 2002 was \$14.5 million compared with \$2.1 million of cash provided by investing activities for the same period in 2001. The cash provided by investing activities for the year ended December 31, 2002 resulted primarily from the sale of \$29.9 million of marketable securities offset by the purchase of \$13.1 of marketable securities and the purchase of \$2.2 million of fixed assets

including capital equipment and leasehold improvements as we

[Back to Contents](#)

acquired and built out additional research and development space. We expect to spend about the same amount during 2003 to install a new bioreactor. Actual cash expended may decrease in 2003 as we are negotiating a lease line of credit to finance certain capital expenditures.

Cash provided by financing activities for the year ended December 31, 2002 was \$1.4 million as compared with \$1.0 million of cash provided by financing activities for the same period in 2001. The cash provided by financing activities for the year ended December 31, 2002 reflects the exercise of stock options under our Employee Stock Option Plans, the exercise of warrants and the sale of common stock under the Employee Stock Purchase Plans. During 2003, we expect that cash received from exercises under the above plans will increase due to increased headcount.

We are required to make capital contributions to fund 50% of the current and future spending on the PSMA projects under the terms of the JV. Such amount was \$2.3 million during 2002. The level of commitment by Progenics and Cytogen to fund the JV is based on a budget that is approved by both parties. That budget is intended to be sufficient to fund research and development projects for the current year. The budget must also consider the ability of the Members to fund the JV. During the first quarter of 2003, each Member contributed \$1.5 million to the JV. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002.

We provide services to the JV under a Services Agreement. As of March 31, 2002, and through December 31, 2002, the Company was performing services for the JV under a month-to-month extension of the Services Agreement. At December 31, 2002, and through March 28, 2003, the Members were negotiating the terms of a new Services Agreement. For the year ended December 31, 2002, we recognized approximately \$5,298,000 of contract research and development revenue for services performed on behalf of the JV. A portion of these revenues is reimbursement for costs expended to outside parties. Beginning in 2003, all costs to outside parties will be paid directly by the JV. The level of future revenues from the JV will be dependent upon the extent of research and development services requested by the JV, the future financial position of the JV and the extension, if any, and terms of an amended Services Agreement.

Our total expenses for research and development from inception through December 31, 2002 have been approximately \$94.8 million. We currently have major research and development programs investigating cancer, symptom management and supportive care, and human immunodeficiency virus-related diseases (□HIV□), for which we are or have licensed technology and collaborated with other pharmaceutical and biotechnology companies as well as academic institutions. In addition, we are conducting several smaller research projects in the areas of virology and cancer. For various reasons, many of which are outside of our control, including the early stage of our programs, the timing and results of our clinical trials and our dependence on third parties, we cannot estimate the total remaining costs to be incurred and timing to complete our research and development programs. However, we expect to increase our spending on MNTX to approximately \$15.0 million in 2003 for purchases of clinical supplies and the conduct of clinical trials. Spending on other programs is expected to remain relatively constant in 2003. For the years ended December 31, 2000, 2001 and 2002, research and development costs incurred were as follows:

	<b>Years Ended December 31,</b>		
	<b>2000</b>	<b>2001</b>	<b>2002</b>
	<b>(in \$ million)</b>		
Cancer	\$ 5.7	\$ 4.2	\$ 7.0
MNTX	7.0		
HIV	6.9	9.8	7.3
Other programs	.5	.5	2.5
<b>Total</b>	<b>\$ 13.1</b>	<b>\$ 14.5</b>	<b>\$ 23.8</b>

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

We believe that our existing capital resources together with revenue from currently approved government grants and contracts and revenue from the Services Agreement should be sufficient to fund operations for at



[Back to Contents](#)

least the next 12 months. During the next 12 months, we expect to expend substantial funds to conduct research and development activities, preclinical studies, clinical trials and other related general and administrative activities. Our expenditures for these activities will include required payments under operating leases and licensing, collaboration and service agreements as noted in the table below.

For periods beyond 12 months, we may seek additional financing to fund operations through future offerings of equity or debt securities or agreements with corporate partners and collaborators with respect to the development of our technologies. We also plan to seek funding from additional grants and government contracts. We cannot assure you, however, that we will be able to obtain additional funds on acceptable terms, if at all. We will require substantial funds to conduct research and development activities, preclinical studies, clinical trials and other general and administrative activities. Our expenditures for these activities will include required payments under operating leases and licensing, collaboration and service agreements as noted in the table below.

Our cash requirements may vary materially from those now planned because of results of research and development and product testing, changes in existing relationships with, 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.

Other than currently approved grants, we have no committed external sources of capital and, as discussed above, expect no significant product revenues for a number of years as it will take at least that much time, if ever, to bring our products to the commercial marketing stage.

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

The following table summarizes our contractual obligations as of December 31, 2002, for future operating lease payments and license and milestone payments for license and corporate collaboration agreements:

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than one year</b>	<b>1 to 3 years</b>	<b>4 to 5 years</b>	<b>Greater than 5 years</b>
	(in \$ millions)				
Operating leases	\$ 2.0	\$ 0.8	\$ 1.2		
License and collaboration agreements (1)	25.6	4.3	4.2	\$ 4.2	\$ 12.9

(1) Assumes attainment of milestones covered under each agreement. 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. Certain of these agreements require us to pay annually minimum royalties or maintenance fees in a maximum aggregate amount of \$500,000, which are not included in this table. This table also does not reflect the payment obligations of our joint venture with Cytogen.

### **Critical Accounting Policies**

#### *Revenue Recognition*

We recognize revenue from contract research and development as we perform services, provided a contractual agreement exists, the contract price is fixed or determinable, and our collection of the resulting receivable is probable. In situations where we receive payment in advance of the performance of services, these amounts are deferred and recognized as revenue as we perform the related services. Non-refundable fees, including payments we receive for services, up-front licensing fees and milestone payments are recognized as revenue based on the percentage of costs incurred to date, estimated costs to complete and total expected contract revenue in



[Back to Contents](#)

Power Sales Contracts, which is a systematic method that is representative of the revenue earned or obligations fulfilled under these arrangements. However, the revenue we recognize is limited to the amount of non-refundable fees received. Non-refundable fees that we receive in consideration for granting collaborators the right to license product candidates developed by us are recognized as revenue on a straight-line basis over the term of the underlying agreements. With regard to our revenues from non-refundable fees, changes in estimates of our costs to complete could have a material impact on the revenues we recognize.

In connection with the formation of the equally-owned JV, we have funded the first \$3.0 million of research and development costs incurred on behalf of the JV. Prior to reaching \$3.0 million of such costs, we recognized reimbursements on a net basis and did not recognize any revenue from the JV. Subsequent to having funded \$3.0 million of research and development costs, in the fourth quarter of 2001, both Members are required to fund the JV to support ongoing research and development efforts conducted by us on behalf of the JV. Accordingly, following \$3.0 million of funding, we, acting as a principal, recognize payments for research and development as revenue. We are the primary obligor responsible for providing the service, by conducting research and development, desired by the JV, including the acceptability of the research and development services and we have established the amounts we will be reimbursed for the services by selecting the subcontractors and suppliers we employ in conducting the research and development for the JV. Changes in those factors may have a significant impact on the revenue that we recognize in the future.

For the year ended December 31, 2002, we recognized approximately \$5,298,000 of contract research and development revenue for services performed on behalf of the JV. A portion of these revenues was reimbursement for costs expended to outside parties. Beginning in 2003, all costs to outside parties will be paid directly by the JV. The level of future revenues from the JV will be dependent upon the extent of research and development services requested by the JV, the future financial position of the JV and the extension, if any, and terms of an amended Services Agreement. The level of commitment by Progenics and Cytogen to fund the JV is based on an annual budget that is approved by both parties. That budget is intended to be sufficient to fund research and development projects for 2003. The budget must also consider the ability of the Members to fund the JV. During the first quarter of 2003, each Member contributed \$1.5 million to the JV. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002.

### **Clinical Trial Expenses**

Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our contracts with various clinical research organizations in connection with conducting clinical trials for our product candidates. Such costs are expensed 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 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.

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

In June 2002, the Financial Accounting Standards Board issued Statement on Financial Accounting Standards No. 146 (FAS 146) Accounting for Costs Associated with Exit or Disposal Activities. FAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). FAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred rather than on the date of an entity's commitment to an exit plan and establishes that fair value is the objective for initial measurement of the liability. The provisions of this Statement shall be effective for exit or disposal activities initiated after December 31, 2002. The provisions of Issue 94-3 shall continue to apply for an exit activity initiated under an exit plan that met the criteria of Issue 94-3 prior to this Statement's initial application.

[Back to Contents](#)

On December 31, 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation" Transition and Disclosure" an amendment of FAS 123" ("FAS 148"). FAS 148 provides several transition provisions that may be used upon adoption of the accounting provisions of FAS 123. FAS 148 also mandates certain new disclosures, whether or not FAS 123 is adopted, that are incremental to those required by FAS 123. Those disclosures must be made in both interim and annual financial statements. The transition and annual disclosure provisions of FAS 148 are effective for fiscal years ending after December 15, 2002. The new interim disclosure provisions are effective for the first interim period beginning after December 15, 2002.

On November 21, 2002, the EITF finalized Issue No. 00-21 "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF 00-21") which addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. EITF 00-21 also addresses how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003.

On November 25, 2002, the Financial Accounting Standards Board issued FASB Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of this Interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The interpretive guidance incorporated without change from Interpretation 34 continues to be required for financial statements for fiscal years ending after June 15, 1981 the effective date of Interpretation 34.

Management believes that the future adoption of these accounting standards will not have a material impact on the Company's financial statements.

#### **Item 8. Financial Statements and Supplementary Data**

See page F-1, "Index to Financial Statements."

### **PART IV**

#### **Item 15. Exhibits, Financial Statement Schedule and Reports on Form 8-K**

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

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

1. Report of Independent Accountants
2. Financial Statements of Progenics Pharmaceuticals, Inc.

Balance Sheets at December 31, 2001 and 2002

Statements of Operations for the years ended December 31, 2000, 2001 and 2002

Statements of Stockholders' Equity and Comprehensive Loss for the years ended December 31, 2000, 2001 and 2002

Statements of Cash Flows for the years ended December 31, 2000, 2001 and 2002

Notes to the Financial Statements

3. Financial Statements of PSMA Development Company LLC

Balance Sheets at December 31, 2001 and 2002

[Back to Contents](#)

Statements of Operations for the period from June 15, 1999 (inception) to December 31, 1999, the years ended December 31, 2000, 2001 and 2002 and the cumulative period from June 15, 1999 (inception) to December 31, 2002

Statements of Stockholders' (Deficit) Equity for the period from June 15, 1999 (inception) to December 31, 2001, including the period from June 15, 1999 (inception) to December 31, 1999 and the years ended December 31, 2000, 2001 and 2002

Statements of Cash Flows for the period from June 15, 1999 (inception) to December 31, 1999, the years ended December 31, 2000, 2001 and 2002, and the cumulative period from June 15, 1999 (inception) to December 31, 2002

Notes to Financial Statements

*b) Reports on Form 8-K*

On December 20, 2002 we filed a Current Report on Form 8-K in which Item 7 exhibits were filed and an Item 9 Regulation FD disclosure was made and no financial statements were filed.

*c) Item 601 Exhibits*

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

[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.  
INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
	<hr/>
<b>Progenics Pharmaceuticals, Inc.</b>	
Report of Independent Accountants	F-2
Financial Statements:	
Balance Sheets as of December 31, 2001 and 2002	F-3
Statements of Operations for the years ended December 31, 2000, 2001 and 2002	F-4
Statements of Stockholders' Equity and Comprehensive Loss for the years ended December 31, 2000, 2001 and 2002	F-5
Statements of Cash Flows for the years ended December 31, 2000, 2001 and 2002	F-6
Notes to Financial Statements	F-7
<b>PSMA Development Company L.L.C. (a development stage enterprise)</b>	
Report of Independent Accountants	F-25
Financial Statements:	
Balance Sheets as of December 31, 2001 and 2002	F-26
Statements of Operations the years ended December 31, 2000, 2001 and 2002 and the cumulative period from June 15, 1999 (inception) to December 31, 2002	F-27
Statements of Stockholders' (Deficit) Equity for the period from June 15, 1999 (inception) to December 31, 1999, and for the years ended December 31, 2000, 2001 and 2002	F-28
Statements of Cash Flows the years ended December 31, 2000, 2001 and 2002, and the cumulative period from June 15, 1999 (inception) to December 31, 2002	F-29
Notes to Financial Statements	F-30

[Back to Contents](#)

**REPORT OF INDEPENDENT ACCOUNTANTS**

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

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders' equity and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Progenics Pharmaceuticals, Inc. (the "Company") at December 31, 2001 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

New York, New York  
February 14, 2003, except for Note 8,  
as to which the date is March 28, 2003



[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2001</b>	<b>2002</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,759,636	\$ 9,446,982
Marketable securities	30,523,239	27,753,984
Accounts receivable	378,020	334,006
Other current assets	2,086,585	1,573,815
	43,747,480	39,108,787
Total current assets		
Marketable securities	20,594,274	5,172,808
Fixed assets, at cost, net of accumulated depreciation and amortization	2,560,199	3,705,531
Investment in joint venture	579,296	
Restricted cash		130,795
	\$ 67,481,249	\$ 48,117,921
Total assets		
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,597,089	\$ 2,900,028
Amount due to joint venture	500,000	
	3,097,089	2,900,028
Total current liabilities		
Deferred lease liability	38,797	71,264
	3,135,886	2,971,292
Total liabilities		
Commitments and contingencies (Note 7)		
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; shares issued and outstanding 12,429,916 in 2001 and 12,681,585 in 2002	16,159	16,486
Additional paid-in capital	89,664,075	91,332,106
Unearned compensation	(23,150)	
Accumulated deficit	(25,518,834)	(46,307,642)
Accumulated other comprehensive income	207,113	105,679
	64,345,363	45,146,629
Total stockholders' equity		
Total liabilities and stockholders' equity	\$ 67,481,249	\$ 48,117,921

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



[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**

	<b>Years Ended December 31,</b>		
	<b>2000</b>	<b>2001</b>	<b>2002</b>
<b>Revenues:</b>			
Contract research and development from joint venture	\$	\$ 199,123	\$ 5,298,293
Other contract research and development	7,941,185	4,916,341	193,734
Research grants	1,835,564	3,725,375	4,543,505
Product sales	45,524	42,800	49,030
	9,822,273	8,883,639	10,084,562
<b>Expenses:</b>			
Research and development	13,074,815	14,501,400	23,760,544
General and administrative	5,042,485	6,499,153	6,484,001
Loss in Joint Venture	945,519	2,225,454	2,886,423
Depreciation and amortization	708,874	707,382	1,048,960
	19,771,693	23,933,389	34,179,928
<b>Total revenues</b>	<b>9,822,273</b>	<b>8,883,639</b>	<b>10,084,562</b>
<b>Total expenses</b>	<b>19,771,693</b>	<b>23,933,389</b>	<b>34,179,928</b>
<b>Operating loss</b>	<b>(9,949,420)</b>	<b>(15,049,750)</b>	<b>(24,095,366)</b>
<b>Other income (expenses):</b>			
Interest income	4,127,156	3,348,401	1,708,253
Interest expense	(94,892)	(48,816)	(1,695)
Payment from collaborator		9,852,015	
Payment from insurance settlement			1,600,000
	4,032,264	13,151,600	3,306,558
<b>Total other income</b>	<b>4,032,264</b>	<b>13,151,600</b>	<b>3,306,558</b>
<b>Net loss</b>	<b>\$ (5,917,156)</b>	<b>\$ (1,898,150)</b>	<b>\$ (20,788,808)</b>
<b>Net loss per share</b> □ basic and diluted	<b>\$ (0.49)</b>	<b>\$ (0.15)</b>	<b>\$ (1.66)</b>
<b>Weighted-average shares</b> □ basic and diluted	<b>12,137,653</b>	<b>12,376,056</b>	<b>12,550,798</b>

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

[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS**  
**For the Years Ended December 31, 2000, 2001 and 2002**

	Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive		Comprehensive Income (Loss)
	Shares	Amount				Income	Total	
Balance at December 31, 1999	11,905,774	\$ 15,478	\$ 86,329,599	\$ (591,142)	\$ (17,703,528)	\$ (229,704)	\$ 67,820,703	
Amortization of unearned compensation				428,898			428,898	
Issuance of compensatory stock options			164,476				164,476	
Sale of Common Stock under employee stock purchase plans and exercise of stock options	248,413	322	1,729,451				1,729,773	
Exercise of warrants	112,993	147	195,624				195,771	
Net loss for the year ended December 31, 2000					(5,917,156)		(5,917,156)	\$ (5,917,156)
Changes in unrealized gain on marketable securities						331,475	331,475	331,475
Balance at December 31, 2000	12,267,180	15,947	88,419,150	(162,244)	(23,620,684)	101,771	64,753,940	\$ (5,585,681)
Amortization of unearned compensation				139,094			139,094	
Issuance of compensatory stock options			238,333				238,333	
Sale of Common Stock under employee stock purchase plans and exercise of stock options	91,403	119	880,242				880,361	
Exercise of warrants	71,333	93	126,350				126,443	
Net loss for the year ended					(1,898,150)		(1,898,150)	\$ (1,898,150)

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December 31, 2001								
Changes in unrealized gain on marketable securities						105,342	105,342	105,342
Balance at December 31, 2001	12,429,916	16,159	89,664,075	(23,150)	(25,518,834)	207,113	64,345,363	\$ (1,792,808)
Amortization of unearned compensation				23,150			23,150	
Issuance of compensatory stock options			250,126				250,126	
Sale of Common Stock under employee stock purchase plans and exercise of stock options	181,669	236	1,137,996				1,138,232	
Exercise of warrants	70,000	91	279,909				280,000	
Net loss for the year ended December 31, 2002					(20,788,808)		(20,788,808)	\$ (20,788,808)
Changes in unrealized gain on marketable securities						(101,434)	(101,434)	(101,434)
Balance at December 31, 2002	12,681,585	\$ 16,486	\$ 91,332,106	\$	□\$ (46,307,642)	\$ 105,679	\$ 45,146,629	\$ (20,890,242)

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

[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**

	December 31,		
	2000	2001	2002
Cash flows from operating activities:			
Net loss	\$ (5,917,156)	\$ (1,898,150)	\$ (20,788,808)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	708,874	707,382	1,048,960
Amortization of premiums, net of discounts, on marketable securities	436,957	383,613	1,223,948
Amortization of discount on investment in Joint Venture	87,504	42,749	
Loss in Joint Venture	945,519	2,225,454	2,886,423
Non-cash expense incurred in connection with issuance of common stock, stock options	593,374	377,427	273,276
Realized loss from the sale of marketable securities		64,181	
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(1,504,939)	2,273,659	44,014
(Increase) decrease in other current assets	(668,585)	(393,541)	512,770
Decrease in security deposits and other assets	3,039		
Increase (decrease) in accounts payable and accrued expenses	(1,365,603)	519,632	321,164
Increase in investment in Joint Venture	(901,836)	(2,275,389)	(2,800,000)
Increase in deferred lease liability		38,797	32,467
Net cash provided by (used in) operating activities	(7,582,852)	2,065,814	(17,245,786)
Cash flows from investing activities:			
Capital expenditures	(1,325,243)	(1,264,799)	(2,219,644)
Purchase of marketable securities	(41,064,989)	(49,704,020)	(13,068,661)
Sale of marketable securities	30,569,000	52,038,819	29,934,000
Purchase of certificate of deposit	(1,000,000)		
Sale of certificate of deposit		1,000,000	
Increase in restricted cash			(130,795)
Net cash (used in) provided by investing activities	(12,821,232)	2,070,000	14,514,900
Cash flows from financing activities:			
Proceeds from issuance of equity securities	1,925,544	1,006,804	1,418,232
Payment of capital lease obligations	(104,921)	(11,969)	
Net cash provided by financing activities	1,820,623	994,835	1,418,232
Net increase (decrease) in cash and cash equivalents	(18,583,461)	5,130,649	(1,312,654)
Cash and cash equivalents at beginning of period	24,212,448	5,628,987	10,759,636
Cash and cash equivalents at end of period	\$ 5,628,987	\$ 10,759,636	\$ 9,446,982

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Supplemental disclosure of cash flow information:

Cash paid for interest	\$	7,388	\$	6,067	\$	1,695
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Supplemental disclosure of noncash investing and financing activities:

Fixed assets included in accounts payable and

accrued expenses	\$	238,089	\$	25,352
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The accompanying notes are an integral part of the financial statements.

F-6

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[Back to Contents](#)

## PROGENICS PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS

#### 1. Organization and Business

Progenics Pharmaceuticals, Inc. (the "Company") 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. The Company applies its expertise in clinical medicine, immunology and molecular biology to develop biopharmaceuticals to fight viral diseases, such as human immunodeficiency virus ("HIV") infection, and cancers, including malignant melanoma and prostate cancer as well as to enhance symptom management and supportive care. The Company was incorporated in Delaware on December 1, 1986. All of the Company's operations are located in New York. The Company operates under a single segment.

#### 2. Summary of Significant Accounting Policies

##### Revenue Recognition

Payments received from PSMA Development Company L.L.C. ("PSMA") (a related party), the Company's joint venture with Cytogen Corporation for contract research and development are recognized as revenue as the related services are performed by the Company in excess of defined contractual amounts (see Note 8). The gross profit margin on such revenues is not material.

Payments have been received from Bristol-Myers Squibb Company, Hoffmann-LaRoche, the Department of Defense, Aaron Diamond AIDS Research Center and the National Institutes of Health (collectively the "Collaborators") (see Note 7) for contract research and development. Such amounts are recognized as revenue as the related services are performed by the Company, provided the collection of the resulting receivable is probable. In situations where the Company receives payments in advance of performance of services, such amounts are deferred and recognized as revenue as the related services are performed.

The Company has been awarded government research grants and contracts from the National Institutes of Health (the "NIH"). The NIH grants are used to subsidize the Company's research projects ("Projects"). NIH grant revenue is recognized on a pro rata basis as subsidized Project costs are incurred. Such method approximates the straight-line basis over the lives of the Projects. The NIH contracts reimburse the Company for costs associated with manufacturing products ordered by the NIH in the HIV area.

The Company has derived all of its product revenue from the sale of research reagents. Product sales revenue is recognized at the time reagents are shipped. The reagents are products of the Company's research and development efforts. The Company maintains no inventory of reagents and cost of product sales is not material.

On January 1, 2000, the Company adopted Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). In accordance with SAB 101, non-refundable fees, including payments for services, up-front licensing fees and milestone payments, are recognized as revenue based on the percentage of costs incurred to date, estimated costs to complete, and total expected contract revenue in accordance with EITF Issue No. 91-6, "Revenue Recognition of Long-Term Power Sales Contract," which in a systematic method that is representative of the revenue earned on obligations fulfilled under those arrangements. However, revenue recognized is limited to the amount of non-refundable fees received.

Prior to January 1, 2000, the Company recognized revenue as described above, except that certain Non-refundable Fees were recognized as revenue when there were no additional contractual services to be provided or costs to be incurred by the Company in connection with the Non-refundable Fee. There was no cumulative effect of adopting SAB 101 at January 1, 2000.

Interest income is recognized as earned.

For each of the three years in the period ended December 31, 2002, all of the Company's research grant revenue and contract research and development revenue came from PSMA and the Collaborators.



F-7

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[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS □ (Continued)**

**2. Summary of Significant Accounting Policies □ (Continued)**

**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 cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials. All costs associated with research and development are expensed as incurred.

For each clinical trial that the Company conducts, certain clinical trials costs, which are included in research and development expenses, are expensed based on the total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations provide services.

**Patents**

As a result of research and development efforts conducted by the Company, it has applied, or is applying, for a number of patents to protect proprietary inventions. All costs associated with patents are expensed as incurred.

**Net Loss Per Share**

The Company prepares its per share data in accordance with Statement of Financial Accounting Standards No. 128, □Earnings Per Share□ (□SFAS No. 128□). 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. Diluted net loss per share includes, where dilutive, the number of shares issuable upon exercise of outstanding options and warrants. Disclosures required by SFAS No. 128 have been included in Note 12.

**Concentrations of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities and receivables from PSMA and the Collaborators. The Company invests its excess cash in investment grade securities issued by corporations and governments. The Company has established guidelines that relate to credit quality, diversification and maturity and that limit exposure to any one issue of securities.

**Cash and Cash Equivalents**

The Company considers 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 the Company to concentrations of credit risk. At December 31, 2002 and 2001, the Company had invested approximately \$9,281,000 and \$6,223,000, respectively, in funds with two major investment companies and held approximately \$166,000 and \$4,537,000, respectively, in a single commercial bank.

**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. 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

[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****2. Summary of Significant Accounting Policies □ (Continued)**

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	Life of lease

**Income Taxes**

The Company accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, □Accounting for Income Taxes□ (□SFAS No. 109□). SFAS No. 109 requires that the Company 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 liabilities and assets 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.

**Risks and Uncertainties**

The Company has no products approved for sale by the U.S. Food and Drug Administration. There can be no assurance that the Company's research and development will be successfully completed, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. In addition, the Company operates in an environment of rapid change in technology and is dependent upon the continued services of its current employees, consultants and subcontractors.

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relate to revenue recognition, recognition of clinical trial costs, useful lives of fixed assets and deferred taxes. Actual results could differ from those estimates.

**Stock-Based Compensation**

The accompanying financial position and results of operations of the Company have been prepared in accordance with APB Opinion No. 25, □Accounting for Stock Issued to Employees□ (□APB No. 25□). Under APB No. 25, generally, no compensation expense is recognized in the financial statements in connection with the awarding of stock option grants to employees provided that, as of the grant date, all terms associated with the award are fixed and the fair value of the Company's stock, as of the grant date, is equal to or less than the amount an employee must pay to acquire the stock. The Company will recognize compensation expense in situations where the terms of an option grant are not fixed or where the quoted market price of the Company's common stock on the grant date is greater than the amount an employee must pay to acquire the stock.

The fair value of options and warrants granted to non-employees for financing, goods or services are included in the financial statements and expensed over the life of the debt, as the goods are utilized or the services performed, respectively.

The following table summarizes the pro forma operating results of the Company had compensation costs for the Company's incentive stock option and stock purchase plans been determined in accordance with the fair value based method of accounting for stock based compensation as prescribed by Statement of Financial Accounting Standards No. 123 □Accounting for Stock-Based Compensation□ (□SFAS No. 123□). Since option grants awarded during 2000, 2001 and 2002 vest over several years and additional awards are expected to be issued in



[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****2. Summary of Significant Accounting Policies □ (Continued)**

the future, the pro forma results shown below are not likely to be representative of the effects on future years of the application of the fair value based method.

	Years Ended December 31,		
	2000	2001	2002
Net loss, as reported	(5,917,156)	(1,898,150)	(20,788,808)
Add: Stock-based employee compensation expense included in reported net loss	593,374	377,427	273,276
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(7,651,732)	(5,779,756)	(7,736,059)
Pro forma net loss	(12,975,514)	(7,300,479)	(28,251,591)
Net loss per share amounts, basic and diluted:			
As reported	\$ (0.49)	\$ (0.15)	\$ (1.66)
Pro forma	\$ (0.58)	\$ (0.59)	\$ (2.25)

Other disclosures required by SFAS No. 123 have been included in Note 9.

**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. Comprehensive loss of the Company 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, 2000, 2001 and 2002 have been included in the Statements of Stockholders□ Equity and Comprehensive Loss.

**Reclassifications**

Certain reclassifications have been made to the financial statements for 2000 and 2001 to conform with the current year□s presentation.

**Impact of Future Adoption of Recently Issued Accounting Standards**

In June 2002, the Financial Accounting Standards Board issued Statement on Financial Accounting Standards No. 146 (□FAS 146□) □Accounting for Costs Associated with Exit or Disposal Activities□. FAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, □Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).□ FAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, rather than on the date of an entity□s commitment to an exit plan and establishes that fair value is the objective for initial measurement of the liability. The provisions of this Statement shall be effective for exit or disposal activities initiated after December 31, 2002. The provisions of Issue 94- 3 shall continue to apply for an exit activity initiated under an exit plan that met the criteria of Issue 94-3 prior to this Statement□s initial application.

On December 31, 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, □Accounting for Stock-Based Compensation □ Transition and Disclosure □ an



[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****2. Summary of Significant Accounting Policies □ (Continued)**

amendment of FAS 123□ (□FAS 148□). FAS 148 provides several transition provisions that may be used upon adoption of the accounting provisions of FAS 123. FAS 148 also mandates certain new disclosures, whether or not FAS 123 is adopted, that are incremental to those required by FAS 123. Those disclosures must be made in both interim and annual financial statements. The transition and annual disclosure provisions of FAS 148 are effective for fiscal years ending after December 15, 2002. The new interim disclosure provisions are effective for the first interim period beginning after December 15, 2002.

On November 21, 2002, the EITF finalized Issue No. 00-21 □Accounting for Revenue Arrangements with Multiple Deliverables□, (□EITF 00-21□) which addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. EITF 00-21 also addresses how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003.

On November 25, 2002, the Financial Accounting Standards Board issued FASB Interpretation No. 45 (□FIN 45□), □Guarantor□s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others□. FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of this Interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor□s fiscal year-end. The disclosure requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The interpretive guidance incorporated without change from Interpretation 34 continues to be required for financial statements for fiscal years ending after June 15, 1981□the effective date of Interpretation 34.

Management believes that the future adoption of these accounting standards will not have a material impact on the Company□s financial statements.

**3. Marketable Securities**

The Company considers its marketable securities to be □available-for-sale,□ as defined by Statement of Financial Accounting Standards No. 115, □Accounting for Certain Investments in Debt and Equity Securities□, and, accordingly, unrealized holding gains and losses are excluded from operations and reported as a net amount in a separate component of stockholders□ equity.

As of December 31, 2001 and 2002, marketable securities had maturities of less than three years. The following table summarizes the amortized cost basis, the aggregate fair value, and gross unrealized holding gains and losses at December 31, 2001 and 2002:

	Amortized Cost Basis	Fair Value	Unrealized Holding		
			Gains	(Losses)	Net
<b>2002:</b>					
Maturities less than one year					
Corporate debt securities	\$ 27,656,725	27,753,984	\$ 103,439	\$ (6,180)	\$ 97,259
Maturities between one and two years					
Corporate debt securities	5,164,388	5,172,808	10,985	(2,565)	8,420
	<u>\$ 32,821,113</u>	<u>\$ 32,926,792</u>	<u>\$ 114,424</u>	<u>\$ (8,745)</u>	<u>\$ 105,679</u>

F-11

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[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****3. Marketable Securities □ (Continued)**

	Amortized Cost Basis	Fair Value	Unrealized Holding		
			Gains	(Losses)	Net
<b>2001:</b>					
Maturities less than one year					
Corporate debt securities	\$ 30,237,360	\$ 30,523,239	\$ 288,111	\$ (2,232)	\$ 285,879
Maturities between one and three years					
Corporate debt securities	20,673,040	20,594,274	32,402	(111,168)	(78,766)
	<u>\$ 50,910,400</u>	<u>\$ 51,117,513</u>	<u>\$ 320,513</u>	<u>\$ (113,400)</u>	<u>\$ 207,113</u>

There were no realized gains and losses from the sale of marketable securities for the years ended December 31, 2000 and 2002. The realized loss for the year ended December 31, 2001 was \$64,181. The Company 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. The fair value of marketable securities has been estimated based on quoted market prices.

**4. Fixed Assets**

Fixed assets, including amounts under capitalized lease obligations, consist of the following:

	December 31,	
	2001	2002
Computer equipment	\$ 391,975	\$ 372,162
Machinery and equipment	3,326,612	4,168,486
Furniture and fixtures	525,637	536,573
Leasehold improvements	1,821,759	2,372,946
	<u>6,065,983</u>	<u>7,450,167</u>
Less, Accumulated depreciation and amortization	(3,505,784)	(3,744,636)
	<u>\$ 2,560,199</u>	<u>\$ 3,705,531</u>

**5. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following:

	December 31,	
	2001	2002
Accounts payable	\$ 916,711	\$ 1,199,998
Accrued consulting and clinical trial costs	703,508	557,113
Accrued payroll and related costs	543,283	568,358
Legal fees payable	433,587	567,432
Other		7,127

<u>                    </u>	<u>                    </u>
\$ 2,597,089	\$ 2,900,028
<u>                    </u>	<u>                    </u>

**6. Stockholders' Equity**

The Company is authorized to issue 40,000,000 shares of common stock, par value \$.0013 (Common Stock), and 20,000,000 shares of preferred stock, par value \$.001. The Board has the authority to issue common and preferred shares, in series, with rights and privileges as determined by the Board.

In connection with the issuance of equity securities in 1995 and 1996, the Company issued 260,455 five-year warrants (the Warrants). Each Warrant entitled the holder to purchase one share of Common Stock at \$6.67. The number of Warrants and their exercise price were subject to adjustment in the event the Company issued additional shares of Common Stock at below defined per share prices. During each of the years ended

[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****6. Stockholders' Equity □ (Continued)**

December 31, 2000 and 2001, 136,753, and 101,275 warrants were exercised. As of December 31, 2001, all of the Warrants had been exercised.

During March 1997, the Company obtained a line of credit (□Line□) from a bank. The terms of the Line provide for the Company to borrow up to \$2.0 million. The Line expired on July 31, 1997. The payment of the Line was guaranteed by two affiliates of a stockholder of the Company (□Affiliates□). In consideration for the guarantee of the Line, which has since been terminated, the Company issued 70,000 warrants to the Affiliates. Such warrants vested immediately, expired after five years and had an exercise price of \$4.00. During the year ended December 31, 2002, all 70,000 warrants were exercised.

**7. Commitments and Contingencies****a. Operating Leases**

The Company leases office and laboratory space under a noncancelable sublease agreement. The sublease, as amended, provides for fixed monthly rental expense of approximately \$60,000 through December 31, 2002 and \$65,081 from January 2003 through June 30, 2005. Such amounts are recognized as rent expense on a straight-line basis over the term of the sublease. The sublease also provides for additional charges based upon usage of certain utilities in excess of defined amounts (□Additional Utility Charges□). The sublease can be extended at the option of the Company for two additional two-year terms.

The Company also leases certain office equipment under noncancelable operating leases. The leases expire at various times through March 2005. As of December 31, 2002, future minimum annual payments under all operating lease agreements, are as follows:

<b>Years ending December 31,</b>	<b>Minimum Annual Payments</b>
2003	\$ 792,312
2004	792,312
2005	401,826
	\$ 1,986,450

Rental expense totalled approximately \$441,000, \$611,000 and \$752,000 for the years ended December 31, 2000, 2001 and 2002, respectively. For the years ended December 31, 2001, 2002, the Company recognized rental expense in excess of amounts paid of approximately \$39,000 and \$32,000, respectively. Additional utility charges for the years ended December 31, 2000, 2001 and 2002 were approximately \$551,000, \$805,000 and \$1,060,000, respectively.

**b. Licensing, Corporate Collaboration and Service Agreements****i. Universities**

The Company (as licensee) has a worldwide licensing agreement with Columbia University (□Columbia□). The license, as amended during October 1996, provides the Company with the exclusive right to use certain technology developed on behalf of Columbia. According to the terms of the agreement, the Company is required to pay nonrefundable licensing fees (□Licensing Fees□), payable in installments by defined dates or, if earlier, as certain milestones associated with product development (□Milestones□) occur, as defined, which include the manufacture and distribution of a product which uses the licensed technology by 2004. The Company expenses Licensing Fees when they become payable by the Company to Columbia. In addition, the Company is required to remit royalties based upon the greater of minimum royalties, as defined, or a percentage of net sales of products

which utilize the licensed technology and a portion of sublicensing income, as defined. The licensing agreement may be terminated by Columbia under certain circumstances which includes the Company's failure to achieve the

[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****7. Commitments and Contingencies □ (Continued)**

Milestones; however, Columbia shall not unreasonably withhold its consent to revisions to the due dates for achieving the Milestones under certain circumstances. If not terminated early, the agreement shall continue until expiration, lapse or invalidation of Columbia's patents on the licensed technology. The Company has the right to terminate the agreement at any time upon 90 days prior written notice. The termination of the license could have a material adverse effect on the business of the Company. Although the Company intends to use its best efforts to comply with the terms of the agreement, there can be no assurances that the agreement will not be terminated.

In September 1996, the Company (as licensee) entered into a licensing agreement with The Regents of the University of California (□Regents□). According to the terms of the agreement, the Company is required to remit royalties based upon the greater of minimum of royalties or a percentage of product sales and a portion of sublicensing income, as defined. The agreement can be terminated by the Company upon 90 days notice or by Regents in the event the Company fails to perform, which includes the achievement of certain defined milestones; otherwise the agreement terminates upon the lapse of Regents' patent regarding the licensed technology. In December 2002, the Regents Agreement expired.

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

In November 1994, the Company (as licensee) entered into a worldwide exclusive licensing agreement with Sloan-Kettering Institute for Cancer Research (□Sloan-Kettering□) whereby the Company has the exclusive right to use certain technology owned by Sloan-Kettering. Certain employees of Sloan-Kettering are consultants to the Company (see Note 7(d)). The Company is required to remit royalties based upon the greater of minimum royalties, as defined, or as a percentage of sales of any licensed product, as defined (□Product Royalties□), and sublicense income, as defined, earned under sublicenses granted by the Company in accordance with this licensing agreement (□Sublicense Royalties□). In the event that no Product Royalties or Sublicense Royalties are due in a given calendar year, then a defined percentage of that year's minimum royalty will be creditable against future Product Royalties or Sublicense Royalties due Sloan-Kettering. The licensing agreement may be terminated by Sloan-Kettering in the event that the Company fails to achieve certain defined objectives, which include the manufacture and distribution of a product which uses the licensed technology, by 2004, or if the Company fails to satisfy certain other contractual obligations (□Early Termination□); otherwise the agreement shall terminate either upon the expiration or abandonment of Sloan-Kettering's patents on the technology licensed, or 15 years from the date of first commercial sale, as defined, whichever is later. With regard to Early Termination, Sloan-Kettering shall not unreasonably withhold its consent to revisions to the due dates for achieving the defined objectives under certain circumstances. The Company has the right to terminate the agreement at any time upon 90 days prior written notice (□Company Termination□). In the event of Early Termination or Company Termination, all licensing rights under the agreement would revert to Sloan-Kettering. Early Termination of the license could have a material adverse effect on the business of the Company. The Company is also party to a license agreement with Sloan-Kettering whereby the Company has an exclusive, worldwide license to certain patents relating to DHA, which license continues for 20 years or until the expiration of the subject patents. Although the Company intends to use its best efforts to comply with the terms of the license, there can be no assurance that the licensing agreement will not be terminated.

**iii. Aquila Biopharmaceuticals, Inc.**

In August 1995, the Company (as licensee) entered into a license and supply agreement (the □L&S Agreement□) with Aquila Biopharmaceuticals, Inc., a wholly owned subsidiary of Antigenics, Inc. (□Aquila□). Under the terms of the L&S Agreement, the Company obtained a coexclusive license to use certain technology and a right to purchase QS-21 adjuvant (the □Product□) from Aquila for use in the Company's research and development activities. In consideration for the license, the Company paid a nonrefundable, noncreditable license fee and issued 45,000 restricted shares of the Company's Common Stock (□Restricted Shares□) to Aquila. The Restricted Shares are nontransferable with this restriction lapsing upon the Company's achievement of certain milestones (□L&S Milestones□), as defined. In the event that any one or more L&S Milestones do not occur, the



[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****7. Commitments and Contingencies □ (Continued)**

underlying Restricted Shares would be returned to the Company. As of December 31, 2002, the restrictions on 22,500 shares of common stock have lapsed. The fair value of the Restricted Shares, combined with the noncreditable license fee, were expensed during 1995 as research and development. In addition, the Company will be required to remit royalties based upon the net sales of products sold using the licensed technology (□Licensed Products□) and a defined percentage of any sublicense fees and royalties payable to the Company with respect to Licensed Products. The L&S Agreement may be terminated by Aquila in the event that the Company fails to achieve certain defined objectives, which include the manufacture and distribution of a Licensed Product, by 2004 (□Early Termination□); otherwise the L&S Agreement shall terminate upon the expiration of Aquila's patents on the technology licensed. With regard to Early Termination, Aquila shall not unreasonably withhold its consent to revisions to the due dates for achieving the L&S Milestones under certain circumstances. The Company has the right to terminate the L&S Agreement at any time upon 90 days prior written notice (□Company Termination□), as defined. In the event of Early Termination or Company Termination, all licensing rights under the agreement would revert to Aquila. Early termination of the L&S Agreement could have a material adverse effect on the business of the Company. Although the Company intends to use its best efforts to comply with the terms of the L&S Agreement, there can be no assurance that the agreement will not be terminated.

**iv. Bristol-Myers Squibb Company**

In July 1997, the Company and Bristol-Myers Squibb Company (□BMS□) entered into a Joint Development and Master License Agreement (the □BMS License Agreement□) under which BMS obtained an exclusive license to certain therapeutic cancer vaccines (the □Cancer Vaccines□). Upon execution of the agreement, BMS made non-refundable cash payments as reimbursement for certain expenses incurred by the Company in the development of the Cancer Vaccines and as a licensing fee. In addition, BMS was obligated to make future non-refundable payments as defined upon the achievement of specified milestones and pay royalties on any product sales. BMS also subsidized ongoing development, clinical trials and regulatory filings (□Development Costs□) conducted by the Company on a time and material basis related to the Cancer Vaccines.

In May 2001, BMS and the Company mutually agreed to terminate the BMS License Agreement. Under the terms of the settlement agreement, BMS relinquished all future rights to the Cancer Vaccines and paid the Company \$15.5 million. Approximately \$5.6 million of the payment related to contract work performed prior to termination and the balance was a contract termination payment. Under the terms of certain license agreements, a portion of the termination payment was paid to certain licensors.

**v. Hoffmann-LaRoche**

On December 23, 1997 (the □Effective Date□), the Company entered into an agreement (the □Roche Agreement□) to conduct a research collaboration with F. Hoffmann-LaRoche Ltd and Hoffmann-LaRoche, Inc. (collectively □Roche□) to identify novel HIV therapeutics (the □Compound□). The Roche Agreement grants to Roche an exclusive worldwide license to use certain of the Company's intellectual property rights related to HIV to develop, make, use and sell products resulting from the collaboration.

The terms of the Roche Agreement require Roche to pay the Company an upfront fee and defined amounts annually for the first year, with annual adjustments thereafter, for the funding of research conducted by the Company. Roche's annual payment is made quarterly in advance. In addition, the Company will receive non-refundable milestone payments and royalty payments based on achievement of certain events and a percentage of worldwide sales of products developed from the collaboration, respectively. The collaboration had an original term of three years and was subsequently extended for two additional years by mutual agreement.

In March 2002, Roche exercised its right to discontinue funding the research being conducted under the Roche Agreement. Discussions between Roche and the Company resulted in an agreement by which the Company gained the exclusive rights to develop and market the Compound, as defined. Provided Roche has not





[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS [ (Continued)**

**7. Commitments and Contingencies [ (Continued)**

elects its option to resume joint development and commercialization of the Compound, Roche is entitled to receive certain milestone payments and royalties, as defined

**vi. Development and License Agreement with Protein Design Labs, Inc.**

Effective April 30, 1999, the Company and Protein Design Labs, Inc. ([PDL]) entered into a Development and License Agreement (the [License Agreement]) under which PDL agreed to develop a humanized antibody (the [Technology]) on behalf of the Company and granted to the Company an exclusive worldwide license under certain patents and patent applications to develop, use and sell products arising from the Technology ([Products]). PDL also granted to the Company non-exclusive licenses to PDL technical information, as defined, and sublicenses to PDL licenses from third parties to the extent necessary to enable the Company to make, use and sell Products. In addition, in June 1999 the Company exercised its right under the License Agreement to acquire an option to obtain a sublicense to certain additional patents and paid PDL a fee in connection therewith.

Upon the achievement by PDL of certain performance-based milestones, as defined, the Company is required to make non-refundable payments to PDL. The Company is also required to pay royalties based on a percentage of net sales, as defined, of all Products for a specified period and non-refundable annual maintenance fees under certain conditions.

The Company has the ability to terminate the License Agreement upon 60 days prior written notice. If terminated prior to a defined date, the Company will reimburse PDL for costs and expenses to the date of termination. Either party may terminate the License Agreement upon 10 or 30 days written notice of default in making scheduled payments or other breach, respectively, that is not cured by the other party. Otherwise, the License Agreement will continue until expiration of the Company's obligation to pay royalties to PDL.

**vii. Genzyme Transgenics Corporation**

The Company has entered into a collaboration with Genzyme Transgenics to develop a transgenic source of the PRO 542 molecule. Under this agreement, Genzyme Transgenic is engaged in a program designed to result in the establishment of a line of transgenic goats capable of expressing the molecule in lactation milk. The Company is obligated to pay Genzyme Transgenics certain fees to conduct the program as well as additional fees upon the achievement of specified milestones.

**viii. Pharmacopeia, Inc.**

In March 2000, the Company entered into a research and license agreement with Pharmacopeia, Inc. to discover therapeutic treatments related to HIV. This agreement expanded on a collaboration with Pharmacopeia commenced in September 1997. Under the terms of the new agreement, the Company will provide proprietary assays and expertise and Pharmacopeia will engage in a screening program of its internal compound library. In August 2000, the Company expanded its collaboration with Pharmacopeia to add two additional programs. Progenics will be granted a license to active compounds identified in the program. The Company is obligated to pay Pharmacopeia fees as well as additional amounts upon the achievement of specified milestones and royalties on any sales of therapeutics marketed as a result of the collaboration.

**ix. UR Labs, Inc.**

In October 2001, the Company entered into an agreement with UR Labs, Inc. (the [URL Agreement]) to obtain worldwide exclusive rights to methylnaltrexone (MNTX), an investigational drug in late-stage clinical development. UR Labs has exclusively licensed MNTX from the University of Chicago, where it was discovered. In consideration for the license, the Company paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of certain defined milestones associated with the MNTX product development and commercialization program. In addition, the Company is required to pay royalties based upon



[Back to Contents](#)

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS □ (Continued)**

**7. Commitments and Contingencies □ (Continued)**

net sales of the licensed products, subject to certain set off rights of the Company and the right of the Company to buy-down the royalty rate under defined circumstances. The URL Agreement may be terminated by UR Labs under specified circumstances that include the Company's failure to achieve certain milestones; however the consent of UR Labs to revisions to the due dates for the milestones shall not be unreasonably withheld under certain circumstances. If not terminated early, the URL Agreement continues until the later of the expiration of the UR Labs patents or defined period. The Company has the right to terminate the URL Agreement upon 60 days prior written notice. The termination of the URL Agreement could have a material adverse effect on the business of the Company. Although the Company intends to use its best efforts to comply with the terms of the URL Agreement, there can be no assurances that the agreement will not be terminated.

In connection with all the agreements discussed above, the Company has recognized milestone, license and sub-license fees, which are included in research and development expenses, totaling approximately \$2,110,000, \$2,141,000 and \$1,090,000 for the years ended December 31, 2000, 2001 and 2002, respectively. In addition, as of December 31, 2002, remaining payments associated with milestones and defined objectives with respect to the above agreements total approximately \$22 million. Future annual minimum royalties under the licensing agreements described in (i) through (iii) and (vi) through (ix) above are not significant.

**c. Consulting Agreements**

As part of the Company's research and development efforts it enters into consulting agreements with external scientific specialists (□Scientists□) and others. These Agreements contain varying terms and provisions including fees to be paid by the Company and royalties, in the event of future sales, and milestone payments, upon achievement of defined events, payable to the Company. Certain Scientists, some of who are members of the Company's Scientific Advisory Board, have purchased Common Stock or received stock options which are subject to vesting provisions, as defined. The Company has recognized expenses with regards to these consulting agreements totaling approximately \$719,000, \$538,000 and \$500,000 for the years ended December 31, 2000, 2001 and 2002, respectively. For the years ended December 31, 2000, 2001 and 2002, such expenses include the fair value of stock options granted during 2000, 2001 and 2002, which were fully vested at grant date, of approximately \$164,000, \$238,000 and \$250,000, respectively.

**8. PSMA Development Company LLC**

On June 15, 1999, the Company and CYTOGEN Corporation (□CYTOGEN□) (collectively, the □Members□) formed a joint venture in the form of a limited liability company (the □LLC□ or □JV□) for the purposes of conducting research, development, manufacturing and marketing of products related to prostate-specific membrane antigen (□PSMA□). Each Member currently owns 50% of the JV and accounts for such investment under the equity method. In connection with the formation of the JV, the Members entered into a series of agreements, including an LLC Agreement, a License Agreement and a Services Agreement, as amended, (collectively, the □Agreements□). Each Member made an initial capital contribution of \$100,000. In general, each Member has equal representation on the JV's management committee and equal voting rights and equal rights to profits and losses of the JV.

Under the LLC Agreement, the Company was required to pay to the JV \$2.0 million in supplemental capital contributions at certain defined dates or upon the achievement of defined milestones by the JV. As discussed below, since it was probable that the Company would be required to fund the \$2.0 million supplemental capital contribution, the Company, on June 15, 1999, recorded a liability to the JV of approximately \$1.8 million. Such amount represented the present value of the supplemental capital contribution discounted at 10%. The discount was amortized as interest expense over the term of the remaining payments. One million dollars was paid in 1999 and \$500,000 was paid during each of 2000 and 2001.

In accordance with the Agreements, the Company's \$2.0 million supplemental capital contribution was used by the JV to pay a \$2.0 million non-refundable licensing fee to CYTOGEN (□CYTOGEN Payment□). The



[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****8. PSMA Development Company LLC □ (Continued)**

payment terms of the CYTOGEN Payment were identical to the payment terms of the Company's required supplemental capital contribution. Accordingly, at inception, the JV discounted the CYTOGEN Payment along with the Company's supplemental capital contribution thereby recording approximately a \$1.8 million liability to CYTOGEN and a \$1.8 million receivable from the Company.

The Company is engaged in a research program on behalf of the JV under the Services Agreement and is compensated for its services based on agreed upon terms. As of March 31, 2002, and through December 31, 2002, the Company was performing services for the JV under a month-to-month extension of the Services Agreement. At December 31, 2002, and through March 28, 2003, the Members were negotiating the terms of a new Services Agreement.

The Company was originally required to fund the cost of research up to \$3.0 million. As of December 31, 2001, the Company had surpassed the \$3.0 million in funding for research costs. Accordingly, each Member made capital contributions of \$900,000 and \$2.3 million in the years ended December 31, 2001 and 2002, respectively to fund future research costs and share such costs equally. The level of commitment by the Members to fund the JV is based on an annual budget that is approved by both Members. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002.

Amounts received from the JV as reimbursement of research and development costs in excess of the initial \$3.0 million (see above) provided in accordance with the Services Agreement are recognized as contract research and development revenue. For the years ended December 31, 2001 and 2002, such amounts totaled approximately \$200,000 and \$5.3 million, respectively and the gross profit margin on such revenue was not material. Contract research and development revenue recognized by the Company related to services provided to the JV may vary in the future due to potential future funding limitations on the part of the Members, the extent to which the JV continues to rely on Progenics to perform research and development under the Services Agreement and the terms of any amendments to the Services Agreement. All inventions made by the Company in connection with the Services Agreement will be assigned to the JV for its use and benefit.

The Agreements generally terminate upon the last to expire of the patents granted by the Members to the JV or upon breach by either party, which is not cured within 60 days of written notice.

The Company accounts for its investment in the JV in accordance with the equity method of accounting. Selected financial statement data of the JV are as follows:

	<b>December 31,</b>	
	<b>2001</b>	<b>2002</b>
<b>Balance Sheet Data</b>		
Cash	\$ 1,009,929	\$ 289,904
Accounts payable to Progenics	351,333	304,154
Capital contributions:		
CYTOGEN	1,000,000	3,300,000
Progenics	5,798,424	8,098,424
Contribution receivable from Progenics	(500,000)	
Accumulated deficit	(5,639,828)	(11,412,674)
Total liabilities and stockholders' equity	\$ 1,009,929	\$ 289,904

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F-18

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[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****8. PSMA Development Company LLC □ (Continued)****Statement of Operations Data****For the Year Ended**

	<b>2000</b>	<b>2001</b>	<b>2002</b>
Total revenue (interest income)	\$ 96,233	\$ 47,111	\$ 12,680
Total expenses (1)	1,085,435	2,623,372	5,785,526
Net loss (2)	\$ (989,202)	\$ (2,576,261)	\$ (5,772,846)

(1) Includes contract research and development services performed by Progenics.

(2) The terms of the joint venture agreement provided for the Company to fund up to \$3.0 million in certain costs of the joint venture. During 2000 and 2001, prior to reaching the \$3.0 million threshold, the loss resulting from such costs was allocated to the capital account of the Company and accordingly, the Company's allocated share of the joint venture's loss was greater than its ownership interest.

**9. Stock Option and Employee Stock Purchase Plans**

The Company adopted three stock option plans, the Non-Qualified Stock Option Plan, the Stock Option Plan and the Amended Stock Incentive Plan (individually the "89 Plan," "93 Plan" and "96 Plan," respectively, or collectively, the "Plans"). Under the 89 Plan, the 93 Plan and the 96 Plan as amended, a maximum of 375,000, 750,000 and 5,000,000 shares of Common Stock, respectively, are available for awards to employees, consultants, directors and other individuals who render services to the Company (collectively, "Optionees"). The Plans contain certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment as defined. The 89 Plan and 93 Plan provide for the Board, or the Compensation Committee ("Committee") of the Board, to grant stock options to Optionees and to determine the exercise price, vesting term and expiration date. The 96 Plan provides for the Board or Committee to grant to Optionees stock options, stock appreciation rights, restricted stock performance awards or phantom stock, as defined (collectively "Awards"). The Committee will also determine the term and vesting of the Award and the Committee may in its discretion accelerate the vesting of an Award at any time. Options granted under the Plans generally vest pro rata over five to ten year periods and have terms of ten to twenty years. Except as noted below, the exercise price of outstanding awards was equal to the fair value of the Company's Common Stock on the dates of grant. Under the 89 Plan, for a period of ten years following the termination for any reason of an Optionee's employment or active involvement with the Company, as determined by the Board, the Company has the right, should certain contingent events occur, to repurchase any or all shares of Common Stock held by the Optionee and/or any or all of the vested but unexercised portion of any option granted to such Optionee at a purchase price defined by the 89 Plan, which is equal to or exceeds fair value. The 89 Plan terminated in April, 1994 and the 93 Plan and the 96 Plan will terminate in December, 2003 and October, 2006, respectively; however, options granted before termination of the Plans will continue under the respective Plans until exercised, cancelled or expired.

[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****9. Stock Option and Employee Stock Purchase Plans □ (Continued)**

The following table summarizes stock option information for the Plans as of December 31, 2002:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted-Average Remaining Contractual Life	Average Weighted Exercise Price	Number Exercisable	Weighted-Average Exercise Price	
\$ 1.33 □ \$ 1.33	134,398	6.3	\$ 1.33	134,398	\$ 1.33	
\$ 3.27 □ \$ 4.00	527,501	3.8	\$ 4.00	477,501	\$ 4.00	
\$ 5.02 □ \$ 7.15	333,870	3.4	\$ 5.45	319,870	\$ 5.43	
\$ 7.98 □ \$ 11.76	438,283	6.8	\$ 9.65	278,883	\$ 9.48	
\$ 12.00 □ \$ 17.70	2,352,450	7.6	\$ 13.59	1,169,122	\$ 13.36	
\$ 18.47 □ \$ 27.56	242,400	8.2	\$ 21.62	98,000	\$ 21.57	
\$ 28.00 □ \$ 28.00	50,000	7.7	\$ 28.00	20,000	\$ 28.00	
\$ 42.38 □ \$ 48.88	70,000	7.0	\$ 43.77	37,000	\$ 45.01	
\$ 70.00 □ \$ 70.00	15,000	7.3	\$ 70.00	15,000	\$ 70.00	
	<u>4,163,902</u>	<u>6.7</u>	<u>\$ 12.26</u>	<u>2,549,774</u>	<u>\$ 10.77</u>	

Transactions involving stock option awards under the Plans during 2000, 2001 and 2002 are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price
Balance outstanding, December 31, 1999	2,313,063	\$ 7.86
2000: Granted (1)	809,500	\$ 30.61
Cancelled	(39,100)	\$ 24.22
Exercised	(206,295)	\$ 5.39
Expirations	(38,724)	\$ 1.33
Balance outstanding, December 31, 2000	2,838,444	\$ 14.39
2001: Granted (1)	906,850	\$ 16.20
Cancelled	(192,750)	\$ 54.44
Exercised	(25,967)	\$ 6.39
Expirations	(52,650)	\$ 47.89
Balance outstanding, December 31, 2001	3,473,927	\$ 12.19
2002: Granted (1)	790,500	\$ 12.46
Cancelled	(54,500)	\$ 15.61
Exercised	(18,750)	\$ 4.34
Expirations	(27,275)	\$ 9.82



Balance outstanding, December 31, 2002	<u>4,163,902</u>	\$	12.26
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(1) For 771,500 in 2002, 886,600 in 2001 and 805,500 in 2000, the option exercise price equaled the fair value of the Company's common stock on the date of grant. For 2002, 2001 and 2000, 19,000, 20,250, and 4,000 options, respectively, were granted, with an exercise price below the fair market value of the Company's common stock on the date of grant.

As of December 31, 2000, 2001 and 2002, 1,500,728, 2,073,513 and 2,549,774 options with weighted average exercise prices of \$8.91, \$9.99 and \$10.77, respectively, were exercisable under the Plans.

F-20

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[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****9. Stock Option and Employee Stock Purchase Plans □ (Continued)**

As of December 31, 2002, shares available for future grants under the 93 Plan and the 96 Plan amounted to 37,028 and 1,183,050, respectively.

The Company, prior to the year ended December 31, 1999, granted certain options with exercise prices below the estimated fair value of the Common Stock on the date of grant. Accordingly, the Company is recognizing compensation expense on a pro rata basis over the respective options' vesting periods for the difference between the estimated fair value of the Common Stock on the date the option was granted and the exercise price (□Unamortized Compensation□). The Unamortized Compensation as of December 31, 2000 and 2001 has been included within stockholders equity. For the years ended December 31, 2000, 2001 and 2002, the annual amortization of Unearned Compensation totaled \$428,898, \$139,094 and \$23,150, respectively.

During 1993, the Company adopted an Executive Stock Option Plan (the □Executive Plan□), under which a maximum of 750,000 shares of Common Stock, adjusted for stock splits, stock dividends, and other capital adjustments, as defined, are available for stock option awards. Awards issued under the Executive Plan may qualify as incentive stock options (□ISOs□), as defined by the Internal Revenue Code, or may be granted as non-qualified stock options. Under the Executive Plan, the Board may award options to senior executive employees (including officers who may be members of the Board) of the Company, as defined. The Executive Plan will terminate on December 15, 2003; however, any option 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 awarded a total of 750,000 stock options under the Executive Plan to one officer, of which 664,774 were non-qualified options (□NQOs□) and 85,226 were ISOs. The NQOs and ISOs have a term of ten years and entitle the officer to purchase an equal number of shares of Common Stock at prices of \$5.33 and \$5.87 per share, respectively, which represented the estimated fair market value and 110% of the estimated fair market value, respectively, of the Company's Common Stock at the date of grant, as determined by the Board of Directors. As of December 31, 2002, all options are fully vested and 474,774 remain outstanding.

The following table summarizes stock option information for the Executive Plan as of December 31, 2002:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Exercise Price
\$5.33	474,774	4.9	\$ 5.33	474,774	\$ 5.33

On May 1, 1998, the Company adopted 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□). The Purchase Plans provide for the grant to all employees of options to use 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 the 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 grants. The Qualified Plan is not available for employees owning more than 5% 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 the option grants are restricted under the Qualified Plan. The Qualified and Non-Qualified Plans provide for the issuance of up to 400,000 and 75,000 shares of Common Stock, respectively.



[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****9. Stock Option and Employee Stock Purchase Plans □ (Continued)**

Purchases of Common Stock during the years ended December 31, 2000, 2001 and 2002 are summarized as follows:

	Qualified Plan		Non-Qualified Plan	
	Shares Purchased	Price Range	Shares Purchased	Price Range
2002	158,658	\$ 3.55 □ \$13.90	7,092	\$ 4.27 □ \$15.70
2001	64,160	\$ 9.46 □ \$18.25	4,069	\$ 9.46 □ \$16.24
2000	37,245	\$ 12.61 □ \$60.00	4,873	\$ 14.125 □ \$60.00

At December 31, 2002, shares reserved for future purchases under the Qualified and Non-Qualified Plans were 107,701 and 55,511, respectively.

For the purpose of the pro forma calculation, compensation costs for the Plans, the Executive Plan and the Purchase Plans were determined in accordance with SFAS No. 123 (see Note 2), based upon an estimation of the fair value of each option granted under the Plans, the Executive Plan and the Purchase Plans on the date of grant using the Black-Scholes option pricing model. The following assumptions were used in computing the fair value of option grants: expected volatility of 93% in 2000, 86% in 2001 and 79% in 2002, expected lives of 5 years after vesting; zero dividend yield and weighted-average risk-free interest rates of 6.3% in 2000, 4.7% in 2001 and 4.0% in 2002.

During the years ended December 31, 2000, 2001 and 2002, 805,000, 886,600 and 771,500 options, respectively, whose exercise price was equal to the market price of the stock on the date of grant were granted under the Plans. The weighted average exercise price of those options was \$30.68, \$16.34 and \$12.65, respectively, and the weighted average grant date fair value of those options was \$22.92, \$11.49 and \$8.36, respectively. During the years ended December 31, 2000, 2001 and 2002, 4,000, 20,250 and 19,000 options whose exercise price was less than the market price of the stock on the date of grant were granted under the Plans. The weighted average exercise price of those options was \$15.88, \$9.93 and \$6.74, respectively, and the weighted average grant date fair value was \$42.64, \$12.10 and \$10.70, respectively.

**10. Employee Savings Plan**

The Company, during 1993, adopted the provisions of the amended and restated Progenics Pharmaceuticals 401(k) Plan (the "Amended Plan"). The terms of the Amended Plan, among other things, allow eligible employees, as defined, 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, as defined. The Company has agreed to match 100% of those employee contributions that are equal to 5% □ 8% of compensation and are made by eligible employees to the Amended Plan, as defined. In addition, the Company may also make a discretionary contribution, as defined, each year on behalf of all participants who are non-highly compensated employees, as defined. The Company made matching contributions of approximately \$257,000, \$317,000 and \$413,000 to the Amended Plan for the years ended December 31, 2000, 2001 and 2002, respectively.

**11. Income Taxes**

There is no benefit for federal or state income taxes for the years ended December 31, 2002, 2001 and 2000, since the Company has incurred an operating loss and has established a valuation allowance equal to the total deferred tax asset.



[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****11. Income Taxes □ (Continued)**

The tax effect of temporary differences, net operating losses and tax credits carryforwards as of December 31, 2001 and 2002 are as follows:

	<b>December 31,</b>	
	<b>2001</b>	<b>2002</b>
Deferred tax assets and valuation allowance:		
Net operating loss carry-forwards	\$ 15,202,535	\$ 22,064,826
Fixed assets	314,150	386,326
Deferred charges	1,430,280	343,726
Research and experimental tax credit carry-forwards	1,956,378	2,684,952
Alternative minimum tax credit carry-forward	211,384	211,384
Capital loss carry-forwards		25,575
Charitable contribution carry-forwards		43,357
Valuation allowance	(19,114,727)	(25,760,146)
	<u>\$</u>	<u>□ \$</u>

The Company does not recognize deferred tax assets considering the history of taxable losses and the uncertainty regarding the Company's ability to generate sufficient taxable income in the future to utilize these deferred tax assets.

As of December 31, 2002, the Company has available, for tax purposes, unused net operating loss carry-forwards of approximately \$55.4 million which will expire in various years from 2003 to 2022. The Company's research and experimental tax credit carry-forwards expire in various years from 2003 to 2022. In addition, the Company's alternative minimum tax credit can be carried forward indefinitely. The capital loss carry-forwards and charitable contribution carry-forwards generated by the Company will expire in various years from 2006 to 2007. Future ownership changes may limit the future utilization of these net operating loss and tax credit carry-forwards as defined by the federal and state tax codes.

**12. Net Loss Per Share**

The Company's 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, 2002, 2001 and 2000, the Company reported a net loss and, therefore, common stock equivalents were not included since such inclusion would have been anti-dilutive. The calculations of net loss per share, basic, and diluted are as follows:

	<b>Net Loss (Numerator)</b>	<b>Weighted Average Common Shares (Denominator)</b>	<b>Per Share Amount</b>
<b>2002:</b>			
Basic and diluted	\$ (20,788,808)	12,550,798	\$ (1.66)
<b>2001:</b>			
Basic and diluted	\$ (1,898,150)	12,376,056	\$ (0.15)

**2000:**

Basic and diluted	\$ (5,917,156)	12,137,653	\$ (0.49)
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F-23

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[Back to Contents](#)**PROGENICS PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS □ (Continued)****12. Net Loss Per Share □ (Continued)**

For the years ended December 31, 2000, 2001 and 2002 common stock equivalents which have been excluded from diluted per share amounts because their effect would have been anti-dilutive, include the following:

	2000		2001		2002	
	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
Options and warrants	3,442,455	\$ 12.37	3,685,245	\$ 11.86	4,362,153	\$ 8.79

**13. Unaudited Quarterly Results**

Summarized quarterly financial data for the years ended December 31, 2002 and 2001 are as follows:

	Quarter Ended March 31, 2002 (unaudited)	Quarter Ended June 30, 2002 (unaudited)	Quarter Ended September 30, 2002 (unaudited)	Quarter Ended December 31, 2002 (unaudited)
Revenue	\$ 2,370,079	\$ 2,653,871	\$ 2,741,992	\$ 2,318,620
Net loss	(2,001,015)	(5,355,126)	(6,412,294)	(7,020,373)
Net loss per share Basic and diluted	(0.16)	(0.43)	(0.51)	(0.56)

  

	Quarter Ended March 31, 2001 (unaudited)	Quarter Ended June 30, 2001 (unaudited)	Quarter Ended September 31, 2001 (unaudited)	Quarter Ended December 31, 2001 (unaudited)
Revenue	\$ 4,942,305	\$ 1,293,916	\$ 1,387,229	\$ 1,260,189
Net income (loss)	461,249	5,250,852	(3,041,838)	(4,568,413)
Net income (loss) per share Basic	0.04	0.42	(0.25)	(0.36)
Diluted	0.03	0.38	(0.25)	(0.36)

**14. Subsequent Events (unaudited)**

- In September 2003, the Company was awarded a contract by the NIH, an agency of the Department of Health and Human Services, to develop an HIV vaccine. The contract provides for up to \$28.6 million in funding to the Company over five years. Funding under this contract is subject to compliance with its terms, and the payment of fees is subject to achievement of specified milestones. The Company anticipates that these funds will be used principally in connection with its ProVax HIV vaccine program.
- On September 30, 2003, the Company executed a lease for additional laboratory, manufacturing and office space in Tarrytown, New York. The base monthly rent for the lease will be approximately \$74,000 from commencement until August 31, 2007 and approximately \$79,000 from September 1, 2007 until December 31, 2009.





[Back to Contents](#)

### **Report of Independent Accountants**

To the Board of Directors and Stockholders of  
PSMA Development Company LLC:

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders' (deficit) equity and of cash flows present fairly, in all material respects, the financial position of PSMA Development Company LLC (the "Company") (a development stage enterprise) at December 31, 2001 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 and the cumulative period from June 15, 1999 (inception) to December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audit of these financial statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

New York, New York  
February 14, 2003, except for Notes 1 and 3  
as to which the date is March 28, 2003

[Back to Contents](#)

**PSMA Development Company L.L.C.**  
**(a development stage enterprise)**

**Balance Sheets**

	<b>December 31,</b>	
	<b>2001</b>	<b>2002</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,009,929	\$ 289,904
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Account payable to Progenics Pharmaceuticals, a related party	\$ 351,333	\$ 304,154
Total liabilities	351,333	304,154
Capital contributions	6,798,424	11,398,424
Contribution receivable, Progenics Pharmaceuticals, Inc.	(500,000)	
Deficit accumulated during the development stage	(5,639,828)	(11,412,674)
Total stockholders' (deficit) equity	658,596	(14,250)
Total liabilities and stockholders' (deficit) equity	\$ 1,009,929	\$ 289,904

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

[Back to Contents](#)

**PSMA Development Company LLC**  
**(a development stage enterprise)**

**Statements of Operations**

	<b>Year Ended December 31, 2000</b>	<b>Year Ended December 31, 2001</b>	<b>Year Ended December 31, 2002</b>	<b>Cumulative from June 15, 1999 (inception) to December 31, 2002</b>
Revenue:				
Interest income	\$ 96,233	\$ 47,111	\$ 12,680	\$ 228,837
Expenses:				
Research and development	901,835	2,373,768	5,138,193	10,434,250
General and administrative	96,096	206,856	647,333	1,004,196
Interest	87,504	42,748		203,065
Total expenses	1,085,435	2,623,372	5,785,526	11,641,511
Net Loss	\$ (989,202)	\$ (2,576,261)	\$ (5,772,846)	\$ (11,412,674)

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

[Back to Contents](#)

**PSMA Development Company LLC**  
(a development stage enterprise)

**Statements of Stockholders' (Deficit) Equity**  
**For the period from June 15, 1999 (inception) to December 31, 2002,**  
**including the period from June 15, 1999 (inception) to December 31 1999,**  
**and the years ended December 31, 2000 and 2001 and 2002**

	<u>Capital Contributions</u>	<u>Contribution Receivable</u>	<u>Accumulated Deficit</u>	<u>Total</u>	<u>Comprehensive Loss</u>
Capital contributions	\$ 2,220,454			\$ 2,220,454	
Contribution receivable, Progenics Pharmaceuticals Inc. License Fee		\$ (796,934)		(796,934)	
Amortization of discount on capital contribution		(72,813)		(72,813)	
Net loss for the period from June 15, 1999 (inception) to December 31, 1999			\$ (2,074,365)	(2,074,365)	\$ (2,074,365)
<b>Balance at December 31, 1999</b>	2,220,454	(869,747)	(2,074,365)	(723,658)	
Capital contributions	901,835			901,835	
Amortization of discount on capital contribution		(87,504)		(87,504)	
Contribution receivable, Progenics Pharmaceuticals Inc. License Fee		500,000		500,000	
Net loss for the year ended December 31, 2000			(989,202)	(989,202)	\$ (989,202)
<b>Balance at December 31, 2000</b>	3,122,289	(457,251)	(3,063,567)	(398,529)	
Amortization of discount on capital contribution		(42,749)		(42,749)	
Capital contributions	3,676,135	500,000		4,176,135	
Contribution receivable, Progenics Pharmaceuticals Inc. License Fee		(500,000)		(500,000)	
Net loss for the year ended December 31, 2001			(2,576,261)	(2,576,261)	(2,576,261)
<b>Balance at December 31, 2001</b>	6,798,424	(500,000)	(5,639,828)	658,596	
Capital contributions	4,600,000			4,600,000	
Contribution receivable, Progenics Pharmaceuticals Inc. License Fee		500,000		500,000	
Net loss for the year ended December 31, 2002			(5,772,846)	(5,772,846)	(5,772,846)
<b>Balance at December 31, 2002</b>	\$ 11,398,424		\$ (11,412,674)	\$ (14,250)	

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



[Back to Contents](#)

**PSMA Development Company L.L.C.**  
**(a development stage enterprise)**

**Statements of Cash Flows**

	<b>Year Ended December 31, 2000</b>	<b>Year Ended December 31, 2001</b>	<b>Year Ended December 31, 2002</b>	<b>Cumulative from June 15, 1999 (Inception) to December 31, 2002</b>
Cash flows from operating activities:				
Net loss	\$ (989,202)	\$ (2,576,261)	\$ (5,772,846)	\$ (11,412,674)
Amortization of discount on capital contribution	(87,504)	(42,749)		(203,066)
Adjustment to reconcile net loss to net cash used in operating activities:				
(Decrease) increase in accounts payable to Progenics Pharmaceuticals, a related party	(316,400)	(255,925)	(47,179)	304,154
Net cash used in operating activities	(1,393,106)	(2,874,935)	(5,820,025)	(11,311,586)
Cash flows from financing activities:				
Capital contributions	901,835	3,676,135	4,600,000	11,398,424
Contributions receivable from Progenics Pharmaceuticals, Inc.	500,000		500,000	203,066
Net cash provided by financing activities	1,401,835	3,676,135	5,100,000	11,601,490
Increase in cash and cash equivalents	8,729	801,200	(720,025)	289,904
Cash and cash equivalents at beginning of period	200,000	208,729	1,009,929	
Cash and cash equivalents at end of period	\$ 208,729	\$ 1,009,929	\$ 289,904	\$ 289,904

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

[Back to Contents](#)

**PSMA Development Company LLC  
(a development stage enterprise)  
NOTES TO FINANCIAL STATEMENTS**

**1. Organization and Business**

PSMA Development Company LLC (the "JV") was formed on June 15, 1999 as a joint venture between Progenics Pharmaceuticals, Inc. ("Progenics") and CYTOGEN Corporation ("CYTOGEN") (each a "Member" and collectively, the "Members") for the purposes of conducting research, development, manufacturing and marketing of products related to prostate-specific membrane antigen ("PSMA"). Each Member has equal ownership, representation on the JV's management committee and equal voting rights and rights to profits and losses of the JV, as defined. In connection with the formation of the JV, the Members entered into a series of agreements, including an LLC Agreement, a Licensing Agreement and a Services Agreement (collectively, the "Agreements") which define the rights and obligations of each Member, including but not limited to the obligations of the Members with respect to future capital contributions and funding of research and development of the JV (see Note 3). The Members must approve an annual budget in order to provide such funding. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002.

**2. Summary of Significant Accounting Policies**

***Cash and Cash Equivalents***

The JV considers 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. At December 31, 2002, cash consisted of a single interest bearing money market account in a commercial bank.

***Revenue Recognition***

Interest income from the investment of excess cash balances is recognized as earned. Interest income from the amortization of the discount on the payments to Cytogen (see Note 3), was recognized ratably over the term of the financial instrument.

***Research and Development***

Research and development costs are expenses as incurred.

***Concentrations of Credit Risk***

Financial instruments which potentially subject the JV to concentration of credit risk consist of cash and receivables from Members.

***Risks and Uncertainties***

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

***Income Taxes***

The JV's financial statements do not include a provision (credit) for income taxes. Income taxes, if any, are the liability of the individual Members.



[Back to Contents](#)

**PSMA Development Company LLC  
(a development stage enterprise)  
NOTES TO FINANCIAL STATEMENTS □ (Continued)**

### 3. Joint Venture Agreements

In connection with the formation of the JV, the Members entered into a series of agreements, including an LLC Agreement, a Licensing Agreement and a Services Agreement. Under the terms of the LLC Agreement, Progenics was required to pay to the JV \$2.0 million in supplemental capital contributions at certain defined dates or upon the achievement of defined milestones by the JV.

In accordance with the Agreements, Progenics' \$2.0 million supplemental capital contribution was used by the JV to pay a \$2.0 million non-refundable licensing fee to CYTOGEN (the "CYTOGEN Payment"). The payment terms of the CYTOGEN Payment were identical to the payment terms of Progenics' required supplemental capital contribution. Since it was probable that Progenics would be required to fund the \$2.0 million supplemental capital contribution and that the JV would be required to pay the licensing fee to CYTOGEN, the JV, upon execution of the Agreements, recognized a receivable and payable from Progenics and CYTOGEN, respectively, for \$1,796,934. Such amount represented the present value of the supplemental capital contribution and the CYTOGEN Payment discounted at 10%. The discount on those payments was amortized ratably over the term of the LLC Agreement as interest income and interest expense. During the period from June 15, 1999 (inception) to December 31, 1999, and the years ended December 31, 2000 and 2001, the JV received \$1.0 million, \$500,000 and \$500,000, respectively, from Progenics which was, in turn, paid to CYTOGEN during that same periods. In addition, \$72,813, \$87,504 and \$42,749 of discount was amortized during the period from June 15, 1999 (inception) to December 31, 1999 and the years ended December 31, 2000 and 2001, respectively.

Under the terms of the Services Agreement, Progenics is engaged in a research program on behalf of the JV. As of March 31, 2002, and through December 31, 2002, Progenics was performing services for the JV under a month-to-month extension of the Services Agreement. At December 31, 2002, and through March 28, 2003, the Members were negotiating the terms of a new Services Agreement. During the year ended December 31, 2002, research and development expenses paid to Progenics for services under the Services Agreement were approximately \$5.3 million. Progenics was required to fund the cost of the research up to \$3.0 million and was compensated based on agreed upon terms. As of December 31, 2001, Progenics had surpassed the \$3.0 million in funding for research costs. Accordingly, each Member then made capital contributions of \$900,000 and \$2.3 million in the years ended December 31, 2001 and 2002, respectively, to fund future research costs and will share such costs equally. The level of commitment by the Members to fund the JV is based upon an annual budget that is approved by both parties. As of March 28, 2003, the Members were in the process of negotiating the 2003 annual budget for the JV and have committed to the JV that the operating budget for 2003 will be no less than the total expenses as set forth on the Statement of Operations for the JV for the year ended December 31, 2002. All inventions made by Progenics in connection with the Services Agreement will be assigned to the JV for its use and benefit.

The Agreements terminate upon the last to expire of the patents granted by the Members to the JV or upon breach by a Member which is not cured within 60 days of written notice.

### 4. Collaboration Agreements

#### *i. AlphaVax Human Vaccines, Inc.*

In September 2001, the JV entered into a worldwide exclusive license agreement (the "AVX Agreement") with AlphaVax Human Vaccines, Inc., to use the AlphaVax Replicon Vector (ArV™) system (the "AVRV System") to conduct internal research and development to create a therapeutic prostate cancer vaccine incorporating the JV's proprietary PSMA antigen. In consideration for the license, the JV paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating the AVRV System (the "Products"). In addition, the JV is required to pay an annual maintenance fee until the commencement of commercial sales of Products and then royalties based on net sales of Products, subject to certain adjustments, exceptions and set off rights of the JV under defined circumstances. The AVX Agreement



[Back to Contents](#)

**PSMA Development Company LLC  
(a development stage enterprise)  
NOTES TO FINANCIAL STATEMENTS □ (Continued)**

**4. Collaboration Agreements □ (Continued)**

may be terminated, after an opportunity to cure, by AlphaVax under specified circumstances that include, among other things, the JV's failure to achieve certain milestones which may be revised under certain circumstances. If not terminated early, the AVX Agreement continues until the later of (i) the expiration of the AVRV System patents or the invalidation of such patents or (ii) seven years after the First Commercial Sale, as defined, of a Product. The JV has the right to terminate the AVX Agreement upon 30 days prior written notice. The termination of the AVX Agreement could have a material adverse effect on the business of the JV. Although the JV intends to use its best efforts to comply with the terms of the AVX Agreement, there can be no assurances that the agreement will not be terminated.

**ii. Abgenix, Inc.**

In February 2001, the JV entered into an exclusive licensing agreement (the "ABX Agreement") with Abgenix, Inc. ("Abgenix"), to use Abgenix's XenoMouse technology (the "XenoMouse Technology") for generating human antibodies to the JV's proprietary PSMA antigen. In consideration for the license, the JV paid a nonrefundable, noncreditable license fee and is obligated to pay additional license fees on each of the first three anniversary dates and milestone payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating an antibody generated utilizing the XenoMouse Technology (the "Antibody Products"). In addition, the JV is required to pay royalties based upon net sales of the Antibody Products, subject to certain set off rights of the JV under defined circumstances. The ABX Agreement may, upon a material breach, be terminated, after an opportunity to cure, by either party upon 30 days prior written notice. If not terminated early, the ABX Agreement continues until the later of the expiration of the XenoMouse Technology patents or defined period. The JV has the right to terminate the ABX Agreement upon 30 days prior written notice. The termination of the ABX Agreement could have a material adverse effect on the business of the JV. Although the JV intends to use its best efforts to comply with the terms of the ABX Agreement, there can be no assurances that the agreement will not be terminated.

In connection with all the agreements discussed above, the JV has recognized contractual payments, including license fees, which are included in research and development expenses, totaling approximately \$400,000 and \$200,000 for the years ended December 31, 2001 and 2002, respectively. In addition, as of December 31, 2002, remaining payments associated with milestones and defined objectives with respect to the above agreements total approximately \$13.8 million. Future annual minimum royalties under the agreements described in (i) and (ii) above, are not significant.

[Back to Contents](#)

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities and 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.**

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Paul J. Maddon, M.D., Ph.D.  
(Duly authorized officer of the  
Registrant and Chairman of the  
Board and Chief Executive Officer)

Date: October 22, 2003

S-1

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[Back to Contents](#)**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
*3.1	Certificate of Incorporation of the Registrant, as amended.
*3.2	By-laws of the Registrant
*4.1	Specimen Certificate for Common Stock, \$.0013 par value per share, of the Registrant
*10.1	Form of Registration Rights Agreement
*10.2	1989 Non-Qualified Stock Option Plan <input type="checkbox"/>
*10.3	1993 Stock Option Plan, as amended <input type="checkbox"/>
*10.4	1993 Executive Stock Option Plan <input type="checkbox"/>
****10.5	Amended and Restated 1996 Stock Incentive Plan <input type="checkbox"/>
*10.6	Form of Indemnification Agreement <input type="checkbox"/>
**10.7	Employment Agreement dated December 22, 1998 between the Registrant and Dr. Paul J. Maddon <input type="checkbox"/>
*10.8	Letter dated August 25, 1994 between the Registrant and Dr. Robert J. Israel <input type="checkbox"/>
* <input type="checkbox"/> 10.9	gp 120 Supply Agreement dated July 19, 1995, as amended, between the Registrant and Perkin Eumer, Inc., as successor to E.I. Dupont DeNemours and Company
* <input type="checkbox"/> 10.10	SCD4 Supply Agreement dated July 27, 1995, as amended, between the Registrant and Perkin Eumer, Inc., as successor to E.I. Dupont DeNemours and Company
* <input type="checkbox"/> 10.11	License Agreement dated November 17, 1994 between the Registrant and Sloan-Kettering Institute for Cancer Research
* <input type="checkbox"/> 10.12	QS-21 License and Supply Agreement dated August 31, 1995 between the Registrant and Cambridge Biotech Corporation, a wholly owned subsidiary of bioMerieux, Inc.
* <input type="checkbox"/> 10.13	gp 120 Sublicense Agreement dated March 17, 1995 between the Registrant and Cambridge Biotech Corporation, a wholly owned subsidiary of bioMerieux, Inc.
* <input type="checkbox"/> 10.14	Cooperative Research and Development Agreement dated February 25, 1993 between the Registrant and the Centers for Disease Control and Prevention
* <input type="checkbox"/> 10.15	License Agreement dated March 1, 1989, as amended by a Letter Agreement dated March 1, 1989 and as amended by a Letter Agreement dated October 22, 1996 between the Registrant and the Trustees of Columbia University
*****10.16	Amended and Restated Sublease dated June 6, 2000 between the Registrant and Crompton Corporation
** <input type="checkbox"/> 10.17	Development and License Agreement effective as of April 30, 1999, between Protein Design Labs, Inc. and the Registrant
** <input type="checkbox"/> 10.18	PSMA/PSMP License Agreement dated June 15, 1999, by and among the Registrant, CytoGen Corporation and PSMA Development Company LLC
** <input type="checkbox"/> 10.19	Limited Liability Company Agreement of PSMA Development Company LLC, dated June 15, 1999, by and among the Registrant, CytoGen Corporation and PSMA Development Company LLC
10.20	Amendment Number 1 to Limited Liability Company Agreement of PSMA Development Company LLC dated March 22, 2002 by and among the Registrant, CytoGen Corporation and PSMA Development Company LLC
****10.21	Director Stock Option Plan <input type="checkbox"/>
*****10.22	Employment Agreement dated as of May 16, 2001 between the Registrant and Ronald J. Prentki <input type="checkbox"/>
*****10.23	Exclusive Sublicense Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.24	Master Virologic Services Agreement, dated May 22, 2002, between the Registrant and Virologic, Inc.
23.1	Consent of PricewaterhouseCoopers LLP (regarding the Registrant)
23.2	Consent of PricewaterhouseCoopers LLP (regarding PSMA Development Company LLC)
31.1	Certification of Paul J. Maddon, M.D., Ph.D., Chairman and 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, Vice President, Finance and Operations of the Registrant pursuant to 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

*(footnotes on following page)*



[Back to Contents](#)

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- \* Previously filed as an exhibit to the Company's Registration Statement on Form S-1, Commission File No. 333-13627, and incorporated by reference herein.
- \*\* Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, and incorporated by reference herein.
- \*\*\* Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1999, and incorporated by reference herein.
- \*\*\*\* Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 1999, and incorporated by reference herein.
- \*\*\*\*\* Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, and incorporated by reference herein.
- \*\*\*\*\* Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2000, incorporated by reference herein.
- \*\*\*\*\* Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter period ended September 30, 2001, and incorporated by reference herein.
- \*\*\*\*\* Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, incorporated by reference herein.
- † Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Commission.
- ‡ Management contract or compensatory plan or arrangement.