

# PROGENICS PHARMACEUTICALS INC

## FORM 10-K (Annual Report)

Filed 3/31/1998 For Period Ending 12/31/1997

Address	777 OLD SAW MILL RIVER ROAD TARRYTOWN, New York 10591
Telephone	914-789-2800
CIK	0000835887
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549 **FORM 10-K**  
(Mark One)

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

For the fiscal year ended December 31, 1997  
or

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

For the transition period from . . . . . to . . . . .

*Commission file number 000-23143* **PROGENICS PHARMACEUTICALS,  
INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of  
incorporation or organization)

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

777 Old Saw Mill River Road  
Tarrytown, New York 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, \$.0013 par  
value 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 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 state- ments 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 24, 1998 (based on the closing price of \$20.50 on such date as reported on the Nasdaq National Market) was approximately \$110 million.(1) As of March 24, 1998, 9,002,353 shares of Common Stock, \$.0013 par value per share, were outstanding.

**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.

(1) Calculated by excluding all shares that may be deemed to be beneficially owned by executive officers, directors and five percent shareholders of the Registrant, without conceding that all such persons are "affiliates" of the Registrant for purposes of the Federal securities laws.

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## PART I

THIS ANNUAL REPORT ON FORM 10-K CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. THE COMPANY'S 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 WHEN PLANNED, THE RISKS AND UNCERTAINTIES ASSOCIATED WITH DEPENDENCE UPON THE ACTIONS OF THE COMPANY'S 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 UNDER THE CAPTION "BUSINESS-RISK FACTORS."

### Item 1. Business

#### GENERAL OVERVIEW

Progenics Pharmaceuticals, Inc. ("Progenics" or the "Company") is a biopharmaceutical company focusing on the development and commercialization of innovative products for the treatment and prevention of cancer and viral diseases. The Company applies its immunology expertise to develop biopharmaceuticals that induce an immune response or that mimic natural immunity in order to fight cancers, such as malignant melanoma, and viral diseases, such as human immunodeficiency virus ("HIV") infection. Progenics' most advanced product candidate, GMK, is a therapeutic vaccine that is currently undergoing two pivotal Phase III clinical trials for the treatment of melanoma, a deadly form of skin cancer. Progenics' second vaccine product candidate, MGV, is being developed for the treatment of various cancers and commenced Phase I/II clinical trials in September 1996. Based on its participation in the discoveries of two major receptors for HIV, the Company is engaged in research and development of therapeutic products designed to block entry of HIV into human immune system cells. Progenics commenced Phase I/II clinical trials of one of these product candidates, PRO 542, in September 1997 and plans to initiate Phase I/II clinical trials of another product candidate, PRO 367, in the first half of 1998. The Company has entered into a collaboration with Bristol-Myers Squibb Company ("BMS") to develop and commercialize GMK and MGV. The Company has also entered into a collaboration with the Roche Group of Basel, Switzerland ("Roche") to discover and develop novel HIV therapeutics which target the recently identified fusion co-receptors of the virus.

#### Cancer Therapeutics

The Company's GMK and MGV cancer therapeutics are based on proprietary ganglioside conjugate vaccine technology designed to stimulate the immune system to destroy cancer cells. This technology is exclusively licensed by the Company from Memorial Sloan-Kettering Cancer Center ("Sloan-Kettering"). GMK is designed to prevent recurrence of melanoma in patients who are at risk of relapse after surgery. GMK is composed of a ganglioside antigen which is abundant in melanoma cells, conjugated to an immunogenic carrier protein and combined with an adjuvant (an immunological stimulator). In August 1996, the Company commenced the first of three pivotal, randomized, multicenter Phase III clinical trials of GMK. This trial is being conducted in the United States by cooperative cancer research groups supported by the National Cancer Institute ("NCI"). The two additional Phase III clinical trials of GMK will be conducted in a number of countries outside of the United States. One of these trials commenced enrollment of patients in June 1997. The other is expected to commence in the first half of 1998 and will be conducted in Europe by the European Organization for Research and Treatment of Cancer ("EORTC").

MGV is being developed to treat a wide range of cancers, including colorectal cancer, lymphoma, small cell lung cancer, sarcoma, gastric cancer, neuroblastoma and melanoma. MGV incorporates two ganglioside antigens that are abundant in these and other types of cancer cells. In September 1996, MGV entered Phase I/II clinical trials at Sloan-Kettering.

In July 1997, the Company and BMS entered into a Joint Development and Master License Agreement (the "BMS License Agreement") and related agreements with BMS under which Progenics granted BMS an exclusive worldwide license to GMK and MGX. BMS made related cash payments to the Company of approximately \$13.3 million and is obligated to make future payments of up to \$61.5 million upon the achievement of specified milestones. In addition, BMS is required to fund continued clinical development of GMK and MGX and to pay royalties on any product sales.

### **HIV Therapeutics**

There is a considerable need for the development of new HIV therapeutics that address the major problems of viral resistance and drug toxicity that are inherent in currently approved drugs, which target certain enzymes necessary for viral infection and replication. In contrast, the Company's HIV therapeutic programs are based on the CD4 receptor and recently discovered co-receptors, CCR5 and CXCR4, to which binding is necessary for attachment, fusion and entry of the virus into the cell. Progenics applies its universal antiviral binding agent ("UnAB") technology to produce antibody-like molecules designed to neutralize or destroy HIV or HIV-infected cells. This program and the Company's HIV attachment screening program are based on the CD4 receptor. The Company's HIV co-receptor/fusion program is based on CCR5 and CXCR4.

Progenics' PRO 542 and PRO 367 product candidates utilize the Company's proprietary UnAB technology. Progenics is developing PRO 542 to selectively target HIV and prevent it from infecting healthy cells by binding to the sites on the virus that are required for entry into the cell. PRO 542 is being developed as an immunotherapy to treat HIV-positive individuals and has been shown in vitro to neutralize a wide range of HIV clinical strains. The Company initiated Phase I/II clinical trials of PRO 542 in September 1997.

Progenics is developing PRO 367 as a therapeutic agent designed to kill HIV-infected cells. PRO 367 consists of a UnAB molecule linked to a therapeutic radioisotope and is designed to bind to and destroy HIV-infected cells by delivering a lethal dose of radiation. The Company plans to begin Phase I/II clinical trials of PRO 367 in the first half of 1998.

In June 1996, the Company's scientists in collaboration with researchers at the Aaron Diamond AIDS Research Center ("ADARC") described in an article published in Nature the discovery of CCR5, a co-receptor for HIV that mediates fusion of HIV with the cell membrane. Viral fusion is necessary to permit entry of the virus into the cell. The Company recently entered into a collaboration with Roche to discover and develop novel HIV therapeutics which target CCR5 and other fusion co-receptors of the virus. Under the terms of the collaboration, Roche has received from Progenics an exclusive worldwide license to the Company's HIV co-receptor technology. Roche is obligated to make up-front and milestone payments, research funding for up to three years and royalty payments on the sale of any products commercialized as a result of the collaboration.

In addition, the Company is using its proprietary HIV attachment assay in a collaborative research program to identify small-molecule compounds that inhibit attachment of the virus to the CD4 receptor.

### **The Human Immune System**

The human immune system functions to protect the body from disease by specifically recognizing and destroying foreign invaders, including viruses and bacteria. In addition, the immune system is capable of recognizing and eliminating from the body abnormal cells, such as cancer cells and cells infected with viruses and bacteria. White blood cells, particularly B and T lymphocytes, have the ability to recognize antigens made by these infectious agents and abnormal cells and react to them. For example, B lymphocytes produce antibodies that recognize specific antigens. Antibodies can bind to these antigens and neutralize or eliminate infectious agents and cancer cells. Vaccines are designed to induce the production of antibodies against 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 also being developed as therapeutics 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 antibody molecules are intended to function by mimicking the body's own immune response in situations where the immune response has been suppressed or otherwise compromised.

## Product Development

The Company applies its expertise in immunology to the development of therapeutic biopharmaceuticals that use components of the immune system, particularly antibodies, to fight diseases. The Company's two principal programs are directed towards cancer and HIV. In the case of cancer, the Company is developing vaccine products that are designed to induce specific antibody responses to cancer antigens. In the case of HIV, the Company is developing therapeutic products by genetically engineering molecules that function as antibodies and selectively target HIV and HIV-infected cells for neutralization or destruction. The Company also is actively engaged in research and discovery of compounds based on the HIV receptor, CD4, and HIV co-receptors, including CCR5 and CXCR4, and their roles in viral attachment, fusion and entry.

The following table summarizes the status of the principal development programs, product candidates and products of the Company and identifies any related corporate collaborator:

Program/product	Indication/use	Status(1)	Corporate Collaborator
<b>Cancer Therapeutics</b>			
GMK	Vaccine for melanoma	Phase III	BMS
MGV	Vaccine for colorectal cancer, lymphoma, small cell lung cancer, sarcoma, gastric cancer, and neuroblastoma	Phase I/II	BMS
<b>HIV Therapeutics</b>			
PRO 542	HIV therapy	Phase I/II	--
PRO 367	HIV therapy	Phase I/II expected to commence in the first half of 1998	--
HIV Co-receptor/Fusion (using ProSys assays)	HIV therapy	Research	Roche
HIV Attachment Drug Screen	HIV therapy	Research	AHP (2)
ProVax	HIV vaccine	Research	--
<b>Assays and Reagents</b>			
ONCOTECT GM	Clinical assay for cancer prognosis	In clinical investigational use	--
sCD4, gp120	Research reagents	On market	DuPont de Nemours & Company, Intracel Corporation

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

Phase I-III clinical trials denote safety and efficacy tests in humans as follows:

"Phase I": Evaluation of safety.

"Phase II": Evaluation of safety, dosage and efficacy.

"Phase III": Larger scale evaluation of safety and efficacy potentially requiring larger patient numbers, depending on the clinical indication for which marketing approval is sought.

"In clinical investigational use" means being used by the Company to measure antibody levels of patients in clinical trials.

See "Business--General-Government Regulation" and "--Assays and Reagents."

(2)"AHP" means the Wyeth-Ayerst Research Division of American Home Products Corporation.

## Cancer Therapeutics

Cancer is a set of different 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 elimination of cancer cells by the immune system. Eradication of malignant cells which can metastasize (i.e., spread) to vital organs, leading to death, is central to the effective treatment of cancer.

Despite recent advances in treatment, cures in many cancer areas continue to 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 occult (i.e., hidden) or residual disease is difficult or impossible to eliminate fully, which can lead to relapse. Surgery may be used to remove primary masses of some solid tumors; however, it cannot be used to remove occult disease. Conventional treatment with combination chemotherapy and radiation may not be capable of eradicating cancers completely because of inadequate potency at the tumor site resulting from limitations on drug or radiation doses due to potential side-effects to healthy tissues. Moreover, while more recently introduced biological drugs, such as interferons, have in some cases represented an improvement over traditional cytotoxic therapy, they have proven effective only on a limited basis and only in certain types of cancer and have adverse side effects.

Because of the inability of traditional cancer therapies to address adequately occult and residual cancers, non-specific toxicities and limited potency, a significant need exists for new therapeutic products. To address this demand, cancer vaccines are now being developed to stimulate the natural defense mechanisms of the immune system to fight cancer. Unlike traditional infectious disease vaccines that are used to prevent infection in the general population, most cancer vaccines are therapeutic, meaning that they are being developed to prevent recurrence of cancer in people whose cancer is in remission following treatment by conventional therapies (including surgical removal). In some cases, cancer vaccines are also being designed for use in the prevention of cancer in individuals who are at high risk for the disease.

A major challenge in cancer vaccine development results from the fact that the natural human immune response generally does not produce sufficient antibodies to fight cancer cells because the immune system often does not recognize the difference between normal cells and cancer cells. Consequently, a primary objective in the development of cancer vaccines is to train the immune system to recognize cancer cells as a threat. If this can be achieved and the immune system can produce sufficient antibodies to the cancer, then the recurrence of the cancer may be prevented. Most cancer vaccines of parties other than the Company that are in clinical development consist of dead cancer cells or crude extracts from cancer cells. Unlike the Company's vaccine technology, these approaches are limited by their inability to identify the active components of the vaccine or measure specific immune responses.

### Progenics' Technology: Ganglioside Conjugate Vaccines

Progenics' cancer vaccine program involves the use of purified gangliosides as cancer antigens. Gangliosides are chemically-defined molecules composed of carbohydrate and lipid components. Certain gangliosides are usually found in low amounts in normal human tissue, but are abundant in certain cancers, such as melanoma, colorectal cancer, lymphoma, small cell lung cancer, sarcoma, gastric cancer and neuroblastoma.

Because gangliosides alone do not normally trigger an immune response in humans, Progenics attaches gangliosides to large, highly immunogenic carrier proteins to form "conjugate" vaccines designed to trigger specific immune responses to ganglioside antigens. To further augment this immune response, Progenics adds an immunological stimulator, known as an "adjuvant," to its ganglioside-carrier protein conjugate.

The Company's ganglioside conjugate vaccines stimulate the immune system to produce specific antibodies to ganglioside antigens. These antibodies have been shown in vitro to recognize and destroy cancer cells. Based on these tests and the clinical trial results described below, the Company believes that vaccination of cancer patients with ganglioside conjugate vaccines will delay or prevent recurrence of cancer and prolong overall survival.

The Company's cancer vaccines use known amounts of chemically-defined antigens, not dead cancer cells or crude extracts from cancer cells. As a result, Progenics is able to measure specific immune responses to the gangliosides in its vaccines. The Company also believes that there is a reduced likelihood of variability in its products as compared to vaccines which are prepared from dead cancer cells or crude extracts from cancer cells or which require complicated manufacturing processes.

#### GMK: Therapeutic Vaccine For Malignant Melanoma

Progenics' most advanced product under development is GMK, a proprietary therapeutic vaccine for melanoma that is currently in pivotal Phase III clinical trials. The Company is collaborating with BMS on this program. GMK is the first cancer vaccine based on a defined cancer antigen to enter Phase III clinical trials. GMK 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 ("KLH") and combined with the adjuvant QS-21. QS-21 is the lead compound in the Stimulon\_ family of adjuvants developed and owned by Aquila Biopharmaceuticals Inc. ("Aquila").

### 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 spreads to the lungs, liver, brain and other organs. The Company estimates that there are 300,000 melanoma patients in the United States today. The American Cancer Society estimates that 40,300 patients in the United States will be newly diagnosed with melanoma in 1997. In the United States, the incidence of melanoma is increasing at a rate of approximately 6% per year, an increase in incidence that is faster than that of any other cancer in men and second only to lung cancer in women. Projections suggest that by the year 2000 one in 75 Americans will develop melanoma within their lifetime. Increased exposure to the ultraviolet rays of the sun may be an important factor contributing to the increase in new cases of melanoma.

Melanoma patients are categorized according to the following staging system:

Melanoma Staging			
Stage I	Stage II	Stage III	Stage IV
lesion less than 1.5 mm thickness	lesion greater than 1.5 mm thickness	metastasis to regional draining lymph nodes	distant metastasis
No apparent metastasis	local spread from primary cancer site	regional spread from primary cancer site	

GMK is designed for the treatment of patients with Stage II or Stage III melanoma. It is estimated that these patients comprise about 50% of the total number of melanoma patients and, accordingly, the Company estimates that there are currently 150,000 Stage II and III melanoma patients in the United States. According to the American Cancer Society, an estimated 60% to 80% of 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. In a recently reported study, the median recurrence-free survival period after surgery for patients treated with high-dose alpha interferon was 20 months versus 12 months for patients who received no treatment. In addition, the median overall survival period after surgery was 46 months for the treated group versus 34 months for the untreated group. However, treatment with high-dose alpha interferon causes substantial toxicities, requires an intensive treatment over twelve months (intravenous injections five days a week for the first month followed by subcutaneous injections three times a week for the remaining eleven months) and costs about \$35,000 per year.

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

## Clinical Trials

GMK entered pivotal Phase III clinical trials in the United States in August 1996. In addition, Progenics plans two international Phase III clinical trials of GMK, one of which commenced enrollment of patients in June 1997 and the other of which is expected to commence in the first half of 1998. GMK is administered in the studies on an out-patient basis by 12 subcutaneous injections over a two-year period.

The ongoing U.S. Phase III 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 is expected to enroll 850 patients, is being 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 NCI and are comprised of several hundred participating hospitals and clinics, primarily in the United States. The primary endpoint of the trial is to compare the recurrence of melanoma in patients receiving GMK versus in patients receiving high-dose alpha interferon. The study will also compare quality of life and overall survival of patients in both groups.

The second Phase III clinical trial is a randomized double-blind, placebo-controlled study in Stage IIb and Stage III melanoma patients who have undergone surgery but are at high risk for recurrence. This trial, which enrolled its first patients in June 1997 in New Zealand, will be conducted by major cancer centers, hospitals and clinics in Europe, Australia, New Zealand and South Africa. In the United Kingdom, the study will be conducted by the Institute of Cancer Research ("ICR") of the United Kingdom, a major government-sponsored cancer research organization. The primary endpoint of the trial is to compare the recurrence of melanoma in patients receiving GMK versus in patients receiving placebo. The study will also compare overall survival of patients in both groups.

The third Phase III clinical trial will be a randomized study exclusively in Stage IIa (early Stage II) melanoma patients who have undergone surgery but are at intermediate risk for recurrence. This trial, which the Company expects will commence in the first half of 1998, will be conducted in Europe by the EORTC, the major cooperative cancer research group in Europe. Patients will be randomized to receive either GMK or observation with no treatment. The primary endpoint of the 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.

A predecessor of GMK, called GM2-BCG, which combined GM2 ganglioside with the adjuvant BCG, underwent clinical testing at Sloan-Kettering in the late 1980s. In a double-blind, randomized Phase II study in 122 Stage III melanoma patients, subjects in the treated group received GM2-BCG for six months after surgery; subjects in the control group received the same regimen with BCG alone. The median recurrence-free survival period after surgery for patients treated with GM2-BCG was 33 months versus 17 months for the patients in the control group. In addition, the median overall survival period after surgery for patients in the treated group was 70 months versus 30 months for patients in the control group. Approximately 85% of treated patients developed antibodies to GM2 ganglioside. The presence of these antibodies significantly correlated with improved recurrence-free and overall survival of patients.

Phase I/II clinical trials of GMK under institutional INDs were conducted at Sloan-Kettering over the last six years. In these studies, approximately 120 patients, most of whom had Stage III melanoma, were treated with GMK. All patients receiving GMK at the dose level being used in the current Phase III trials of GMK developed antibodies to GM2 ganglioside. Patients treated with GMK had levels of antibody to GM2 ganglioside that were on average four times higher and also were longer lasting than in patients treated with GM2-BCG in the GM2-BCG Phase II trial. In addition, GMK was well tolerated by all patients in these studies, and no clinically significant side effects attributable to the vaccine were observed.

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

Progenics' second ganglioside conjugate vaccine in development, 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, neuroblastoma and melanoma. The Company is collaborating with BMS on this program. MGV has three components: (i) GM2- KLH (GM2 ganglioside conjugated to KLH); (ii) GD2-KLH (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.

#### **Clinical Trials**

MGV entered Phase I/II clinical trials in September 1996 under an institutional investigational new drug application ("IND") at Sloan-Kettering. The primary objectives of the study are to establish the safety of MGV and the ability of the vaccine to induce specific immune responses to both GD2 and GM2 gangliosides in patients with different cancer types, beginning with melanoma patients. In addition, a goal of the study is to optimize the ratio of GD2 and GM2 gangliosides in MGV to be used in future clinical trials.

The GM2-KLH/QS-21 (GMK) and GD2-KLH/QS-21 components of MGV have each undergone separate clinical testing. To date, six melanoma patients have received GD2-KLH/QS-21 alone in Phase I/II clinical trials under an institutional IND at Sloan-Kettering. All six subjects developed antibodies to GD2 ganglioside following vaccination. In addition, the vaccine was well tolerated and no clinically significant side effects attributable to the vaccine were observed. Based on these results as well as the results of clinical studies with GMK discussed above, the Company expects that patients receiving MGV will develop antibodies to both GD2 and GM2 gangliosides.

#### **HIV Therapeutics**

HIV infection causes a slowly progressive deterioration of the immune system which results in AIDS. AIDS is characterized by a general collapse of the immune system leading to a wasting syndrome, frequent opportunistic infections, rare forms of cancer, central nervous system degeneration and eventual death. HIV infection is unusual in that individuals testing positive for the virus can survive for many years without symptoms of the disease. There are three major routes of transmission of the virus: sexual contact, exposure to HIV-contaminated blood or blood products and mother-to-child transmission.

HIV specifically infects cells that have the CD4 receptor on their surface ("CD4+"). CD4+ cells are critical components of the immune system, and include T lymphocytes, monocytes, macrophages and dendritic cells. The deleterious effects of HIV are largely due to the replication of the virus in these cells and the resulting dysfunction and destruction of these cells.

HIV-positive individuals display both antibodies and other immune system responses which are specific to the virus. However, the high fatality rate of this disease makes it clear that these natural immune system responses do not provide adequate long-term protection. There are two reasons why these natural responses are inadequate. First, as described above, the CD4+ T lymphocytes required to mount an effective immune response against HIV are destroyed, leaving the immune system too weak to eliminate the virus. Second, HIV displays a remarkable degree of variability as a result of high rates of mutation that permit different strains of the virus to escape the immune system response and progressively replicate throughout the body.

Viral infection involves the binding of the virus to cells, viral entry into those cells and, ultimately, the commandeering of the host cells' reproductive machinery, which permits replication of the viral genetic information and the generation of new copies of the virus. The Company's scientists and their collaborators have made important discoveries in understanding how HIV enters human cells and initiates viral replication. In the 1980s, Company scientists in collaboration with researchers at Columbia University, the ICR and the Centers for Disease Control and Prevention ("CDC") 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 the gp120 glycoprotein located on the HIV envelope binds with high affinity to the CD4 receptor. Although these researchers demonstrated that CD4 was necessary for HIV attachment, this step is not sufficient to enable the virus to enter the cell and initiate viral replication.

In June 1996, Company scientists in collaboration with researchers at 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. Recently, Company scientists in collaboration with researchers at ADARC demonstrated that it is the gp120 glycoprotein that binds to the CCR5 co-receptor as well as to the CD4 receptor. Recently, these scientists localized the gp120 binding site on CCR5 to a discrete region at one end of the molecule.

### **Progenics' HIV Receptor Technologies**

Based on the Company's participation in the discoveries of two major receptors for HIV, Progenics is pursuing several approaches in the research and development of products designed to block entry of HIV into human immune system cells. The Company's UnAB and attachment screening programs are based on the CD4 receptor while its HIV co-receptor fusion program is based on recently discovered co-receptors, CCR5 and CXCR4.

Because HIV must first attach to the CD4 receptor to infect human cells, the Company believes that the part of the gp120 glycoprotein that attaches to the CD4 receptor must remain constant across all strains of the virus. The gp120 glycoprotein is located on the exterior of both HIV and HIV-infected cells. Progenics' UnABs incorporate 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 or HIV-infected cells. In *in vitro* tests, the Company's UnABs have demonstrated the ability to bind with high affinity to gp120 glycoproteins from a wide range of HIV strains, including the strains most prevalent in the United States and the rest of the world. Because the Company's UnAB technology is targeted to a part of HIV that is believed to be necessary for the virus to enter cells and not to mutate, the Company believes that its technology may address the obstacles presented by the high mutation rate of the virus.

Two of the Company's HIV products under development are based on its proprietary UnAB technology, although they employ the technology in different ways. PRO 542 is designed to bind to the gp120 glycoprotein located on the virus itself, neutralizing the virus and thereby preventing it from infecting healthy cells. PRO 367 is designed to bind to the gp120 glycoprotein located on the exterior of HIV-infected cells and destroy those cells by delivering a lethal dose of radiation. The two products also differ in that each molecule of PRO 542 has four binding sites for HIV while each molecule of PRO 367 has two binding sites.

Progenics also is applying its HIV technology in two programs designed to use the Company's proprietary screening assays to identify and develop potential HIV therapeutics. In its co-receptor/fusion program, the Company is using its ProSys assays to identify compounds that inhibit the interaction between HIV and HIV co-receptors, including CCR5 and CXCR4, thereby blocking viral fusion and entry. In the Company's HIV attachment program, Progenics is using its proprietary HIV attachment assay to identify small-molecule compounds that inhibit the interaction between HIV and CD4, thereby blocking viral attachment.

### **Target Market**

Progenics' therapeutic product candidates are designed primarily for use in asymptomatic HIV-positive individuals. Accordingly, the target population for these products is patients who are aware of their infection but do not yet have AIDS. Although there are few signs of disease in an HIV-positive individual during the asymptomatic period, the virus is replicating in the body by infecting healthy cells. It is estimated that in 1996 more than 830,000 people in North America and 20,000,000 people worldwide were infected with HIV. The CDC estimated that as of December 1996, approximately 220,000 people in the United States had AIDS.

### **Current Therapies**

At present, two classes of products have received marketing approval from the U.S. Food and Drug Administration (the "FDA") for the treatment of HIV infection and AIDS: reverse transcriptase inhibitors and protease inhibitors. Both types of drugs are inhibitors of 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 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 as these drug regimens require more than a dozen tablets to be taken at specific times each day. An additional problem is that currently approved drugs exhibit substantial toxicities in many patients, affecting a variety of organs and tissues, including the peripheral nervous system and gastrointestinal tract. These toxicities often result in patients interrupting or discontinuing therapy.

#### **Pro 542: HIV Therapy**

Progenics is developing PRO 542 for the treatment of HIV infection. PRO 542 is a proprietary UnAB-based 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 conducted by Progenics in collaboration with scientists at ADARC and the CDC, PRO 542 neutralized a wide variety of clinical strains of HIV as well as viruses in the plasma of HIV-positive individuals. In comparative in vitro studies at ADARC using a panel of neutralizing antibodies to HIV, PRO 542 was found to be more potent and broadly neutralizing than the antibodies to which it was compared. In further studies at ADARC, PRO 542 protected severe combined immune deficient ("SCID") mice transplanted with human peripheral blood lymphocytes against infection by the three HIV strains tested, including strains of the virus isolated from HIV-positive individuals.

Progenics initiated two dose-escalation Phase I/II clinical trials of PRO 542 in September 1997. The first study is being conducted in HIV-positive adult patients at Mount Sinai Medical Center in New York City. The second trial is being 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, ("ACTG"), a leading cooperative HIV research group supported by the National Institute of Allergy and Infectious Diseases ("NIAID"). Both trials will measure safety, pharmacokinetics and antiviral activity of PRO 542.

In September 1997, the Company entered into a collaboration agreement with Genzyme Transgenics Corporation ("GTC") with the objective of developing a transgenic source of PRO 542 using GTC proprietary technology. This collaboration is designed to result in the commercial-scale manufacture of PRO 542 by GTC using a herd of transgenic goats.

#### PRO 367: HIV Therapy

Progenics is developing PRO 367 as a therapeutic agent designed to destroy HIV-infected cells. PRO 367 is composed of a proprietary UnAB molecule with two binding sites for the gp120 glycoprotein linked to a therapeutic radioisotope. PRO 367 is designed to specifically bind with high affinity to the gp120 glycoprotein on HIV-infected cells and to destroy these cells by delivering a lethal dose of radiation.

The Company plans to initiate dose-escalation Phase I/II clinical trials of PRO 367 in the first half of 1998, subject to obtaining necessary regulatory clearances. The study will assess safety, pharmacokinetics, biodistribution and antiviral effects of PRO 367 in HIV-positive adult patients.

In in vitro tests, PRO 367 specifically bound with high affinity to the gp120 glycoprotein on the cell surface. In addition, a pilot Phase I clinical trial in AIDS patients of a trace-labeled precursor of PRO 367 was conducted under an institutional IND at Sloan-Kettering. This trial assessed the safety and pharmacology of the compound with low doses of iodine-131. The compound was well tolerated by all patients, no clinically significant side effects attributable to the compound were observed and the compound exhibited suitable pharmacokinetics for further development.

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

The Company's first application of its HIV co-receptor technology is through the use of its proprietary ProSys assays. These assays model fusion of HIV with human cells rapidly, automatically, sensitively and without the use of infectious virus. The Company recently entered into a collaboration with Roche to discover and develop novel HIV therapeutics which target CCR5 and other fusion co-receptors of the virus. Under the terms of the collaboration, Roche has received from Progenics an exclusive worldwide license to its HIV co-receptor technology. Roche is obligated to make up-front and milestone payments, research funding for up to three years and royalty payments on the sale of any products commercialized as a result of the collaboration.

#### HIV Attachment Drug Screen: HIV Therapy

As part of a collaborative research project with the Wyeth-Ayerst Research Division of American Home Products Corporation ("AHP"), Progenics has developed a proprietary drug screening assay designed to identify small-molecule compounds which inhibit attachment of HIV to the CD4 receptor. This assay has been used in a high-throughput screening program, and the compounds discovered are undergoing additional studies by the Company and AHP to evaluate further their antiviral activity.

#### ProVax: HIV Vaccine

Progenics is conducting research with respect to its ProVax vaccine, a vaccine candidate which it believes may be useful as a preventative or a therapeutic treatment for HIV-positive individuals. Progenics is currently performing government-funded research and development of the ProVax vaccine in collaboration with ADARC, the Southwest Foundation for Biomedical Research in San Antonio and the University of Oklahoma Medical Center.

## **Assays and Reagents**

Through its immunology expertise, Progenics has developed certain assays, in addition to its ProSys and HIV attachment assays, which are used both independently and in collaboration with partners, as well as certain reagents which are being sold for research use only. These assays are described below.

### **ONCOTECT GM**

Progenics has developed ONCOTECT GM, a clinical assay for assessing prognosis in patients with melanoma and other cancers. ONCOTECT GM measures the levels of antibody to GM2 ganglioside in the blood. In clinical trials of a therapeutic vaccine for melanoma, the presence of these antibodies significantly correlated with improved recurrence-free and overall survival of patients. The Company is currently using ONCOTECT GM in its cancer vaccine clinical trials.

Research Reagents: sCD4 and gp120

Progenics manufactures the research reagents sCD4 and gp120 which it sells to DuPont de Nemours & Company ("DuPont") and Intracel Corporation ("Intracel") for resale. DuPont markets and sells gp120 and sCD4 under both the Progenics and the DuPont names. Intracel markets and sells gp120 and sCD4 under both the Progenics and Intracel names. These products are sold worldwide for research use. While the Company's only customers for these reagents are DuPont and Intracel, in light of the limited revenues received from sales of these reagents, the Company does not believe that the loss of either of these customers would have a material adverse effect on the Company.

## **Corporate Collaborations**

### **Bristol-Myers Squibb Company**

In July 1997, the Company and BMS entered into the BMS License Agreement. Pursuant to the BMS License Agreement, the Company granted to BMS an exclusive, worldwide license to make, have made, use, sell, have sold and develop GMK and MGV and any other product to which Progenics has rights that include the GM2 or GD2 ganglioside antigens and are used for the treatment or prevention of human cancer. BMS is entitled under the BMS License Agreement to grant sublicenses, subject to certain restrictions.

Pursuant to the BMS License Agreement and the related sublicense agreements (collectively, the "BMS Agreements"), BMS has made certain payments to the Company and is required to make milestone payments and pay royalties on sales of licensed products. In July 1997, BMS paid the Company approximately \$13.3 million, representing (i) \$11.5 million as reimbursement for expenses previously incurred by Progenics in the development of GMK and MGV and licensing fees and (ii) \$1.8 million as reimbursement of the Company's clinical development costs for the period from April 15, 1997 to September 30, 1997. BMS is also required to make future payments of up to \$61.5 million upon achievement of specified milestones relating to the development and regulatory approval of GMK, MGV or other products that include the GM2 or GD2 ganglioside antigens. The amount of these milestone payments will depend on the product candidate achieving the specified milestone and, with respect to MGV, the indications for which it is developed. BMS is also required to pay royalties on any sale of licensed products and to fund continued development, clinical trials and regulatory activities of GMK and MGV pursuant to plans agreed to by the parties. There can be no assurance that the Company will receive milestone or royalty payments from BMS or that funding for the GMK or MGV programs will not be curtailed or terminated.

In connection with the BMS License Agreement, the Company granted to BMS sublicenses to the technology and other rights licensed to the Company from each of Sloan-Kettering, The Regents of the University of California (the "Regents") and Aquila under the licenses with these entities discussed under "--Licenses." These sublicenses are exclusive as to the Sloan-Kettering and the Regents sublicenses and non-exclusive as to the Aquila sublicense and are intended, in general, to make available to BMS the technology licensed by the Company from these entities and used to make GMK and MGV. BMS is entitled under these sublicenses to grant further sublicenses, subject to certain restrictions.

In connection with payments made by BMS to the Company under the BMS License Agreement, the Company made certain payments to licensors as an inducement to these licensors to enter into agreements with the Company and BMS amending certain provisions of the prime licenses and granting to BMS certain related rights. Future payments made by BMS to the Company under the BMS License Agreement also trigger payment obligations to these licensors. See "--Licenses."

The BMS Agreements terminate at various times related, in general, to the expiration or abandonment of the related patents or to the first commercial sale of products. The agreements can also be terminated by either party upon a material, uncured breach by the other party. BMS has the further right to terminate the BMS License Agreement (including its funding and milestone obligations) as to specified licensed products at specified times.

### **Roche Group**

In December 1997, the Company entered into a collaboration agreement with Roche to discover and develop novel HIV therapeutics which target the recently identified fusion co-receptors of the virus (the "Roche Agreement"). This collaboration, among other things, provides for Roche to apply its library of compounds to original screening assays of the Company to identify inhibitors of the interaction between HIV co-receptors and HIV.

Under the terms of the Roche Agreement, Progenics has granted to Roche an exclusive worldwide license to develop, make, have made, use, sell, offer to sell and import any covered products for the therapy of HIV infection. The license covers products to which Progenics has rights or that are developed as a result of the collaboration and which have been identified as, or developed for the purpose of, inhibiting the interaction between chemokine receptors that act as HIV co-receptors, including CCR5 and CXCR4, and HIV, which interaction results in fusion of HIV with cells. The license does not extend to certain classes of molecules, as to which Progenics has retained rights. Subject to certain restrictions, Roche retains the right to grant sublicenses under the Roche Agreement.

Pursuant to the Roche Agreement, Roche will provide to Progenics up-front and milestone payments, research funding for up to three years, as well as royalty payments on the sale of any products commercialized as a result of the collaboration. The Company is also entitled to certain contingent licensing rights.

The collaboration remains in full force, subject to the exceptions identified below, until the expiration of all obligations to pay royalties pursuant to any of the licenses granted therein. The Agreement can be terminated by either party upon a material, uncured breach by the other party. Roche has the further right to terminate the Roche Agreement or the collaboration contemplated under the Roche Agreement at specified times; however, in either case, Roche will not be relieved of certain minimum research funding obligations.

This collaboration is in the early stage of drug discovery. There can be no assurance that the Company will receive additional milestone or any royalty payments from Roche, that funding for the program contemplated by the collaboration will not be curtailed or terminated or that any contingent licensing rights will be granted.

### **Licenses**

The Company is a party to license arrangements under which it has obtained rights to use certain technologies in its cancer and HIV programs. Set forth below is a summary of those licenses that the Company believes to be important to its business.

The Company is party to a license agreement with Sloan-Kettering under which the Company 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. The Sloan-Kettering license terminates upon the expiration of the last of the licensed patents or 15 years from the date of the first commercial sale of a licensed product pursuant to the agreement, whichever is later. In addition to patent applications, the Sloan-Kettering license includes the exclusive rights to use certain relevant technical information and know-how. A number of Sloan-Kettering physician-scientists also serve as consultants to the Company.

The Company is party to a license agreement with the Regents under which the Company obtained the exclusive rights to an issued U.S. patent covering certain ganglioside conjugate vaccines. The license agreement terminates upon the expiration of the patent.

The Company is party to a license agreement with Columbia University under which the Company has obtained exclusive, worldwide rights to certain technology and materials relating to CD4 and its use to treat or prevent HIV infection. The license agreement will terminate upon the expiration of the last of the licensed patents.

The Company has entered into a license and supply agreement with Aquila pursuant to which Aquila agreed to supply the Company with all of its requirements for the QS-21 adjuvant for use in certain ganglioside-based cancer vaccines, including GMK and MGV. QS-21 is the lead compound in the Stimulon\_ family of adjuvants developed and owned by Aquila. The license terminates upon the expiration of the last of the licensed patents.

The licenses to which the Company is a party impose various milestone, commercialization, sublicensing, royalty and other payment, insurance, indemnification and other obligations on the Company and are subject to certain reservations of rights. Failure by the Company to comply with these requirements could result in the termination of the applicable agreement, which could have a material adverse effect on the Company's business.

In connection with the BMS License Agreement, the Company granted to BMS sublicenses to the technology and other rights licensed to the Company from each of Sloan-Kettering, the Regents and Aquila under the licenses with these entities described above. See "--BMS Collaboration."

### **Government Grants And Contracts**

Through December 31, 1997, the Company had been awarded government grants aggregating approximately \$2,677,000 under the Small Business Innovation Research ("SBIR") program of the NIH for the Company's commercial development of PRO 542, PRO 367, ProVax vaccine and ProSys assays. Through December 31, 1997 the Company had recognized approximately \$2,135,000 of such amount as revenue. In addition, the Company has been awarded a \$812,000 multi-year grant under a contract with the Department of Defense for work related to ProVax vaccine. Through December 31, 1997 the Company had recognized approximately \$748,000 of such amount as revenue.

In general, under the terms of these grants the Company has, subject to certain rights of the government described below, all right, title and interest to all patents, copyrights and data pertaining to any product developed. However, under existing regulations, the government receives a royalty-free license for federal government use with respect to patents developed by grant recipients. In addition, the government may, in certain circumstances, require the Company to license technology resulting from the funded projects to third parties and may require that the Company manufacture substantially all of the products resulting from a particular grant in the United States.

The government's obligation to make payments under these grants is subject to appropriation by the United States Congress for funding in each such year. Moreover, it is possible that Congress or the government agencies that administer these government research programs will determine to scale back these programs or terminate them or that the government will award future grants to competitors of the Company instead of the Company. In addition, while Progenics intends to pursue additional government grants related to its areas of research and development, there can be no assurances that the Company will be awarded any such grants in the future or that any amounts derived therefrom will not be less than those received to date.

In September 1997, the Company was awarded a two-year, protein manufacturing contract for \$1,601,000 from the NIH.

## **Patents and Proprietary Technology**

Progenics' policy is to protect its proprietary technology, and the Company considers the protection of such rights to be important to its business. In addition to seeking U.S. patent protection for many of its inventions, the Company generally files patent applications in Canada, Japan, Western European countries and additional foreign countries on a selective basis in order to protect the inventions deemed to be important to the development of its foreign business.

Under a license agreement with Sloan-Kettering, Progenics 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 application filed by Sloan-Kettering in the U.S. 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.

Under a license agreement with Columbia University, Progenics obtained worldwide, exclusive rights to certain technology relating to CD4 and its use to treat or prevent HIV infection. 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. Progenics has also filed a number of U.S. and foreign patent applications on its UnAB, ProSys and ProVax technologies and clinical uses of these technologies.

Progenics has also filed a number of U.S. and foreign patent applications (one of which is owned jointly with ADARC) relating to the discovery of an HIV co-receptor, CCR5. In addition to the risks described above, the Company is aware that other groups have claimed discoveries similar to that covered by the Company's patent applications. These groups may have made their discoveries prior to the discoveries covered by the Company's patent applications and may have filed their applications prior to the Company's patent applications. The Company does not expect to know for several years the relative strength of its patent position as compared to these other groups.

The enactment of the legislation implementing the General Agreement on Tariffs and Trade has resulted in certain changes to United States patent laws that became effective on June 8, 1995. Most notably, the term of patent protection for patent applications filed on or after June 8, 1995 is no longer a period of seventeen years from the date of grant. The new term of United States patents will commence on the date of issuance and terminate twenty years from the earliest effective filing date of the application. Because the time from filing to issuance of patent applications is often more than three years, a twenty-year term from the effective date of filing may result in a substantially shortened term of patent protection, which may adversely impact the Company's patent position.

## **Government Regulation**

The Company and its products are subject to comprehensive regulation by the FDA 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 the Company's products.

FDA approval of the Company's 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. There can be no assurance that approvals of the Company's proposed products, processes, or facilities will be granted on a timely basis, or at all. Any failure to obtain or delay in obtaining such approvals would adversely affect the ability of the Company to market its proposed products. Moreover, even if regulatory approval is granted, such approval may include significant limitations on indicated uses for which a product could be marketed.

The process required by the FDA before the Company's products may be approved for marketing in the United States generally involves (i) preclinical laboratory and animal tests, (ii) submission to the FDA of an IND, which must become effective before clinical trials may begin, (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication, (iv) submission to the FDA of a marketing application and (v) FDA review of the marketing application in order to determine, among other things, whether the product is safe and effective for its intended uses. There is no assurance that the FDA review process will result in product approval on a timely basis, or at all.

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.

A New Drug Application ("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; nonclinical 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 Product License Application ("PLA") is an application to the FDA to market a biological product. The PLA 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 product license is issued and until the establishment where the product is to be manufactured has been issued an establishment license.

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 cGMP, 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 and are reviewed by the FDA prior to the commencement of human clinical trials. Unless the FDA objects to, or 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. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. See "Risk Factors--Uncertainty Associated with Preclinical and Clinical Testing."

Clinical trials involve the administration of the investigational new drug to healthy volunteers and 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 must be conducted under the auspices of an Institutional Review Board ("IRB"). The IRB 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 I, when the drug is initially administered to human subjects, the product is tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion. Phase II involves studies in a limited patient population to (i) evaluate preliminarily the efficacy of the product for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage and (iii) 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 II evaluation, Phase III 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 PLA, approval of which must be obtained prior to commencement of commercial sales. The FDA may refuse to accept the NDA or PLA for filing if certain administrative and content criteria are not satisfied, and even after accepting the NDA or PLA for review, the FDA may require additional testing or information before approval of the NDA or PLA. The Company's analysis of the results of its clinical studies is subject to review and interpretation by the FDA, which may differ from the Company's analysis. There can be no assurance that the Company's data or its interpretation of data will be accepted by the FDA. In any event, the FDA must deny an NDA or PLA if applicable regulatory requirements are not ultimately satisfied. In addition, delays or rejections may be encountered 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.

Under current FDA regulations, in addition to the licensing of a vaccine product itself through the PLA process, any establishment used to manufacture a vaccine product must also be licensed. To obtain the necessary establishment license, an establishment license application ("ELA") describing the facilities, equipment, processes, and personnel used to manufacture the product in question must be submitted to the FDA. The establishment license will be granted only after the FDA inspects the establishment and determines that the establishment complies with all applicable standards, including, but not limited to, compliance with cGMP and the ability to consistently manufacture the product at the establishment in accordance with the PLA. FDA approval of both the PLA and ELA must be received prior to marketing of a vaccine product. Therefore, any delay in FDA's approval of the ELA, or refusal to approve the ELA, would delay or prevent the marketing of the product in question.

On May 14, 1996, the FDA adopted a new regulation, effective May 24, 1996, regarding the license application process for certain biological products. Those biological products that fall within the regulation will be reviewed on the basis of a single biologics license application ("BLA"), rather than a PLA/ELA. The BLA includes the same information as the current PLA, but certain of the data now required as part of the ELA do not have to be submitted or reviewed during the approval process. This new rule is intended, at least in part, to lessen the regulatory burden on manufacturers of certain biologics and accelerate the approval process. There can be no assurance, however, that the FDA will consider the new regulation applicable to any of the Company's products, or that the BLA process, if applicable to the Company's products, will have the intended effect of reducing review times.

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 (including after approval) 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 and/or the imposition of criminal penalties against the manufacturer and/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 the Company's products under development.

The FDA has implemented accelerated approval procedures for certain pharmaceutical agents that treat serious or life-threatening diseases and conditions, and that provide meaningful therapeutic benefit over existing treatments. The Company believes that certain of its products in development may qualify for accelerated approval. The Company cannot predict the ultimate impact, however, of the FDA's accelerated approval procedures on the timing or likelihood of approval of any of its potential products or those of any competitor. In addition, the approval of a product under the accelerated approval procedures is subject to various conditions, including the requirement to verify clinical benefit in postmarketing studies, and the authority on the part of the FDA to withdraw approval under streamlined procedures if such studies do not verify clinical benefit or under various other circumstances.

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. The Company does not currently have any facilities or personnel outside of the United States.

In addition to regulations enforced by the FDA, the Company also is 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. The Company's research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although the Company believes that its safety procedures for storing, handling, using and disposing of such materials comply with the standards prescribed by applicable regulations, the risk of accidental contaminations or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could have a material adverse effect of the Company.

### **Manufacturing**

The Company currently manufactures GMK, MGV, PRO 542 and PRO 367 in its 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. The Company believes that its existing production facilities will be sufficient to meet the Company's initial needs for clinical trials. However, these facilities may be insufficient for all of the Company's late-stage clinical trials and for its commercial-scale requirements. Accordingly, the Company expects to be required in the future to expand its manufacturing staff and facilities and obtain new facilities or to contract with third parties or its corporate collaborators to assist with production. Pursuant to the BMS License Agreement, the Company granted to BMS manufacturing rights with respect to GMK and MGV. In the event the Company decides to establish a full-scale commercial manufacturing facility, the Company will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with the extensive cGMP regulations applicable to such a facility. In addition, if any of the Company's products produced at its facilities were regulated as biologics, the Company could be required to submit an ELA and obtain an establishment license for its facilities.

### **Sales and Marketing**

Progenics plans to market products for which it obtains regulatory approval through co-marketing, co-promotion, licensing and distribution arrangements with third party collaborators. The Company believes that this approach will both increase market penetration and commercial acceptance of its products and enable the Company to avoid expending significant funds to develop a large sales and marketing organization. Pursuant to their collaboration, the Company granted to BMS exclusive worldwide marketing rights to GMK and MGV. In addition, the Company has entered into collaborative marketing arrangements with DuPont and Intracel with respect to the sCD4 and gp120 research reagents.

## **Competition**

Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. The Company faces competition from many companies and major universities and research institutions in the United States and abroad. Many of the Company's 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 those of the Company. There can be no assurance that the products under development by the Company and its collaborators will be able to compete successfully with existing products or products under development by other companies, universities and other institutions. With respect to GMK, the FDA and certain other regulatory authorities have approved high-dose alpha interferon for marketing as a treatment of patients with high risk melanoma. High-dose alpha interferon has demonstrated some efficacy for this indication. With respect to the Company's products for the treatment of HIV infection, two classes of products made by competitors of the Company have been approved for marketing by the FDA for the treatment of HIV infection and AIDS: reverse transcriptase inhibitors and protease inhibitors. Both types of drugs are inhibitors of viral enzymes that 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.

A significant amount of research in the biopharmaceutical field is also being carried out at academic and government institutions. The Company's strategy is to in-license technology and product candidates from academic and government institutions. These institutions are becoming increasingly aware of 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 the Company 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 affect the Company's business strategy.

Competition with respect to the Company's technologies and product candidates is and will be based, among other things, on effectiveness, safety, reliability, availability, price and patent position. Another important factor will be the timing of market introduction of the Company's or competitive products. Accordingly, the speed with which Progenics can develop products, complete the clinical trials and approval processes and ultimately supply commercial quantities of the products to the market is expected to be an important competitive factor. The Company's competitive position will also depend upon its 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.

## **Product Liability**

The testing, manufacturing and marketing of the Company's products involves an inherent risk of product liability attributable to unwanted and potentially serious health effects. To the extent the Company elects to test, manufacture or market products independently, it will bear the risk of product liability directly. Pursuant to the BMS License Agreement, BMS is required to indemnify the Company for liabilities and expenses resulting from, among other things, the manufacture, use or sale of Licensed Products (as defined in the BMS License Agreement), subject to certain conditions. The Company has obtained insurance in the amount of \$5,000,000 against the risk of product liability. This insurance is subject to certain deductibles and coverage limitations. There is no guarantee that insurance will continue to be available at a reasonable cost, or at all, or that the amount of such insurance will be adequate.

## Human Resources

At December 31, 1997, the Company had 32 full-time employees, three of whom (including Dr. Maddon) hold Ph.D. degrees or foreign equivalents and two of whom (including Dr. Maddon) hold M.D. degrees. At such date, 25 employees were engaged in research and development, medical and regulatory affairs and manufacturing activities and seven were engaged in finance, administration and business development. The Company considers its relations with its employees to be good. None of its employees is covered by a collective bargaining agreement.

### Executive Officers and Key Management

The directors, executive officers and key management of the Company as of December 31, 1997 were as follows:

Name	Age	Position
Paul J. Maddon, M.D., Ph.D.	38	Chairman of the Board, Chief Executive Officer, President and Chief Science Officer
Robert J. Israel, M.D.	41	Vice President, Medical Affairs
Robert A. McKinney, CPA	41	Vice President, Finance and Operations and Treasurer
William C. Olson, Ph.D.	35	Director, Research and Development
Patricia C. Fazio	39	Senior Director, Project Management and Health & Safety

Paul J. Maddon, M.D., Ph.D. is the founder of the Company and has served in various capacities since its inception, including 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 scientific review committees and is a member of the editorial board of the JOURNAL OF VIROLOGY. 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.

Robert J. Israel, M.D. joined the Company in October 1994 and has been Vice President, Medical Affairs since that time. From 1991 to 1994, Dr. Israel was Director, Clinical Research-Oncology and Immunohematology at Sandoz Pharmaceuticals Corporation, a pharmaceutical company. From 1988 to 1991, he was Associate Director, Oncology Clinical Research at Schering-Plough Corporation, a pharmaceutical company. Dr. Israel is a licensed physician and is board certified in both internal medicine and medical oncology. He received a B.A. in 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 the Company 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 L.L.P., 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.

William C. Olson, Ph.D. joined the Company in May 1994 and presently serves as Director, Research and Development. 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.

Patricia C. Fazio joined the Company in August 1992. Ms. Fazio has served in various management positions at Progenics, most recently as Senior Director, Project Management and Health & Safety. From 1987 to 1992, she was Senior Research Technician and Laboratory Manager at the Howard Hughes Medical Institute at Columbia University. From 1982 to 1987, Ms. Fazio was Chief Laboratory Technologist in the Department of Pathology at Columbia Presbyterian Medical Center. She received a B.S. in biology and chemistry at the College of New Rochelle.

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

### **Cancer Scientific Advisory Board**

#### **Name Position/Affiliation**

Alan N. Houghton, M.D. (Chairman) Chairman, Immunology Program,

	Sloan-Kettering and Professor, Cornell University Medical College ("CUMC")
Angus G. Dalgleish, 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, Memorial Sloan-Kettering Research Institute and Professor of Chemistry, Columbia University
David W. Golde, M.D.	Physician-in-Chief, Sloan- Kettering and Professor, CUMC
David R. Klatzmann, M.D., Ph.D.	Professor of Immunology, Pitie-Salpetriere Hospital, Paris
Philip O. Livingston, M.D.	Associate Member, Sloan- Kettering and Associate Professor, CUMC
John Mendelsohn, M.D.	President, The University of Texas M.D. Anderson Cancer Center

David A. Scheinberg, M.D., Ph.D. Chief, Leukemia Service, Sloan-Kettering and Associate Professor, CUMC

## Virology Scientific Advisory Board

### Name Position/Affiliation

Stephen P. Goff, Ph.D. (Chairman) Professor of Biochemistry,

Columbia University

Mark Alizon, M.D., Ph.D.

Director of Research, Institut  
Cochin, Paris

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

Israel Lowy, M.D., Ph.D.

Assistant Professor of  
Medicine, Mount Sinai Medical  
Center

J. Steven McDougal, M.D.

Chief, Immunology Branch, CDC,  
Atlanta

Luc Montagnier, M.D.

Professor and Chairman of  
Virology, Pasteur Institute,  
Paris

Sherie L. Morrison, Ph.D.

Professor of Microbiology,  
UCLA

Robin A. Weiss, Ph.D.

Professor and Director of  
Research, ICR, Royal Cancer  
Hospital, London

## RISK FACTORS

The Company's business and operations entail a variety of risks and uncertainties, including those described below.

### Early Stage of Product Development; Technological Uncertainties

The Company is at an early stage of development, and the successful commercialization of any products will require significant further research, development, testing and/or regulatory approvals and additional investment. Substantially all of the Company's resources have been, and for the foreseeable future will continue to be, dedicated to the development of products for cancer and viral diseases, most of which are still in the early stages of development and testing. There are a number of technological challenges that the Company must successfully address to complete most of its development efforts. In addition, the product development programs conducted by the Company and its collaborators are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include the possibility that the technologies used by the Company will prove to be ineffective or any or all of the Company's product candidates will prove to be unsafe or otherwise fail to receive necessary regulatory approvals; that the product candidates, if safe and effective, will be difficult to manufacture on a large scale or uneconomical to market; that the proprietary rights of third parties will preclude the Company or its collaborators from marketing the products utilizing the Company's technologies; or that third parties will market equivalent or superior products. To the Company's knowledge, no cancer therapeutic vaccine and no drug designed to treat HIV infection by blocking viral entry has been approved for marketing, and there can be no assurance that any of the Company's products will be successfully developed. The commercial success of the Company's products, if any, when and if approved for marketing by the FDA, will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe.

## **Uncertainty Associated with Preclinical and Clinical Testing**

The grant of regulatory approvals for the commercial sale of any of the Company's potential products will depend in part on the Company and/or its collaborators successfully conducting extensive preclinical and clinical testing to demonstrate their safety and efficacy in humans. The results of preclinical studies by the Company and/or its collaborators may be inconclusive and may not be indicative of results that will be obtained in human clinical trials. There can be no assurance that any of the Company's products in the research or preclinical development stage will yield results that would permit or justify clinical testing. Further, there can be no assurance that any of the Company's potential products that undergo clinical trials will have the desired effect or will not have undesirable side effects or other characteristics that may prevent them from being approved or limit their commercial use if approved. In addition, results attained in early human clinical trials relating to the products under development by the Company may not be indicative of results that will be obtained in later clinical trials. As results of particular preclinical studies and clinical trials are received, the Company and/or its collaborators may abandon projects which they might otherwise have believed to be promising, some of which may be described herein. In addition, the Company, its collaborators or the FDA or other regulatory agencies may suspend or terminate clinical trials at any time if the subjects or patients participating in such trials are being exposed to unacceptable health risks. Clinical testing is very expensive and can involve many years. The failure to adequately demonstrate the safety and efficacy of a therapeutic product under development by the Company and/or its collaborators could delay or prevent regulatory approval of the product and would have a material adverse effect on the Company.

The rate of completion of the human clinical trials involving the Company's product candidates, if permitted, will be dependent upon, among other factors, the rate of patient enrollment. Delays in planned patient enrollment might result in increased costs and delays, which could have a material adverse effect on the Company. The Company's most advanced product candidates are intended for treating patients with relatively early stage cancer and are designed to delay or prevent 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.

The Company has limited experience in conducting clinical trials. In certain circumstances the Company and its corporate collaborators rely, in part, on academic institutions and on clinical research organizations to conduct and monitor certain clinical trials. There can be no assurance that such entities will conduct the clinical trials successfully. In addition, certain clinical trials for the Company's products will be conducted by government-sponsored agencies. Because the conduct of such trials will be dependent on government participation and funding, the Company will have less control over such trials than if the Company were the sole sponsor thereof. As a result, there can be no assurance that these trials will commence or be completed as planned. Failure to commence or complete any of its planned clinical trials could have a material adverse effect on the Company's business, financial condition or results of operations.

## Risks Relating to Corporate Collaborations

Progenics' business strategy includes entering into collaborations or marketing and distribution arrangements with corporate partners, primarily pharmaceutical companies, for the development (including clinical development), commercialization, marketing and distribution of certain of its product candidates. The Company has entered into a significant corporate collaboration with BMS covering the Company's most advanced product candidates to date. Pursuant to its agreements with BMS, Progenics has granted to BMS the exclusive worldwide license to manufacture, use and sell GMK and MGV and any other products to which Progenics has rights that include the GM2 or GD2 ganglioside antigens for the treatment or prevention of human cancer. The Company has also entered into a corporate collaboration with Roche pursuant to which the Company has granted to Roche an exclusive worldwide license to the Company's HIV co-receptor technology in a defined field. As a result of the governing agreements, the Company is dependent on BMS and Roche to fund testing, to make certain regulatory filings and to manufacture and market existing and any future products resulting from the collaborations. There can be no assurance that the arrangements with BMS, Roche or any other collaborator will be scientifically, clinically or commercially successful. In the event that any such arrangement is terminated, such action could adversely affect the Company's ability to develop, commercialize, market and distribute certain of its product candidates. The Company's product candidates will only generate milestone payments and royalties after significant preclinical and/or clinical development, the procurement of requisite regulatory approvals, the establishment of manufacturing capabilities and/or the successful marketing of the product.

The amount and timing of resources dedicated by BMS, Roche or any other collaborator to their respective collaborations with the Company is not within the Company's control. If any such collaborator breaches or terminates its agreements with the Company, or fails to conduct its collaborative activities in a timely manner, the commercialization of product candidates may be adversely affected. There can be no assurance that the Company's 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, including the Company's competitors, as a means for developing treatments for the diseases targeted by these collaborative programs. For example, both BMS and Roche manufacture and sell products that may compete against the products that may result from their respective collaborations. The Company's business also will be affected by the effectiveness of its corporate partners in marketing any successfully developed products. A reduction in sales efforts or a discontinuance of sales of any developed products by any collaborative partner could result in reduced revenues and have a material adverse effect on the Company's business, financial position and results of operations.

There can be no assurance that the Company's existing strategic alliances will continue or be successful or that the Company will receive any further research funding or milestone or royalty payments. If the Company's partners do not develop products under these collaborations, there can be no assurance that the Company would be able to do so. Disputes may arise between the Company and its collaborators as to a variety of matters, including 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 certain product candidates. There can be no assurance that the Company will be able to negotiate any additional collaborative or marketing and distribution arrangements, that such arrangements will be available to the Company on acceptable terms or that any such relationships, if established, will be scientifically or commercially successful. Furthermore, any additional collaborations would likely be subject to some or all of the risks described above with respect to the Company's current collaborations.

### History of Operating Losses and Accumulated Deficit; No Product Revenue and Uncertainty of Future Profitability

The Company has incurred substantial losses in each year since its inception. As of December 31, 1997, the Company had an accumulated deficit of approximately \$18.7 million. Such losses have resulted principally from costs incurred in the Company's research and development programs and general and administrative costs associated with the Company's development. The Company has derived no revenues from product sales (other than for research purposes) or royalties and no product sales (other than sales of research reagents) or royalties are likely for a number of years, if ever. The Company expects to incur additional operating losses in the future which are expected to increase significantly as the Company expands development and clinical trial efforts. The Company's ability to achieve long-term profitability is dependent in part on obtaining regulatory approvals for products and entering into agreements for commercialization of such products. There can be no assurance that such regulatory approvals will be obtained or such agreements will be entered into. The failure to obtain any such necessary regulatory approvals or to enter into any such necessary agreements could delay or prevent the Company from achieving profitability and would have a material adverse effect on the business, financial position and results of operations of the Company. Further, there can be no assurance that the Company's operations will become profitable even if any product under development by the Company or any collaborators is commercialized.

## **Need for Additional Financing and Uncertain Access to Capital Funding**

Progenics' current development projects require substantial capital. The Company does not have committed external sources of funding for certain of its drug discovery and development projects. The Company may require substantial additional funds to conduct development activities, preclinical studies, clinical trials and other activities relating to the successful commercialization of any potential products. There can be no assurance, however, that the Company will be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate one or more of its programs; obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize itself; or license the rights to such technologies, product candidates or products on terms that are less favorable to the Company than might otherwise be available. If the Company raises additional funds by issuing equity securities, further dilution to stockholders may result and new investors could have rights superior to existing stockholders.

## **Limited Manufacturing Capabilities**

In order to successfully commercialize its product candidates, Progenics and/or its collaborators must be able to manufacture its products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of the types of biopharmaceutical products being developed by the Company presents several risks and difficulties. The manufacture of some or all of the Company's 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. Although Progenics has constructed two pilot-scale manufacturing facilities, one for the production of vaccines and one for the production of recombinant proteins, which it believes will be sufficient to meet the Company's initial needs for clinical trials, these facilities may be insufficient for all of its late-stage clinical trials and for its commercial-scale manufacturing requirements, if any. Furthermore, there can be no assurance that the Company's collaboration with GTC will result in a cost-effective means for the production of PRO 542. Accordingly, the Company may be required to expand its manufacturing staff and facilities and obtain new facilities or to contract with corporate collaborators or other third parties to assist with production. Manufacture of some of Progenics' initial products for commercialization may require third party contract manufacturers at a significant cost to the Company. In employing third party manufacturers, Progenics will not control all aspects of the manufacturing process. There can be no assurance that the Company will be able to obtain from third party manufacturers adequate supplies in a timely fashion for commercialization, or that commercial quantities of any such products, if approved for marketing, will be available from contract manufacturers at acceptable costs. In the event the Company decides to establish a full-scale commercial manufacturing facility, the Company will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with the extensive regulations applicable to such a facility. There is no assurance that Progenics will be able to develop a current Good Manufacturing Practices ("cGMP") manufacturing facility sufficient for all clinical trials or commercial-scale manufacturing. The cost of manufacturing certain products may make them prohibitively expensive.

## **Availability of Materials**

There can be no assurance that sufficient quantities of raw materials will be available to support continued research, development or commercial manufacture of any of the Company's planned products. The Company currently obtains supplies of critical materials used in production of GMK and MGV from single sources. Specifically, commercialization of the Company's GMK and MGV cancer vaccine candidates requires a certain adjuvant from Aquila. The Company has entered into a license and supply agreement with Aquila pursuant to which Aquila agreed to supply the Company with all of its requirements for the QS-21 adjuvant for use in certain ganglioside-based cancer vaccines, including GMK and MGV. In connection with the Company's collaboration with BMS, Progenics granted to BMS a non-exclusive sublicense under the Company's license and supply agreement with Aquila, and BMS entered into a supply agreement with Aquila. There can be no assurance that Aquila will be able to supply sufficient quantities of QS-21 to the Company or BMS or that the Company or BMS will have the right or capability to manufacture sufficient quantities of QS-21 to meet its needs if Aquila is unable or unwilling to do so. In addition, the Company currently relies on one source of pharmaceutical grade KLH, which is one of the components of the Company's cancer vaccines. There can be no assurance that the Company will not be subject to delays or disruption in the supply of this component. Any delay or disruption in the availability of raw materials could have a material adverse effect on the Company's business, financial condition or results of operations.

## **Government Regulation; No Assurance of Regulatory Approval**

The Company and its products are subject to comprehensive regulation by the FDA 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 the Company's products. Among other requirements, FDA approval of the Company's 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 FDA approvals can be costly, time consuming, and subject to unanticipated delays and the Company has had only limited experience in filing and pursuing applications necessary to gain regulatory approvals. The Company is also subject to numerous and varying foreign regulatory requirements governing the design and conduct of clinical trials and the manufacturing and marketing of its products. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval set forth above, and there can be no assurance that foreign regulatory approvals will be obtained on a timely basis, if at all. There can be no assurance that the Company or its partners will file for regulatory approvals or receive necessary approvals to commercialize product candidates in any market. Delays in receipt of or failure to receive regulatory approvals, or the loss of previously received approvals, would have a material adverse effect on the Company's business, financial condition and results of operations.

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 post-approval marketing activities may result in various adverse consequences.

## **Dependence On Third Parties**

The Company relies heavily on third parties (in addition to its reliance on corporate collaborators) for a variety of functions, including certain functions relating to research and development, manufacturing, clinical trials management and regulatory affairs. As of December 31, 1997, the Company had only 32 full-time employees. The Company is party to several collaborative agreements which place substantial responsibility on third parties for clinical development of the Company's products. The Company also in-licenses technology from medical and academic institutions in order to minimize investments in early research and enters into collaborative arrangements with certain of these entities with respect to clinical trials of product candidates.

Except for payments made to the Company under its collaboration with BMS, most of the Company's revenues to date have been derived from federal research grants. 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 determine to scale back these programs or terminate them or that the government will award future grants to competitors of the Company instead of the Company. In addition, there can be no assurances that the Company will be awarded any such grants in the future or that any amounts derived therefrom will not be less than those received to date. Certain of the Company's clinical trials are expected to be partially paid for by government funds. Any future reduction in the funding the Company receives either from federal research grants or with respect to clinical trials could adversely affect the Company's business, financial condition and results of operations.

There can be no assurance that Progenics will be able to establish and maintain any of the relationships described above on terms acceptable to the Company, that the Company can enter into these arrangements without undue delays or expenditures, or that these arrangements will allow the Company to compete successfully against other companies.

### **Lack of Sales and Marketing Experience**

If FDA and other approvals are obtained with respect to any of its products, Progenics expects to market and sell its products through distribution, co-marketing, co-promotion or licensing arrangements with third parties. The Company's agreement with BMS and Roche grant these collaborators the exclusive right to market any products resulting from their respective collaborations. Progenics has no experience in sales, marketing or distribution. To the extent that the Company enters into distribution, co-marketing, co-promotion or licensing arrangements for the marketing and sale of its products, any revenues received by the Company will be dependent on the efforts of third parties. The Company would not control the amount and timing of marketing resources such third parties would devote to the Company's products. If any of such parties were to breach or terminate its agreement with the Company or otherwise fail to conduct marketing activities successfully and in a timely manner, the commercialization of product candidates would be delayed or terminated, which could have a material adverse effect on the Company's business, financial condition and results of operations. In addition, if the Company markets products directly, significant additional expenditures and management resources would be required to develop an internal sales force. There can be no assurance that the Company will be able to establish a successful sales force, should it choose to do so.

### **Dependence on and Uncertainty of Protection of Patents and Proprietary Rights**

The Company's success is dependent in part on obtaining, maintaining and enforcing patent and other proprietary rights. The Company is required to make substantial cash payments and achieve certain milestones and requirements, including, without limitation, filing INDs, obtaining product approvals and introducing products, to maintain its rights under license granted to the Company, including its licenses from Sloan-Kettering and Columbia University. There is no assurance that the Company will be able to make required cash payments when due or achieve the milestones and requirements in order to maintain its rights under these licenses. Termination of any of such licenses could result in the Company being unable to continue development of its product candidates and production and marketing of approved products, if any, and consequently could have a material adverse effect on the business, financial condition and results of operations of the Company.

There can be no assurance that patent applications owned by or licensed to the Company will result in patents being issued or that, if issued, the patents will afford protection against competitors with similar technology. Although a patent has a statutory presumption of validity in the United States, the issuance of a patent is not conclusive as to such validity or as to the enforceable scope of the claims of the patent. There can be no assurance that the Company's issued patents or any patents subsequently issued to or licensed by the Company will not be successfully challenged in the future. The validity or enforceability of a patent after its issuance by the patent office can be challenged in litigation. The cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of the litigation is adverse to the owner of the patent, third parties may then be able to use the invention covered by the patent without payment. There can be no assurance that the Company's patents will not be infringed or successfully avoided through design innovation.

The Company may not retain all rights to developments, inventions, patents and other proprietary information resulting from its collaborative arrangements, whether in effect as of the date hereof or which may be entered into at some future time with third parties. As a result, the Company may be required to license such developments, inventions, patents or other proprietary information from such third parties, possibly at significant cost to the Company. The Company's failure to obtain any such licenses could have a material adverse effect on the business, financial condition and results of operations of the Company. ADARC is a co-owner with the Company of one of the patent applications relating to the HIV co-receptor CCR5 and upon which the Company's HIV co-receptor/fusion program is based. Unless the Company acquires from ADARC an exclusive license to ADARC's rights in this patent application, there can be no assurance that ADARC will not license such patent to a competitor of the Company.

There may be patent applications and issued patents belonging to competitors that may require the Company to alter its products, pay licensing fees or cease certain activities. If the Company's products conflict with patents that have been or may be granted to competitors, universities or others, such other persons could bring legal actions against the Company claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If any such actions are successful, in addition to any potential liability for damages, the Company could be required to obtain a license in order to continue to manufacture or market the affected products. There can be no assurance that the Company 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. There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. Any litigation involving the Company could require substantial resources and have a material adverse effect on the Company's business, financial position and results of operations.

Progenics has also filed a number of U.S. and foreign patent applications (one of which is owned jointly with ADARC) relating to the discovery of the HIV co-receptor CCR5. In addition to the risks described above, the Company is aware that other groups have claimed discoveries similar to that covered by the Company's patent applications. These groups may have made their discoveries prior to the discoveries covered by the Company's patent applications and may have filed their applications prior to the Company's patent applications. The Company does not expect to know for several years the relative strength of its patent position as compared to these other groups.

In addition to the patents, patent applications, licenses and intellectual property processes described above, the Company also relies on unpatented technology, trade secrets and information. No assurance can be given that others will not independently develop substantially equivalent information and techniques or otherwise gain access to the Company's technology or disclose such technology, or that the Company can meaningfully protect its rights in such unpatented technology, trade secrets and information. The Company requires each of its employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with the Company. The agreements generally provide that all inventions conceived by the individual in the course of employment or in providing services to the Company and all confidential information developed by, or made known to, the individual during the term of the relationship shall be the exclusive property of the Company and shall be kept confidential and not disclosed to third parties except in limited specified circumstances. There can be no assurance however, that these agreements will provide meaningful protection for the Company's information in the event of unauthorized use or disclosure of such confidential information.

#### **Dependence Upon Key Personnel; Attraction and Retention of Personnel**

Progenics is dependent upon certain key management and scientific personnel. In particular, the loss of Dr. Maddon could have a materially adverse effect on Progenics, unless a qualified replacement could be found. Progenics maintains a key man life insurance policy on Dr. Maddon in the amount of \$2.5 million. The Company's employment agreement with Dr. Maddon expires in December 1998, and there can be no assurance that it will be renewed by the parties thereto.

Competition for qualified employees among companies in the biopharmaceutical industry is intense. Progenics' future success depends upon its ability to attract, retain and motivate highly skilled employees. In order to successfully commercialize its products, the Company may be required to substantially expand its personnel, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and marketing. There can be no assurance that the Company will be successful in hiring or retaining qualified personnel.

### **Uncertainty Related to Health Care Reform Measures and Reimbursement**

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 certain medical procedures and treatments or subject the pricing of pharmaceuticals to government control. Significant changes in the health care system in the United States or elsewhere might have a substantial impact on the manner in which the Company conducts its business. Such changes also could have a material adverse effect on the Company's ability to raise capital. Furthermore, the Company's ability to commercialize products may be adversely affected to the extent that such proposals have a material adverse effect on the business, financial condition and profitability of other companies that are collaborators or prospective collaborators of the Company.

The Company's and its collaborators' success in generating revenue from sales of products may depend, in part, on the extent to which reimbursement for the costs of such products will be available from third-party payors, such as government health administration authorities, private health insurers and health maintenance organizations ("HMOs"). Significant uncertainty exists as to the reimbursement status of newly-approved health care products. In addition, the trend towards managed health care in the United States, as well as legislative proposals to reduce government insurance programs, may result in lower prices for products and affect the market for products. If the Company or one or more of its collaborators succeeds in bringing one or more of Progenics' products to market, there can be no assurance that adequate third-party payors will establish and maintain price levels sufficient for realization of an appropriate return on the Company's investment in product development. Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new products approved for marketing by the FDA. If adequate coverage and reimbursement levels are not provided by government and third-party payors for uses of the Company's products, the market acceptance of such products would be adversely affected.

### **Risk of Product Liability; Limited Availability of Insurance**

The Company's business exposes it to potential product liability risks which are inherent in the testing, manufacturing, marketing and sale of human vaccine and therapeutic products, and there can be no assurance that the Company will be able to avoid significant product liability exposure. Product liability insurance for the biopharmaceutical industry is generally expensive, if available at all. The Company has obtained product liability insurance coverage in the amount of \$5 million per occurrence, subject to a \$5 million aggregate limitation. However, there can be no assurance that the Company's present insurance coverage is now or will continue to be adequate as the Company further develops products. In addition, certain of the Company's license and collaborative agreements require the Company to obtain product liability insurance, and it is possible that license and collaborative agreements which the Company may enter into in the future may also include such a requirement. There can be no assurance that in the future adequate insurance coverage will be available in sufficient amounts or at a reasonable cost, or that a product liability claim or recall would not have a material adverse effect on the Company.

## **Hazardous Materials; Environmental Matters**

The Company's research and development work and manufacturing processes involve the use of hazardous, controlled and radioactive materials. The Company is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although the Company maintains safety procedures for handling and disposing of such materials that it believes comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result, and any such liability could exceed the resources of the Company. Although the Company believes that it is in compliance in all material respects with applicable environmental laws and regulations, there can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that the operations, business or assets of the Company will not be materially or adversely affected by current or future environmental laws or regulations.

## **Control by Existing Stockholders; Anti-Takeover Provisions**

Certain stockholders of the Company, including Dr. Maddon and stockholders affiliated with Tudor Investment Corporation and Weiss, Peck & Greer, beneficially own or control a substantial portion of the outstanding shares of the Company's Common Stock (the "Common Stock") and therefore may have the ability, acting together, to elect all of the Company's directors, to determine the outcome of most corporate actions requiring stockholder approval and otherwise control the business of the Company. Such control could have the effect of delaying or preventing a change in control of the Company and consequently adversely affect the market price of the Common Stock. In addition, the Company's Board of Directors is authorized to issue from time to time shares of Preferred Stock, without further stockholder authorization, in one or more designated series or classes. The issuance of Preferred Stock, as well as certain provisions in certain of the Company's stock options which provide for acceleration of exercisability upon a change of control of the Company and certain provisions of the Delaware General Corporation Law (Section 203, in particular), could make the takeover of the Company or the removal of the Company's management more difficult, discourage hostile bids for control of the Company in which stockholders may receive a premium for their shares of Common Stock or otherwise dilute the rights of holders of Common Stock and depress the market price of the Common Stock.

## **Future Sales of Common Stock; Registration Rights; Possible Adverse Effect on Future Market Price**

A substantial number of outstanding shares of Common Stock and shares of Common Stock issuable upon exercise of outstanding options and warrants will become eligible for future sale in the public market at prescribed times. Sales of substantial numbers of shares of Common Stock in the public market could adversely affect prevailing market prices. Commencing November 19, 1998, certain stockholders of the Company are entitled to certain rights with respect to the registration of such shares of Common Stock for offer or sale to the public. The Company plans to file a Form S-8 registration statement registering shares issuable pursuant to the Company's stock option plans. Any sales by existing shareholders or holders of options or warrants may have an adverse effect on the Company's ability to raise needed capital and may adversely affect the market price of the Common Stock.

## **Item 2. Properties**

Progenics leases approximately 24,000 square feet of laboratory, manufacturing and office space in Tarrytown, New York. The Company leases this space under an operating lease which terminates in December 2000. Progenics has two pilot production facilities within its leased facilities for the manufacture of products for clinical trials. The Company believes that its current facilities are adequate for its current needs.

**Item 3. Legal Proceedings**

The Company is not a party to any material legal proceedings.

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

In October 1997 the Company sought and received from its stockholders approval of an amendment to the Company's 1996 Stock Incentive Plan (the "Plan") increasing the number of shares of Common Stock issuable pursuant to the Plan from 750,000 shares to 1,050,000 shares. Approval was obtained by written consent. Stockholders holding 1,516,223 shares (62%) of the Common Stock, 1,380,689 shares (80%) of the Company's Series A Preferred Stock, 1,188,753 shares (80%) of the Company's Series B Preferred Stock and 737,250 shares (71%) of the Company's Series C Preferred Stock consented to the amendment.

## PART II

### Item 5. Market for the Company's Common Equity and Related Stockholder Matters

#### Price Range of Common Stock

The Company's Common Stock is quoted on the Nasdaq National Market under the symbol "PGNX." Shares of the Company's Common Stock were first offered to the public on November 19, 1997 at a price to the public of \$8.00 per share. The following table sets forth, for the periods indicated, the high and low sales price per share of the Common Stock, as reported on the Nasdaq National Market, since November 19, 1997. Such prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

1997:	High	Low
Fourth quarter (from November 19)	\$15 5/16	\$8
1998:		
First quarter (through March 24)	\$22 5/8	\$13

On March 24, 1998, the last sale price for the Common Stock as reported by Nasdaq was \$20.50. There were approximately 211 holders of record of the Company's Common Stock as of March 24, 1998.

#### Dividends

The Company has not paid any cash dividends since its inception and presently anticipates that all earnings, if any, will be retained for development of the Company's business and that no cash dividends on its Common Stock will be declared in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors.

#### Recent Sales of Unregistered Securities

During the year ended December 31, 1997, the Company issued securities to a limited number of persons, as described below, in transactions not registered under the Securities Act of 1933, as amended (the "Securities Act"). Each of these transactions was effected prior to the Company's initial public offering in November 1997. No underwriter or underwriting discounts or commissions were involved. There was no public offering in any such transaction, and the Company believes that each transaction was exempt from the registration requirements of the Securities Act by reason of Section 4(2) thereof based on the private nature of the transactions and the sophistication of the purchasers, all of whom had access to information concerning the Company and acquired the securities for investment and not with a view to the distribution thereof.

In July 1997, the Company issued 120,000 shares of Common Stock to one entity as consideration in part for such entity consenting to certain agreements entered into by the Company with another entity.

In March, June and July of 1997, the Company issued to two entities warrants to purchase in the aggregate 70,000 shares of Common Stock. The exercise price for the warrants was dependent on the occurrence of various corporate transactions within specified time parameters. As a result of the completion of the Company's initial public offering in November 1997, the exercise price for the warrants has been fixed at \$4.00 per share. The warrants were issued in consideration for the provision by the warrant holders of a guarantee of the Company's obligations under a loan extended by a commercial lender.

In January 1997, one person exercised options granted to such person in April 1989 to purchase 27,000 shares of Common Stock at an exercise price of \$1.33 per share.

## Use of Proceeds from Registered Securities

On November 19, 1997, the Securities and Exchange Commission (the "Commission") declared effective the Company's Registration Statement (No. 333- 13627) on Form S-1, as then amended, relating to the Company's initial public offering of 2,300,000 shares of Common Stock, par value \$.0013 per share, (300,000 shares of which were issued upon exercise of an over-allotment option granted by the Company to the underwriters). The managing underwriters for the offering were CIBC Oppenheimer Corp., BancAmerica Robertson Stephens and Vector Securities International, Inc. (the "Underwriters".) In connection with the initial public offering, the Company registered the Common Stock under the Securities Exchange Act of 1934, as amended.

The public offering terminated upon the sale on the effective date of the Registration Statement of all of the 2,300,000 shares of Common Stock registered for sale. The aggregate offering price of securities sold was \$18,400,000. All 2,300,000 shares of Common Stock sold were sold for the account of the Company.

From the effective date of the Registration Statement through December 31, 1997, the Company incurred the following expenses in connection with the issuance and distribution of the Common Stock registered:

Underwriting discounts and commissions \$1,288,000

The net offering proceeds to the Company after deducting the foregoing expenses and before deducting the expenses discussed below were \$17,112,000.

The foregoing excludes other expenses (legal and accounting fees, printing and engraving expenses and miscellaneous) of approximately \$1,097,000 incurred prior to November 19, 1997 and subsequent to December 31, 1997 in connection with the offering and sale of the Common Stock registered. Other than the amounts set forth for underwriting discounts and commissions, the foregoing represent a reasonable estimate of expenses.

The Company did not make, in connection with the offering and sale of the Common Stock registered, any direct or indirect payments to: directors, officers or general partners of the Company or, to the Company's knowledge, their associates; persons owning 10% or more of any class of equity securities of the Company; or affiliates of the issuer.

From November 19, 1997 until December 31, 1997, and through the date of this report, that portion of the net proceeds that has not been used to pay expenses of the offering has been applied to temporary investments as follows:

At March 24, 1998, \$8,860,000 of the net proceeds were invested in corporate debt securities, and the balance was invested in money market funds pending the purchase of corporate debt securities.

**Item 6.**

**Selected Financial Data**

The selected financial data presented below as of December 31, 1996 and 1997 and for each of the years in the three year period ended December 31, 1997 are derived from the Company's audited financial statements, included elsewhere herein. The selected financial data presented below with respect to the balance sheet data as of December 31, 1993, 1994 and 1995 and for each of the years in the two-year period ended December 31, 1994 are derived from the Company's audited financial statements not included herein. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements and related Notes included elsewhere herein.

	YEARS ENDED DECEMBER 31,				
	1993	1994	1995	1996	1997
	(In thousands, except per share data)				
<b>STATEMENT OF OPERATIONS DATA:</b>					
<b>Revenues:</b>					
Contract research and development	\$	\$	\$ 200	\$ 318	\$ 14,591
Research grants	84	504	525	203	665
Product sales	50	52	50	98	57
Interest income	53	108	46	106	301
Total revenues	187	664	821	725	15,614
<b>EXPENSES:</b>					
Research and development	1,547	2,859	3,852	3,700	7,364
General and administrative	748	878	1,094	2,808	2,222
Interest expense	38	50	87	51	312
Depreciation and amortization	249	289	291	309	319
Total expenses	2,582	4,076	5,324	6,868	10,217
Operating (loss) income	(2,395)	(3,412)	(4,503)	(6,143)	5,397
Income taxes					258
Net (loss) income	\$ (2,395)	\$ (3,412)	\$ (4,503)	\$ (6,143)	\$ 5,139
<b>Per share amounts on net (loss) income (1):</b>					
Basic	\$ (1.06)	\$ (1.52)	\$ (1.99)	\$ (2.68)	\$ 1.64
Diluted	\$ (1.06)	\$ (1.52)	\$ (1.99)	\$ (2.68)	\$ 0.66
(1) For all periods presented above, the Company adopted the provisions of Financial Accounting Standard No. 128 "Earnings per Share". (See notes to the Financial Statements)					

	DECEMBER 31				
	1993	1994	1995	1996	1997
<b>BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable Securities	\$ 2,137	\$ 2,275	\$ 559	\$ 647	\$ 23,624
Working capital	1,882	2,019	19	(1,109)	20,562
Total assets	2,858	3,489	1,736	1,663	24,543
Capital lease obligations and deferred Lease liability, long-term portion	75	235	213	156	141
Total stockholders' equity (deficit)	2,523	2,827	852	(385)	23,034

## **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 for the treatment and prevention of cancer and viral diseases. The Company commenced principal operations in late 1988 and since that time has been engaged primarily in organizational efforts, including recruitment of scientific and management personnel, research and development efforts, development of its manufacturing capabilities, establishment of corporate collaborations and raising capital. In order to commercialize the principal products that the Company has under development, the Company 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 the Company receives revenues from sales of any of its products. To date, product sales have consisted solely of limited revenues from the sale of research reagents. The Company expects that sales of research reagents in the future will not significantly increase over current levels. The Company's other sources of revenues through December 31, 1997 have been payments received under its collaboration agreements, research grants related to the Company's HIV programs and interest income.

To date, a majority of the Company's expenditures have been for research and development activities. The Company expects that its research and development expenses will increase significantly as its programs progress and the Company makes filings for related regulatory approvals. The Company has recurring losses and had an accumulated deficit of \$18,661,000 at December 31, 1997. The Company has financed its operations primarily through the private sale and issuance of equity securities, a line of credit that has since been repaid and terminated, payments received under its collaboration with BMS beginning in July 1997 and the proceeds of the Company's initial public offering in November 1997. The Company may require additional funds to complete the development of its products, to fund the cost of clinical trials, and to fund operating losses which are expected to continue for the foreseeable future. The Company does not expect its products under development to be commercialized in the near future.

In July 1997, Progenics entered into a Joint Development and Master License Agreement (the BMS Agreements). These agreements provide for BMS to fund further development, clinical trials and regulatory filings related to GMK and MGV. Consequently, Progenics does not expect to make significant additional expenditures relating to these product candidates for so long as these agreements remain in force. In connection with the establishment of this collaboration, BMS paid to the Company in July 1997 an aggregate of approximately \$13.3 million, representing reimbursement for expenses previously incurred by Progenics in the development of GMK and MGV, licensing fees and reimbursement of clinical development costs for the period April 15, 1997 to September 30, 1997. In connection with payments made by BMS to the Company under the BMS License Agreement, the Company made certain payments to licensors and incurred other related expenses. See "Business-- General Overview-- BMS Collaboration."

### **Results of Operations**

#### **Years Ended December 31, 1996 and 1997**

Contract research and development revenue increased from \$318,000 in 1996 to \$14,591,000 in 1997 as the Company received a licensing fee and reimbursement of clinical development costs in connection with the BMS License Agreement executed in July 1997. Revenues from research grants increased from \$203,000 in 1996 to \$665,000 in 1997. The increase resulted from the funding of a greater number of grants in 1997. Sales of research reagents decreased from \$98,000 in 1996 to \$57,000 in 1997 resulting from decreased orders for such reagents during 1997. Interest income increased from \$106,000 in 1996 to \$301,000 in 1997 due to the increase in cash available for investing as the Company received funding from the BMS License Agreement in July 1997 and its initial public offering in November 1997.

Research and development expenses increased from \$3,700,000 in 1996 to \$7,364,000 in 1997. The increase was principally due to payments to licensors in connection with the BMS License Agreement, additional costs of manufacturing GMK in 1997 for the Company's Phase III clinical trials and compensation expense related to the issuance of stock options to employees and consultants.

General and administrative expenses decreased from \$2,808,000 in 1996 to \$2,222,000 in 1997. The decrease was principally due the reduction of professional fees and printing costs which were associated with the Company's unsuccessful efforts to sell Common Stock in a registered public offering in 1996. Interest expense increased from \$51,000 in 1996 to \$312,000 in 1997 as a result of borrowings commencing in March 1997 under a line of credit. Depreciation and amortization remained relatively unchanged from \$309,000 in 1996 to \$319,000 in 1997.

In 1997, the Company recognized a provision for income taxes of \$258,000 which was based upon prevailing federal and state tax rates reduced by the utilization of net operating loss carryforwards to the extent permitted by the alternative minimum tax rules.

The Company's net loss in 1996 was \$6,143,000 compared to net income of \$5,139,000 in 1997.

### **Years Ended December 31, 1995 and 1996**

Contract research and development revenue increased from \$200,000 in 1995 to \$318,000 in 1996. Such increase resulted from a full year of operations under the Department of Defense contract which commenced in June 1995. Revenues from research grants decreased from \$525,000 in 1995 to \$203,000 in 1996. The decrease for 1996 resulted from a fewer number of grants in that year. Sales of research reagents increased from \$50,000 in 1995 to \$98,000 in 1996 as orders increased due to the addition of Intracel Corporation ("Intracel") as a second seller of such reagents. Interest income increased from \$46,000 in 1995 to \$106,000 in 1996 due to the investment of the proceeds from the private placement of the Company's Series C Preferred Stock which occurred in late 1995 and early 1996.

Although the Company shifted certain resources from its HIV programs into its cancer programs, research and development expenses remained relatively constant in 1995 and 1996.

General and administrative expenses increased from \$1,094,000 in 1995 to \$2,808,000 in 1996. The increase in 1996 was principally due to additional professional services and printing costs associated with the Company's unsuccessful efforts to sell Common Stock in a registered public offering. Interest expense decreased from \$87,000 in 1995 to \$51,000 in 1996 resulting from repayment of a line of credit. Depreciation and amortization remained relatively unchanged from \$291,000 in 1995 to \$309,000 in 1996. The Company's net loss in 1995 was \$4,503,000 compared to a net loss in 1996 of \$6,143,000.

### **Liquidity and Capital Resources**

The Company had funded its operations since inception primarily through private placements of equity securities, which provided aggregate cash proceeds of \$22,817,000 (including loans that were subsequently converted into equity securities) and payments received under its collaboration with BMS. In November 1997, the Company received net cash proceeds of approximately \$16,015,000 in connection with its public offering. Through December 31, 1997, the Company had also received cash proceeds of \$2,135,000 from research grants, \$948,000 from interest on investments and \$445,000 from the sale of research reagents. Through December 31, 1997, the Company had financed \$1,331,000 of equipment purchases through capitalized leases and a promissory note.

During the fourth quarter of 1995 and the first quarter of 1996, the Company raised \$897,000 and \$4,777,000 in net proceeds from the sale of approximately 44,900 units and 241,203 units, respectively, in a private placement of shares of the Company's Series C Preferred Stock in a unit offering. Each \$20.00 unit ("Series C Unit") consisted of four shares of Series C Preferred Stock and one warrant entitling the holder to purchase one share of Series C Preferred Stock for \$5.00 any time within five years of the date of issuance ("Series C Warrant"). In November 1997, all outstanding shares of preferred stock of the Company were converted into shares of Common Stock in connection with the Company's initial public offering. In addition, during December 1995, a note payable in the aggregate principal amount of \$1,200,000, plus accrued and unpaid interest of \$24,000 was converted into approximately 61,200 Series C Units. At December 31, 1997, there were 347,249 Series C Warrants outstanding which if exercised in full would result in \$1,736,000 of net proceeds to the Company and the issuance of 260,455 shares of Common Stock.

In March 1997, the Company entered into a credit agreement with Chase Capital Bank (the "Chase Loan Agreement"), which provided for borrowings of up to \$2,000,000. The Company borrowed the full amount available under this facility in drawings made between March and June 1997. Borrowings made by the Company had a stated interest rate of prime and were used to fund working capital. The Company repaid all outstanding borrowings in July 1997 from proceeds of payments received by the Company under the BMS License Agreement. Upon such repayment, the line of credit terminated. The Company's obligations under the Chase Loan Agreement were guaranteed by two affiliates of the Company, and in consideration of such guarantee these affiliates were issued between March and July 1997 warrants to purchase an aggregate of 70,000 shares of Common Stock at an exercise price of \$4.00 per share as a result of the completion of the Company's initial public offering.

In November 1997, the Company sold 2,300,000 shares of Common Stock in its initial public offering. After deducting underwriting discounts and commissions and other expenses, the Company received net proceeds of \$16,015,000. The net proceeds were invested in short-term, interest bearing investment grade securities pending further application by the Company.

At December 31, 1997, the Company had cash, cash equivalents and marketable securities totaling \$23,624,000 compared with \$647,000 at December 31, 1996. The Company's facility lease was extended from May 1998 to December 1999 at a monthly rental of \$54,000 and can be extended at the option of the Company for three additional one-year terms; however, the second and third options are subject to approval by the landlord. The Company expects to incur during 1998 costs of approximately \$500,000 for leasehold improvements and equipment to enhance its manufacturing capabilities.

The Company believes that its present capital resources should be sufficient to fund operations at least through the end of 1999, based on the Company's current operating plan. No assurance can be given that there will be no change that would consume the Company's liquid assets before such time. The Company will require substantial funds to conduct development activities, preclinical studies, clinical trials and other activities relating to the commercialization of any potential products. In addition, the Company's cash requirements may vary materially from those now planned because of results of research and development and product testing, potential relationships with in-licensors and collaborators, changes in the focus and direction of the Company's research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory approval process, manufacturing and marketing and other costs associated with the commercialization of products following receipt of regulatory approvals and other factors. The Company has no committed external sources of capital and, as discussed above, expects no significant product revenues for a number of years as it will take at least that much time to bring the Company's products to the commercial marketing stage. The Company may seek additional financing, such as through future offerings of equity or debt securities or agreements with corporate partners and collaborators with respect to the development of the Company's technology, to fund future operations. There can be no assurance, however, that the Company will be able to obtain additional funds on acceptable terms, if at all.

The Company is evaluating the need to modify its computer systems and software to properly handle information and transactions relating to the year 2000. Presently the Company believes that with modifications to some existing software, the Year 2000 issue can be mitigated. The Company plans to complete the Year 2000 project not later than December 31, 1998, and does not expect the cost of such modification to be material.

## Impact of the Adoption of Recently Issued Accounting Standard

The FASB issued Financial Accounting Standard No. 130, "Reporting Comprehensive Income" ("SFAS 130") in June 1997. Comprehensive Income represents the change in net assets of a business enterprise as a result of nonowner transactions. Management does not believe that the future adoption of SFAS 130 will have a material effect on the Company's financial position and results of operations. The Company will adopt SFAS 130 for the year ending December 31, 1998.

Also in June 1997, the FASB issued Financial Accounting Standard No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131"). SFAS 131 requires that a business enterprise report certain information about operating segments, products and services, geographic areas of operation, and major customers in complete sets of financial statements and in condensed financial statements for interim periods. Management does not believe that the future adoption of SFAS 131 will have a material effect on the Company's financial position and results of operations. The Company is required to adopt this standard for the year ending December 31, 1998.

In February 1998, the FASB issued Financial Accounting Standard No. 132, "Employer's Disclosures about Pensions and Other Postretirement Benefits" ("SFAS 132"). SFAS 132 modifies financial statement disclosures related to pension and other postretirement plans, and will not have an effect on the Company's financial position or results of operations, and is effective for periods beginning after December 15, 1997.

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

At December 31, 1997, the Company did not hold any market risk sensitive instruments.

### Item 8. Financial Statements and Supplementary Data

#### PROGENICS PHARMACEUTICALS, INC.

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## **REPORT of INDEPENDENT ACCOUNTANTS**

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

We have audited the accompanying balance sheets of PROGENICS PHARMACEUTICALS, INC. (the "Company") as of December 31, 1996 and 1997 and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 1997. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above, present fairly, in all material respects, the financial position of the Company as of December 31, 1996 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1997, in conformity with generally accepted accounting principles.

**COOPERS & LYBRAND L.L.P.**

New York, New York  
March 6, 1998.

**PROGENICS PHARMACEUTICALS, INC.**

**BALANCE SHEETS**

	December 31,	
ASSETS:	1996	1997
Current assets:		
Cash and cash equivalents	\$ 646,664	\$ 21,737,925
Accounts receivable	114,111	164,308
Other current assets	21,050	26,483
Total current assets	781,825	21,928,716
Marketable securities		1,886,200
Fixed assets, at cost, net of accumulated depreciation and amortization	842,607	688,174
Security deposits and other assets	38,212	39,521
Total assets	\$ 1,662,644	\$ 24,542,611
LIABILITIES and STOCKHOLDERS' (DEFICIT) EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,785,844	\$ 1,226,248
Income taxes payable		57,770
Capital lease obligations, current portion	105,076	82,859
Total current liabilities	1,890,920	1,366,877
Capital lease obligations	139,649	141,402
Deferred lease liability	16,735	
Total liabilities	2,047,304	1,508,279
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, \$.001 par value; 20,000,000 shares authorized:		
Series A Preferred Stock, convertible; 4,000,000 shares designated; shares issued and outstanding - 2,308,000 in 1996 and none in 1997 (liquidation value, \$6,055,750)	2,308	
Series B Preferred Stock, convertible; 2,500,000 shares designated; shares issued and outstanding - 1,982,830 in 1996 and none in 1997 (liquidation value, \$8,650,630)	1,983	
Series C Preferred Stock, convertible; 3,750,000 shares designated; shares issued and outstanding - 1,388,996 in 1996 and none in 1997 (liquidation value, \$6,944,980)	1,389	
Total preferred stock	5,680	
Common Stock, \$.0013 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,294,675 in 1996 and 9,001,553 in 1997	2,983	11,702
Additional paid-in capital	23,862,082	43,444,701
Unearned compensation	(454,952)	(1,761,381)
Accumulated deficit	(23,800,453)	(18,661,030)
Net unrealized gain on marketable securities		340
Total stockholders' (deficit) equity	(384,660)	23,034,332
Total liabilities and stockholders' (deficit) equity	\$ 1,662,644	\$ 24,542,611

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

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

	Years Ended December 31,		
	1995	1996	1997
Revenues:			
Contract research and development	\$ 200,399	\$ 318,370	\$ 14,591,505
Research grants	524,949	202,559	664,983
Product sales	49,752	98,049	56,531
Interest income	46,378	105,808	300,966
Total revenues	821,478	724,786	15,613,985
Expenses:			
Research and development	3,853,001	3,700,204	7,364,117
General and administrative	1,093,821	2,807,668	2,221,667
Interest expense	87,279	50,706	311,522
Depreciation and amortization	290,873	308,882	319,486
Total expenses	5,324,974	6,867,460	10,216,792
Operating (loss) income	(4,503,496)	(6,142,674)	5,397,193
Income taxes			257,770
Net (loss) income	\$ (4,503,496)	\$ (6,142,674)	\$ 5,139,423
Net (loss) income per share - basic	\$ (1.99)	\$ (2.68)	\$ 1.64
Net (loss) income per share - diluted	\$ (1.99)	\$ (2.68)	\$ 0.66

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

**PROGENICS PHARMACEUTICALS, INC.**

**STATEMENTS of STOCKHOLDERS' EQUITY (DEFICIT)**

For the years ended December 31, 1995, 1996 and 1997

	Preferred Shares	Stock Amount	Common Shares	Stock Amount	Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Net Un- real- ized Gain on Market Secur- ities	Total
Balance at December 31, 1994	4,290,830	\$ 4,291	2,249,675	\$ 2,924	\$16,605,286	\$ (631,278)	\$(13,154,283)		\$ 2,826,940
Sale of Series C Preferred Stock units for cash (\$20.00 per unit)	179,450	179			897,070				897,249
Amortization of unearned compensation						107,363			107,363
Conversion of note payable and accrued interest of \$23,671 into Series C Preferred Stock units (\$20.00 per unit)	244,734	245			1,223,426				1,223,671
Issuance of Common Stock in consideration for obtaining a license and supply agreement at estimated value (\$6.67 per share)			45,000	59	299,941				300,000
Net loss for the year ended December 31, 1995							(4,503,496)		(4,503,496)
Balance at December 31, 1995	4,715,014	4,715	2,294,675	2,983	19,025,723	(523,915)	(17,657,779)		851,727
Issuance of compensatory stock options					60,000	(60,000)			
Sale of Series C Preferred Stock units for cash, net of expenses (\$20.00 per unit)	964,812	965			4,776,359				4,777,324
Amortization of unearned compensation						128,963			128,963
Net loss for the year ended December 31, 1996							(6,142,674)		(6,142,674)
Balance at December 31, 1996	5,679,826	5,680	2,294,675	2,983	23,862,082	(454,952)	(23,800,453)		(384,660)
Issuance of compensatory stock options and warrants					2,634,950	(2,634,950)			
Amortization of unearned compensation						1,328,521			1,328,521
Exercise of stock options (\$1.33 per share)			27,000	35	35,875				35,910
Issuance of common stock in July in consideration for an amendment to an agreement (\$7.50 per share)			120,000	156	899,844				900,000
Issuance of common stock in an initial public offering (\$8.00 per share), net of expenses			2,300,000	2,990	16,011,808				16,014,798
Conversion of preferred stock to common stock as the result of the initial public offering	(5,679,826)	(5,680)	4,259,878	5,538	142				
Net income for the year ended December 31, 1997							5,139,423		5,139,423
Net unrealized gain on marketable securities								\$340	340
Balance at December 31, 1997	-	\$ -	9,001,553	\$11,702	\$43,444,701	\$(1,761,381)	\$(18,661,030)	\$340	\$23,034,332

Securities issued for non-cash consideration were valued based upon the Board of Directors' estimate of fair value of the securities issued at the time the services were rendered.

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

**PROGENICS PHARMACEUTICALS, INC.**

**STATEMENTS of CASH FLOWS**

Increase (Decrease) in Cash and Cash Equivalents

	Years Ended December 31,		
	1995	1996	1997
Cash flows from operating activities:			
Net (loss) income	\$ (4,503,496)	\$ (6,142,674)	\$ 5,139,423
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	290,873	308,882	319,486
Expenses incurred in connection with issuance of common stock, stock options and warrants	431,034	128,963	1,328,521
Stock issued in consideration for amending an agreement			900,000
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(112,749)	30,756	(50,197)
Decrease (increase) in other current assets	49,522	(34,723)	(5,433)
(Increase) decrease in security deposits and other assets	(5,834)	40,906	(1,309)
Increase (decrease) in accounts payable and accrued expenses	273,399	1,270,099	(559,596)
Increase (decrease) in deferred lease liability	24,307	(4,349)	(16,735)
Increase in income taxes payable			57,770
Net cash (used in) provided by operating activities	(3,552,944)	(4,402,140)	7,111,930
Cash flows from investing activities:			
Capital expenditures	(158,445)	(96,672)	(69,784)
Purchase of marketable securities			(1,886,036)
Redemption of certificates of deposit	113,850		
Net cash used in investing activities	(44,595)	(96,672)	(1,955,820)
Cash flows from financing activities:			
Proceeds from issuance of equity securities, net of offering expenses	897,249	4,777,324	16,050,708
Payment of capital lease obligations	(215,652)	(191,142)	(115,557)
Proceeds from notes payable	1,200,000		2,000,000
Repayments of notes payable			(2,000,000)
Net cash provided by financing activities	1,881,597	4,586,182	15,935,151
Net (decrease) increase in cash and cash equivalents	(1,715,942)	87,370	21,091,261
Cash and cash equivalents at beginning of period	2,275,236	559,294	646,664
Cash and cash equivalents at end of period	\$ 559,294	\$ 646,664	\$ 21,737,925
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 90,060	\$ 50,706	\$ 83,655
Cash paid for income taxes			200,000
Supplemental disclosure of noncash investing and financing activities:			
Increase in capital lease obligations	\$ 139,000	\$ 89,000	\$ 95,000
Conversion of debt for equity	1,224,000		

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

## **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 products for the treatment and prevention of cancer and viral diseases, including human immunodeficiency virus ("HIV") infection. Prior to July 1997, the Company was in the development stage. The Company was incorporated in Delaware on December 1, 1986. The Company has no products approved for sale by the U.S. Food and Drug Administration. In addition to the normal risks associated with a new business venture, 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.

As of December 31, 1997, the Company had cash, cash equivalents and marketable securities of \$23.6 million. The Company estimates that this amount combined with commitments from collaborators and others to fund future clinical development conducted by the Company, will enable it to continue to operate beyond one year. In the future, the Company will need to raise additional financing through public or private equity financings, collaborative or other arrangements with corporate sources, or other sources of financing to fund operations. There can be no assurance that such additional financing, if at all available, can be obtained on terms reasonable to the Company. In the event the Company is unable to raise additional capital, operations will need to be scaled back or discontinued.

#### **2. Summary of Significant Accounting Policies:**

##### **Revenue Recognition**

The Company has derived all of its product revenue from the sale of research reagents to four customers. 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 reagent and cost of product sales is not material.

The Company has been awarded government research grants from the National Institutes of Health (the "NIH"). The NIH grants are used to subsidize the Company's research projects ("Projects") regarding HIV. NIH 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.

**Continued**

# PROGENICS PHARMACEUTICALS, INC.

## NOTES to FINANCIAL STATEMENTS, Continued

Payments from Bristol-Myers Squibb Company, Hoffmann-LaRoche and the Department of Defense (collectively the "Collaborators") (See Note 8) for contract research and development are used to subsidize the Company's research and development efforts. 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.

Upon the achievement of certain events certain Collaborators are required to make defined payments to the Company. Such amounts are included in contract research and development revenue and are recognized as revenue upon the achievement of the event and when collection of the resulting receivable is probable.

Interest income is recognized as earned.

For each of the three years in the period ended December 31, 1997, all of the Company's research grant revenue and contract research and development revenue came from the NIH and the Collaborators, respectively.

### 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 the NIH 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.

### 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 the respective accounts and any gain or loss is recognized in operations. The estimated useful lives of fixed assets are as follows:

Machinery and equipment	5-7 years
Furniture and fixtures	5 years
Leasehold improvements	Life of lease

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

**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.

**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, 1997, the Company had invested approximately \$20,787,000 in funds with two major investment companies and held approximately \$951,000 in a single commercial bank. At December 31, 1996, the Company had invested approximately \$569,000 in funds with a major investment company and held approximately \$78,000 in a single commercial bank.

**Net (loss) Income Per Share**

For the year ended December 31, 1997, the Company adopted Statement of Financial Accounting Standards No. 128, "Earnings Per Share" ("SFAS No. 128"). As required by SFAS No. 128, the prior years' loss per share data have been restated to conform to the provisions of SFAS No. 128; however, the impact of the restatement was not material.

Basic net (loss) income per share is computed on the basis of net (loss) income for the period divided by the weighted average number of shares of common stock outstanding during the period. Diluted net (loss) income per share includes, where dilutive, the number of shares issuable upon exercise of outstanding options and warrants and the conversion of preferred stock. Disclosures required by SFAS No. 128 have been included in Note 13.

**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.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

**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. Significant estimates relate to fixed assets and deferred taxes. Actual results could differ from those estimates. See also Notes 1 and 8(c).

**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 fair value of the Company's common stock on the grant date is greater than the amount an employee must pay to acquire the stock.

Disclosures required by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), including pro forma operating results had the Company prepared its financial statements in accordance with the fair-value-based method of accounting for stock-based compensation, have been included in Note 9.

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.

**Impact of the Future Adoption of Recently Issued Accounting Standards** The Financial Accounting Standards Board (the "FASB") issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130") in June 1997. Comprehensive Income represents the change in net assets of a business enterprise as a result of nonowner transactions. Management does not believe that the future adoption of SFAS 130 will have a material effect on the Company's financial position and results of operations. The Company will adopt SFAS 130 for the year ending December 31, 1998.

Also in June 1997, the FASB issued Financial Accounting Standard No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131"). SFAS 131 requires that a business enterprise report certain information about operating segments, products and services, geographic areas of operation, and major customers in complete sets of financial statements and in condensed financial statements for interim periods. Management does not believe that the future adoption of SFAS 131 will have a material effect on the Company's financial position and results of operations. The Company is required to adopt this standard for the year ending December 31, 1998.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

In February 1998, the FASB issued Financial Accounting Standard No. 132, "Employers' Disclosures about Pensions and other Postretirement Benefits." This statement modifies financial statement disclosures related to pension and other postretirement plans, and therefore will not have an effect on the Company's financial position or results of operations, and is effective for periods beginning after December 15, 1997.

**Reclassifications**

Certain reclassifications have been made to the 1995 and 1996 financial statements to conform with the 1997 presentation.

**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.

The Company did not have any marketable securities at December 31, 1996. For marketable securities with maturities in excess of one and 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, 1997:

Amortized Fair Unrealized Holding Cost Basis Value Gains (Losses) Net

Corporate debt securities \$1,885,860 \$1,886,200 \$1,496 \$(1,156) \$340

For the year ended December 31, 1997, there were no realized gains and losses from the sale of marketable securities. 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.

**Continued**

# PROGENICS PHARMACEUTICALS, INC.

## NOTES to FINANCIAL STATEMENTS, Continued

### 4. Fixed Assets:

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

	December 31,	
	1996	1997
Machinery and equipment	\$ 1,578,643	\$ 1,702,892
Furniture and fixtures	138,415	138,415
Leasehold improvements	29,702	29,702
	1,746,760	1,871,009
Less, Accumulated depreciation and amortization	(904,153)	(1,182,835)
	\$ 842,607	\$ 688,174

### 5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	December 31,	
	1996	1997
Accounts payable	\$ 701,472	\$ 517,714
Fees payable to Scientific Advisory Board members	60,000	38,500
Accrued payroll and related costs	53,874	330,480
Legal and accounting fees payable	937,493	322,819
Deferred lease liability, current portion	33,005	16,735
	\$1,785,844	\$1,226,248

### 6. Stockholders' Equity:

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 60,000,000 shares, of which 40,000,000 shares are designated as common shares, par value \$.0013 ("Common Stock"), and 20,000,000 shares are designated as preferred shares, par value \$.001. The Board has the authority to issue common and preferred shares, in series, with rights and privileges determined by the Board. Prior to the Company's initial public offering ("IPO"), 4,000,000 preferred shares were designated as Series A Preferred Stock ("Series A"), 2,500,000 shares were designated as Series B Preferred Stock ("Series B") and 3,750,000 shares were designated as Series C Preferred Stock ("Series C") (collectively the "Preferred Stock"). Prior to December 31, 1994, the Company sold an aggregate of 4,290,830 shares of Series A and Series B Preferred Stock in consideration for approximately \$15 million.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

During 1995 and 1996, the Company raised \$897,000 and \$4,777,000, net of expenses, from the sale of approximately 44,900 Units and 241,203 Units, respectively (the "C Units") in a private placement. In addition, during December 1995, a stockholder converted a note payable into approximately 61,200 C Units (see Note 7). Each C Unit consists of four shares of Series C and one five-year warrant (the "C Warrant") which currently entitles the holder to purchase .75 share of Common Stock at \$6.67 per share. The number of C Warrants and their exercise price are subject to adjustment in the event the Company issues additional shares of Common Stock at below defined per share prices. As of December 31, 1997, 347,249 C Warrants were issued and outstanding and fully exercisable into 260,455 shares of common stock.

During November 1997, the Company completed an IPO of 2,300,000 shares of its Common Stock, in which the Company raised approximately \$16 million, net of expenses and underwriting discount. Concurrent with the IPO, all outstanding shares of Preferred Stock, were converted automatically into 4,259,878 shares of Common Stock.

**7. Note Payable - Stockholder:**

During 1995, the Company borrowed \$1,200,000 under a promissory note from a stockholder. The promissory note, as amended and restated, provided for interest to accrue at a rate of 10% per annum. Interest and principal were payable upon demand, but not before December 8, 1995. During December 1995, the promissory note plus accrued interest of \$23,671 were exchanged for approximately 61,200 C Units (see Note 6).

**8. Commitments and Contingencies:**

(a) Operating Leases The Company leases office and laboratory space under noncancelable lease agreements expiring April 30, 1998 (the "Leases"). The Leases provide for escalations of the minimum rent during the lease term as well as additional charges based upon usage of certain utilities in excess of defined amounts ("Additional Utility Charges"). The Company recognizes rental expense from the Leases on the straight-line basis. During 1995, the Company recognized rental expense in excess of amounts paid of \$24,000, while during the years ended December 31, 1996 and 1997, approximately \$4,000 and \$33,000, respectively, of previously recognized rent expense, which had been included as a deferred lease liability was paid.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

On January 27, 1998, the Company entered into a sublease agreement ("Sublease") consolidating and extending the Leases for office and laboratory space from May 1, 1998 through December 31, 1999. Fixed monthly rental expense totals approximately \$54,000. The Sublease can be extended at the option of the Company for three additional one-year terms; however, the second and third options are subject to approval by the landlord.

The Company also leases office equipment and an automobile under noncancelable operating leases. The leases expire at various times through March 2002.

Future minimum annual payments under all operating lease agreements, including the Sublease, are as follows:

Years ending December 31,	Minimum Annual Payments
1998	\$ 671,908
1999	657,829
2000	8,569
2001	7,534
2002	1,521
	\$1,347,361

Rental expense totaled approximately \$657,000, \$645,000 and \$628,000 for the years ended December 31, 1995, 1996 and 1997, respectively. Additional Utility Charges, were not material for these periods.

(b) Capital Leases The Company leases certain equipment under various noncancelable capital lease agreements. The leases are for periods ranging from three to five years, after which the Company: (i) either has the option or is required to purchase the equipment at defined amounts or (ii) may extend the lease for up to one additional year at defined monthly payments or (iii) is required to return the equipment, as per the respective lease agreements.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

As of December 31, 1997, minimum annual payments under all capital leases, including required payments to acquire leased equipment, are as follows:

Years Ending December 31,	Minimum Annual Payments
1998	\$112,443
1999	85,602
2000	62,095
2001	22,840
	282,980
Less, Amounts representing interest	(58,719)
Present value of net minimum capital lease payments	\$224,261

Leased equipment included as a component of fixed assets was approximately \$807,000 and \$835,000 at December 31, 1996 and 1997, respectively; related accumulated depreciation was approximately \$383,000 and \$473,000 for the same respective periods.

(c) Licensing and Corporate Collaboration 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 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.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

The Company (as licensee) also has a non-exclusive licensing agreement with Stanford University whereby the Company has the non-exclusive, non-transferable right to use certain technology owned by the university. According to the terms of the agreement, the Company will be required to remit royalties based upon the greater of minimum royalties, as defined or various percentages of sales of products resulting from the use of licensed patent rights, as defined. Royalties shall continue to be payable, irrespective of termination of this license agreement, until such time as all sales of products which utilize the licensed technology shall have ceased.

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. Early termination of the 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 agreement, there can be no assurances that the agreement will not be terminated.

(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 8(d)). According to the terms of the agreement, the Company was required to pay nonrefundable, noncreditable licensing fees in installments. Commencing in 1995, 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 2000, 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. 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.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

(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. ("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 underlying Restricted Shares would be returned to the Company. As of December 31, 1997, the restrictions on 11,250 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 2002 ("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 would 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.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

(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 worldwide license to manufacture, use and sell products resulting from development of the Company's products related to certain therapeutic cancer vaccines (the "Cancer Vaccines"). Upon execution of the agreement, BMS made non-refundable cash payments of \$9.5 million, as reimbursement for expenses previously incurred by the Company in the development of the Cancer Vaccines, \$2.0 million as a licensing fee and approximately \$1.8 million as reimbursement of the Company's budgeted clinical development costs for the Cancer Vaccines for the period April 15, 1997 through September 30, 1997. In addition, BMS is obligated to make future non-refundable payments as defined upon the achievement of specified milestones and pay royalties on any product sales. BMS is also required to fund continued development, clinical trials and regulatory filings ("Development Costs") conducted by the Company on a time and material basis related to the Cancer Vaccines. BMS's funding of future Development Costs are refundable by the Company only to the extent that the Company receives such funding in advance and fails to expend such amounts for their intended purposes. The Company recognized as revenue the reimbursement of prior expenses and the licensing fee upon receipt of the funds. The Company recognizes revenue for the funding of Development Costs on a pro rata basis as the related expenses are incurred.

The BMS License Agreement and related sublicenses terminate at various times, generally upon the expiration or abandonment of the related patents. The agreements can also be terminated by either party upon a material uncured breach by the other party. BMS has the further right to terminate the BMS License Agreement (including its funding and milestone obligations) as to specified licensed products at specified times.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

(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 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. Such funding will continue for a minimum of two years from the Effective Date. 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 Company recognizes as revenue milestone payments as earned and research reimbursements on a pro rata basis as the underlying costs are incurred. The collaboration has a term of three years and may be extended by mutual agreement. The Roche Agreement shall remain in force until the expiration of all obligations to pay royalties pursuant to any licenses specified by the Roche Agreement. Roche may terminate the Roche Agreement at any time with prior written notice, at which time the license granted by the Company will terminate. Either party may terminate the Roche Agreement if the other party defaults on its obligations and such default is not cured within sixty days of written notice of such default.

In connection with the above agreements, the Company has recognized research and development expenses, including transaction costs, totaling approximately \$382,500, \$170,500 and \$1,901,000 for the years ended December 31, 1995, 1996 and 1997, respectively. Such expenses include the fair value of the Restricted Shares and 120,000 shares of common stock issued in July 1997. In addition, as of December 31, 1997, remaining payments associated with milestones and defined objectives with respect to the above agreements total \$650,000. Future annual minimum royalties under the licensing agreements described in (i) through (iii) above are not significant.

**Continued**

**NOTES to FINANCIAL STATEMENTS, Continued**

(d) Consulting Agreements As part of the Company's research and development efforts it enters into consulting agreements with external scientific specialists ("Scientists"). These Agreements contain varying terms and provisions which include fees to be paid by the Company and services to be provided by the Scientists, some of whom are members of the Company's Scientific Advisory Board. Certain Scientists 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 \$245,000, \$268,000, and \$971,000 for the years ended December 31, 1995, 1996 and 1997, respectively. Such expenses include the fair value of stock options of approximately \$107,000 and \$112,000 and \$772,000 for the years ended December 31, 1995, 1996 and 1997, respectively.

**9. Stock Option 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 1,050,000 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 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. 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.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

The following table summarizes stock option information for the Plans as of December 31, 1997:

Range of Exercise Prices	Number Outstanding	Options Outstanding		Options Exercisable	
		Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$1.33	191,823	8.0 yr.	\$1.33	167,260	\$1.33
\$3.67 - \$5.33	1,357,925	7.5 yr.	\$4.48	649,126	\$4.58
\$6.67 - \$8.00	9,600	8.7 yr.	\$6.96	2,200	\$7.09
	1,559,348			818,586	

Transactions involving stock option awards under the Plans during 1995, 1996 and 1997 are summarized as follows:

	Number Of Shares	Weighted-Average Exercise Price (2)
Balance outstanding, December 31, 1994	1,011,236	\$4.40
1995: Granted	4,500	\$6.67
Cancelled	(45,000)	\$4.91
Balance outstanding, December 31, 1995	970,736	\$4.39
1996: Granted	94,500	\$6.56
Cancelled	(24,000)	\$5.33
Balance outstanding, December 31, 1996	1,041,236	\$4.57
1997: Granted (1)	848,000	\$4.00
Cancelled (1)	(302,888)	\$5.36
Exercised	(27,000)	\$1.33
Balance outstanding, December 31, 1997	1,559,348	\$4.17

(1) Includes 216,225 options repriced, as discussed below

(2) For all options granted in 1995 and 1996 and 2,100 in 1997, the option exercise price equaled the fair value of the Company's common stock on the date of grant. For 1997, 845,900 options 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, 1995, 1996 and 1997, 458,742, 488,553, and 818,586 options with weighted average exercise prices of \$3.61, \$3.59 and \$3.92, respectively, were exercisable under the Plans.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

As of December 31, 1997, shares available for future grants under the 93 Plan and the 96 Plan amounted to 30,763 and 532,400, respectively.

The Company, during 1997, granted an aggregate of 520,900 stock options (including 216,225 options repriced as discussed below) to employees, with an average exercise price of \$4.00, which was 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, of one to five years, 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, 1997 has been included within stockholders equity. For the year ended December 31, 1997, the annual amortization of Unearned Compensation for employees totaled \$322,296. As of December 31, 1997 the unamortized portion of Unearned Compensation for employees totaled \$732,404.

The Company since its inception has granted an aggregate of 1,082,000 options with an average exercise price of \$3.86 to consultants in consideration for services. The fair values of these options have been included as Unearned Compensation and are being amortized as compensation expense on a pro rata basis over the service period ranging from four years to ten years. For the years ended December 31, 1995, 1996 and 1997 the annual amortization of Unearned Compensation for consultants totaled \$107,363, \$128,963 and \$778,358, respectively. The above amounts included the fair value of stock options issued to consultants as discussed in Note 8(d). As of December 31, 1997, the unamortized portion of Unearned Compensation for consultants totaled \$1,028,977.

On April 1, 1997, the exercise price of 216,225 options granted under the Plans, having exercise prices in excess of \$4.00 per share, were reduced to \$4.00 per share. The exercise price of the repriced options was less than the fair value of the underlying stock on the date of repricing. Accordingly, the Company is recognizing compensation expense on a pro rata basis over the respective remaining options' vesting periods of one to five years for the difference between the estimated fair value of the Common Stock on the date the option was repriced and \$4.00. All other aspects of the options remain unchanged.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

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 of the Company's Common Stock at the date of grant, as determined by the Board of Directors. 375,000 of the options vest pro rata over a period of four years, with the remaining 375,000 options vesting in full on the tenth anniversary of the date of grant; however, vesting with respect to the options vesting on the tenth anniversary will be accelerated in the event of the effective date of an initial public offering of the Company's Common Stock that yields certain gross per share amounts, as defined, or immediately before the closing of an acquisition of the Company. As the result of the Company's IPO, 75,000 options vested.

The following table summarizes stock option information for the Executive Plan as of December 31, 1997:

Range of	Options Outstanding		Options Exercisable	
	Weighted-Average Remaining	Weighted-Average	Weighted-Average	Weighted-Average
Exercise Number Contractual Exercise Number Exercise Prices Outstanding Life Price Exercisable Price				
\$5.33 - \$5.87	750,000	6.0 yr	\$5.39	450,000 \$5.43

The following table summarizes the pro forma operating results of the Company had compensation costs for the Plans and the Executive Plan been determined in accordance with the fair value based method of accounting for stock based compensation as prescribed by SFAS No. 123. Since option grants awarded during 1995, 1996 and 1997 vest over several years and additional awards are expected to be issued in 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.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

	Years Ended December 31,		
	1995	1996	1997
Pro forma net (loss) income	\$(4,505,130)	\$(6,189,086)	\$5,016,206
Pro forma net (loss) income per share, basic	\$(1.99)	\$(2.70)	\$1.60
Pro forma net (loss) income per share, diluted	\$(1.99)	\$(2.70)	\$0.65

For the purpose of the above pro forma calculation, the fair value of each option granted was estimated on the date of grant using the Black-Scholes option pricing model. The weighted-average fair value of the options granted during 1995, 1996 and 1997 was \$4.59, \$4.60 and \$3.91, respectively. The following assumptions were used in computing the fair value of option grants: expected volatility of 81%, expected lives of 5 years after vesting; zero dividend yield and weighted-average risk-free interest rates of 6.0% in 1995 and 1996 and 6.72% in 1997.

**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 25% of up to the first 8% of compensation that eligible employees contribute 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 \$12,000, \$10,000 and \$9,000 to the Amended Plan for the years ended December 31, 1995, 1996 and 1997, respectively.

**11.Income Taxes:**

The tax provision for year ended December 31, 1997 has been computed based upon the prevailing federal and state tax rates, offset by the utilization of net operating loss carryforwards to the extent permitted by the alternative minimum tax rules of the federal and state tax codes. There is no benefit for federal or state income taxes for the years ended December 31, 1995 and 1996, since the Company has incurred operating losses and has established a valuation allowance equal to the total deferred tax asset.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

The differences between the Company's effective income tax rate, (benefit) provision, and the Federal statutory rate is reconciled below:

	Years Ended December 31,		
	1995	1996	1997
Federal statutory rate	(34)%	(34)%	34%
State income taxes, net of Federal benefit	(6)	(6)	6
Research and experimental tax credit	(1)	(2)	(3)
Change in valuation allowance	41	42	(32)
	- %	- %	5%

The tax effect of temporary differences, net operating losses and tax credits carryforwards as of December 31, 1996 and 1997 are as follows:

	December 31,	
	1996	1997
Deferred tax assets and valuation allowance:		
Net operating loss carry-forwards	\$ 5,995,737	\$ 1,638,783
Fixed assets	165,219	98,894
Deferred charges	3,491,832	5,726,342
Research and experimental tax credit carry-forwards	585,618	785,284
Alternative minimum tax credit		257,770
Valuation allowance	(10,238,406)	(8,507,073)
	\$ -	\$ -

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, 1997, the Company has available, for tax purposes, unused net operating loss carryforwards of approximately \$4.0 million which will expire in various years from 2002 to 2012. The Company's research and experimental tax credit carryforwards expire in various years from 2003 to 2012. In addition, the Company's alternative minimum tax credit can be carried forward indefinitely. Future ownership changes may limit the future utilization of these net operating loss and tax credit carryforwards as defined by the federal and state tax codes.

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

**12.Line of Credit:**

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 million. Outstanding borrowings accrue interest, payable monthly, at the bank's prime rate of interest. The Line expired on July 31, 1997. The repayment of the Line was guaranteed by two affiliates of a stockholder of the Company ("Affiliates").

In consideration for the guarantee of the Line, the Company issued 70,000 warrants to the Affiliates. Such warrants vested immediately and expire after five years. The exercise price was determined to be \$4.00 per share in November 1997 upon completion of the Company's IPO. The aggregate fair value of the warrants totaled approximately \$228,000, which was expensed during the year ended December 31, 1997.

**13.Net (Loss) Income Per Share:**

The Company's basic net (loss) income per share amounts have been computed by dividing net (loss) income by the weighted average number of common shares outstanding during the period. For the years ended December 31, 1995 and 1996, the Company reported net losses and, therefore, common stock equivalents were not included since such inclusion would have been anti-dilutive. For the year ended December 31, 1997, the Company reported net income and, therefore, all common stock equivalents have been included in the calculation, as follows:

	Net Income (Loss) (Numerator)	Shares (Denominator)	Per Share Amount
1997:			
Basic:			
Net income	\$ 5,139,423	3,127,855	\$1.64
Effect of Dilutive Securities			
Options		829,156	
Warrants		77,211	
Effect of conversion of preferred stock		3,769,700	
Diluted:			
Amounts used in computing per share data	\$ 5,139,423	7,803,922	\$0.66
1996:			
Basic and Diluted:			
Net (loss)	\$ (6,142,674)	2,294,675	(\$2.68)
1995:			
Basic and Diluted:			
Net (loss)	\$ (4,503,496)	2,264,839	(\$1.99)

**Continued**

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES to FINANCIAL STATEMENTS, Continued**

For the years ended December 31, 1995 and 1996, common stock equivalents which have been excluded from diluted per share amounts because their effect would have been anti-dilutive, include 1,912,770 and 2,051,691 options and warrants with weighted average exercise prices of \$5.01 and \$5.14, respectively, and 3,536,260 and 4,259,878 shares of convertible preferred stock. For the year ended December 31, 1997, no common stock equivalents were excluded from the computation of diluted per share amounts.

**Continued**

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

## PART III

### **Item 10. Directors and Executive Officers of the Registrant**

This information will be contained in the Company's definitive Proxy Statement with respect to the Company's Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission within 120 days following the end of the Company's fiscal year, and is hereby incorporated by reference thereto.

### **Item 11. Executive Compensation**

This information will be contained in the Company's definitive Proxy Statement with respect to the Company's Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission within 120 days following the end of the Company's fiscal year, and is hereby incorporated by reference thereto.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management**

This information will be contained in the Company's definitive Proxy Statement with respect to the Company's Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission within 120 days following the end of the Company's fiscal year, and is hereby incorporated by reference thereto.

### **Item 13. Certain Relationships and Related Transactions**

This information will be contained in the Company's definitive Proxy Statement with respect to the Company's Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission within 120 days following the end of the Company's fiscal year, and is hereby incorporated by reference thereto.

## PART IV

### **Item 14. 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 and Supplemental Data Balance Sheets at December 31, 1996 and 1997 Statements of Operations for the years ended December 31, 1995, 1996 and 1997 Statements of Stockholders' Equity (Deficit) for the years ended December 31, 1995, 1996 and 1997 Statements of Cash Flows for the years ended December 31, 1995, 1996 and 1997 Notes to the Financial Statements

b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended December 31, 1997.

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.

## 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 Maddon, M.D., Ph.D.  
Paul J. Maddon, M.D., Ph.D.  
Chairman of the Board, Chief Executive Officer  
and President

Date: March 31, 1998

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

<i>Signature</i>	<i>Title</i>	<i>Date</i>
/s/ Paul J. Maddon, M.D., Ph.D. Paul J. Maddon, M.D., Ph.D.	Chairman of the Board, Chief Executive Officer and President (Principal Executive Officer)	March 31, 1998
/s/ Robert A. McKinney Robert A. McKinney	Vice President, Finance and Operations and Treasurer (Principal Financial and Accounting Officer)	March 31, 1998
/s/ Charles A. Baker Charles A. Baker	Director	March 31, 1998
/s/ Mark F. Dalton Mark F. Dalton	Director	March 31, 1998
/s/ Stephen P. Goff, Ph.D. Stephen P. Goff, Ph.D.	Director	March 31, 1998
/s/ Elizabeth M. Greetham Elizabeth M. Greetham	Director	March 31, 1998
/s/ Paul F. Jacobson Paul F. Jacobson	Director	March 31, 1998
/s/ David A. Scheinberg, M.D., Ph.D. David A. Scheinberg, M.D., Ph.D.	Director	March 31, 1998

## EXHIBIT INDEX

Exhibit No.	Description of Exhibit
*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***
*10.3	1993 Stock Option Plan as amended***
*10.4	1993 Executive Stock Option Plan***
*10.5	Amended 1996 Stock Incentive Plan***
*10.6	Form of Indemnification Agreement***
*10.7	Employment Agreement dated December 15, 1993 between the Registrant and Dr. Paul J. Maddon***
*10.8	Letter dated August 25, 1994 between the Registrant and Dr. Robert J. Israel***
*10.9	Sublease dated July 13, 1988 between the Registrant and Union Carbide Corporation

\*+10.10 gp120 Supply Agreement dated July 19, 1995 between the Registrant and E. I. DuPont DeNemours and Company, as amended, October 27, 1995

\*+10.11 sCD4 Supply Agreement dated June 27, 1995 between the Registrant and E. I. DuPont De Nemours and Company \*+10.12 Supply Agreement dated February 8, 1996 between the Registrant and Intracel Corporation Stock Purchase Agreement dated February 11, 1994 between the Registrant and Christopher Ben (Exhibit 10.13 to the 1993 Form 10-K) \*+10.13 License Agreement dated November 17, 1994 between the Registrant and Sloan-Kettering Institute for Cancer Research \*+10.14 Clinical Trial Agreement dated December 12, 1994 between the Registrant and Sloan-Kettering Institute for Cancer Research \*+10.15 QS-21 License and Supply Agreement dated August 31, 1995 between the Registrant and Cambridge Biotech Corporation

(now known as Aquila Biopharmaceuticals, Inc.)

\*+10.16 gp120 Sublicense Agreement dated March 17, 1995 between the Registrant and Cambridge Biotech Corporation (now known as Aquila Biopharmaceuticals, Inc.) \*+10.17 Cooperative Research and Development Agreement dated February 25, 1993 between the Registrant and the Centers for Disease Control and Prevention \*+10.18 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 \*+10.19 License Agreement dated June 25, 1996 between the Registrant and The Regents of the University of California \*+10.20 KLH Supply Agreement dated July 1, 1996 between the Registrant and PerImmune, Inc. \*+10.21 sCD4 Supply Agreement dated November 3, 1993 between the Registrant and E.I. DuPont DeNemours and Company \*+10.22 Lease dated June 30, 1994 between the Registrant and Keren Limited Partnership

\*+10.23 Joint Development and Master License Agreement dated as of April 15, 1997 between Bristol-Myers Squibb Company and the Registrant

\*+10.24 Sublicense Agreement with respect to the Sloan-Kettering License Agreement dated as of April 15, 1997 between Bristol-Myers Squibb Company and the Registrant \*+10.25 Sublicense Agreement with respect to The Regents' License Agreement dated April 15, 1997 between Bristol-Myers Squibb Company and the Registrant \*+10.26 Sublicense Agreement with respect to Aquila Biopharmaceuticals, Inc. License and Supply Agreement dated April 15, 1997 between Bristol-Myers Squibb Company and the Registrant \*+10.27 Letter agreement dated as of April 15, 1997 among Bristol-Myers Squibb Company, Registrant and the Sloan-Kettering Institute for Cancer Research \*+10.28 Letter agreement dated as of April 15, 1997 among Bristol-Myers Squibb Company, Registrant and The Regents of the University of California

\*+10.29 Letter agreement dated as of April 15, 1997 among Bristol-Myers Squibb Company, Registrant and Aquila Biopharmaceuticals, Inc.

\*10.30 Form of Warrant to purchase Series C Preferred Stock \*10.31 Form of Warrant issued to Tudor BVI Futures, Ltd. and Tudor Global Trading LLC

\*\*+10.32 Heads of Agreement, effective as of December 23, 1997, among F. Hoffman-La Roche Ltd., Hoffmann-La Roche Inc. and Registrant.

27.1 Financial Data Schedule.

27.2 Restarted Financial Data Schedule.

\* 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 Current Report on Form 8-K dated February 6, 1998, and 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.

**ARTICLE 5**

This Schedule contains summary financial information extracted from the Financial Statements of Progenics Pharmaceuticals, Inc. at December 31, 1997 and is qualified in its entirety by reference to such Financial Statements.

PERIOD TYPE	12 MOS
FISCAL YEAR END	DEC 31 1997
PERIOD START	JAN 01 1997
PERIOD END	DEC 31 1997
CASH	21,737,925
SECURITIES	1,886,200
RECEIVABLES	164,308
ALLOWANCES	0
INVENTORY	0
CURRENT ASSETS	21,928,716
PP&E	1,871,009
DEPRECIATION	1,181,835
TOTAL ASSETS	24,542,611
CURRENT LIABILITIES	1,366,877
BONDS	0
PREFERRED MANDATORY	0
PREFERRED	0
COMMON	11,702
OTHER SE	23,022,630
TOTAL LIABILITY AND EQUITY	24,542,611
SALES	56,531
TOTAL REVENUES	15,613,985
CGS	0
TOTAL COSTS	0
OTHER EXPENSES	9,905,270
LOSS PROVISION	0
INTEREST EXPENSE	311,522
INCOME PRETAX	5,397,193
INCOME TAX	257,770
INCOME CONTINUING	5,139,423
DISCONTINUED	0
EXTRAORDINARY	0
CHANGES	0
NET INCOME	5,139,423
EPS PRIMARY	1.64
EPS DILUTED	.66

**ARTICLE 5**

RESTATED:

MULTIPLIER: 1000

PERIOD TYPE	YEAR	9 MOS
FISCAL YEAR END	DEC 31 1996	DEC 31 1997
PERIOD END	DEC 31 1996	SEP 30 1997
CASH	647	7,720
SECURITIES	0	0
RECEIVABLES	82	40
ALLOWANCES	0	0
INVENTORY	0	0
CURRENT ASSETS	782	7,826
PP&E	1,747	1,791
DEPRECIATION	904	1,143
TOTAL ASSETS	1,663	8,511
CURRENT LIABILITIES	1,891	810
BONDS	0	0
PREFERRED MANDATORY	0	0
PREFERRED	5	5
COMMON	3	3
OTHER SE	(393)	7,587
TOTAL LIABILITY AND EQUITY	1,663	8,511
SALES	98	50
TOTAL REVENUES	725	13,924
CGS	0	0
TOTAL COSTS	0	0
OTHER EXPENSES	6,817	7,540
LOSS PROVISION	0	0
INTEREST EXPENSE	51	303
INCOME PRETAX	(6,143)	6,081
INCOME TAX	0	151
INCOME CONTINUING	(6,143)	5,930
DISCONTINUED	0	0
EXTRAORDINARY	0	0
CHANGES	0	0
NET INCOME	(6,143)	5,930
EPS PRIMARY	(2.68)	2.43
EPS DILUTED	(2.68)	0.82

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