

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K/A

- Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 1996 or
- Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number: 0-19756

PROTEIN DESIGN LABS, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

94-3023969  
(I.R.S. Employer  
Identification No.)

2375 Garcia Avenue  
Mountain View, CA 94043  
(Address of principal executive offices)  
Telephone Number (415) 903-3700

Securities registered pursuant to Section 12(b) of the Act:

Title of each class -----	Name of each exchange on which registered -----
None	None

Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, Par value \$.01  
(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 statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the Common Stock on January 31, 1997, as reported on the NASDAQ National Market System, was approximately \$577,473,617.

As of January 31, 1997, registrant had outstanding 15,821,195 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

None

## PART I

This Annual Report for Protein Design Labs, Inc. ("PDL" or the "Company") contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to those discussed in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" as well as those discussed elsewhere in this document. Actual events or results may differ materially from those discussed in this Annual Report.

## ITEM 1. BUSINESS

## OVERVIEW

PDL is a leader in the development of humanized and human monoclonal antibodies for the prevention and treatment of a variety of disease conditions, including autoimmune diseases, inflammatory conditions, cancers and viral infections. The Company uses proprietary computer software and other technologies to develop its SMART(TM) humanized antibodies for potential use as effective pharmaceuticals without the limitations of mouse-derived (murine) antibodies. PDL believes that its technologies are broadly applicable to a variety of diseases, as demonstrated by the Company's diverse product development pipeline and its collaborative arrangements with eight pharmaceutical companies. The Company and its collaborative partners currently have four product candidates in multiple clinical trials and numerous additional product candidates in preclinical studies. The Company's most advanced potential product, Zenapax(R), has successfully completed two multinational Phase III clinical trials for the prevention of kidney transplant rejection. In 1996, PDL received U.S. and European patents that the Company believes cover most humanized antibodies, and that may lead to additional corporate partnering, patent licensing and other revenue opportunities.

Antibodies have long had promise as therapeutic compounds to treat a variety of disease conditions. Murine antibodies, however, have significant drawbacks which in most cases prevent them from becoming effective therapeutics. The most important of these is the human anti-mouse antibody ("HAMA") response, whereby the murine antibody is recognized by the body's immune system as being foreign and is rapidly neutralized and rendered ineffective. PDL's antibodies are designed to avoid these drawbacks, including the HAMA response. PDL's SMART antibodies are predominantly human antibodies that incorporate the structural information from the binding region of promising murine antibodies. By applying its proprietary SMART antibody technology, the Company is able to create such recombinant antibodies with molecular structures that are approximately 90% human and 10% murine. The Company also has technologies to produce fully human antibodies to treat additional diseases using antibody therapy.

PDL's business strategy is to leverage its technologies, research expertise and intellectual property in the field of antibodies to become a profitable, research-based biopharmaceutical company that manufactures and, in North America, markets its own products. Key aspects of PDL's strategy are to: (i) expand the Company's product portfolio to provide multiple product candidates to treat a variety of diseases and conditions; (ii) establish collaborative relationships with pharmaceutical companies to reduce development costs and risks and to enhance commercial

opportunities; (iii) leverage its patent position by licensing certain rights in exchange for near-term revenues and future royalty opportunities; and (iv) retain and obtain North American marketing or co-promotion rights to certain products to provide for greater revenue opportunities.

The Company actively seeks partnerships with pharmaceutical companies. The breadth of the Company's antibody technology and its patent position are key assets in attracting other companies to enter into such collaborative relationships with the Company. In one type of collaborative arrangement, the Company licenses certain marketing rights to one or more potential products developed by PDL in return for a licensing fee, research funding and milestone payments, and royalties on potential product sales. In another type of arrangement, PDL uses its proprietary technology to develop a SMART antibody based on a promising murine antibody developed by its corporate partner. In such cases, PDL typically receives a licensing fee and other payments, royalties on potential sales and, in some cases, an option to co-promote in North America.

#### PRODUCTS UNDER DEVELOPMENT

The Company believes it is a leader in the development of antibody-based therapeutics and has one of the broadest product pipelines in this area. The Company has four product candidates under clinical development and a number of product candidates in preclinical development for the treatment of a variety of disease conditions, including autoimmune diseases, inflammatory conditions, cancers and viral infections.

#### CLINICAL PRODUCT CANDIDATES

The following table summarizes the potential therapeutic indications, development status and commercial rights for the four PDL products that have entered clinical trials. The development and commercialization of the Company's clinical product candidates are subject to numerous risks and uncertainties.

PRODUCT	POTENTIAL THERAPEUTIC INDICATIONS	DEVELOPMENT STATUS	COMMERCIAL RIGHTS(1)
Zenapax (SMART Anti-Tac Antibody)	Organ transplant rejection	Completed two Phase II trials (kidney)	Roche
	Certain autoimmune diseases		
	Tropical spastic paraparesis	Phase I/II	
	Uveitis	Phase I/II	
	Psoriasis	Phase I/II planned	
	Certain blood cancers	Phase II	
SMART M195 Antibody	Acute myelogenous leukemia	Phase II/III	PDL and Kanebo
	Acute promyelocytic leukemia	Phase II	
	Myeloid leukemia	Phase I (Japan)	
OST 577 (Human Anti-Hepatitis B)	Chronic hepatitis B ("CHB")	Phase II	PDL, Boehringer Mannheim and
	Liver transplantation	Completed Phase I/II	

Antibody PROTOVIR (Human Anti-Cytomegalovirus Antibody)	due to CHB Cytomegalovirus ("CMV") infections in BMT	Phase II	Novartis PDL, Boehringer Mannheim and Novartis
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(1) The development and marketing rights for each of these products differ. See "-- Collaborative and Licensing Arrangements."

ZENAPAX (SMART ANTI-TAC ANTIBODY). Zenapax is a humanized antibody, developed by PDL and licensed exclusively to Hoffmann-La Roche Inc. and F. Hoffmann-La Roche & Co. Limited Company, subsidiaries of Roche Holding Ltd (collectively, "Roche"), which binds to the IL-2 receptor on T cells. IL-2 is a lymphokine which stimulates T cells to divide and participate in an immune response. By blocking the binding of IL-2 to its receptor, Zenapax inhibits the proliferation of activated T cells, and thus could be useful in preventing or treating organ transplant rejection or certain autoimmune diseases. Such an agent might be more specific and less toxic than current immunosuppressive drugs such as cyclosporine or OKT3, because it would suppress only activated T cells involved in an immune response rather than all T cells and possibly other unrelated cells.

Organ transplantation. In September 1996, the Company's partner, Roche, announced results from two multinational Phase III studies of Zenapax for the prevention of acute rejection episodes in a total of 535 cadaveric kidney transplant recipients. As set forth in the following table, a preliminary analysis of the data by Roche indicated that, when administered with a standard immunosuppressive regimen, Zenapax is effective in reducing the incidence of acute rejection episodes within six months of transplant, the primary endpoint. In the double therapy trial, in which all patients received a background therapy of cyclosporine and prednisone, acute rejection episodes were reduced by 40% in patients treated with Zenapax. In the triple therapy trial, in which all patients received background therapy of cyclosporine, prednisone and azathioprine, the incidence of acute rejection episodes was reduced by 37% in patients treated with Zenapax.

Trial	Incidence of Kidney Rejection Episodes			p-Value
	Without Zenapax	With Zenapax	Reduction With Zenapax	
Double Therapy . . . . .	47%	28%	40%	0.001
Triple Therapy . . . . .	35%	22%	37%	0.03

Roche also noted that secondary endpoints of reduction in the total number of rejection episodes per patient and increase in the time to first rejection episode were achieved with Zenapax in both clinical trials. The addition of Zenapax to the standard immunosuppressive regimen did not result in an increase in drug-related serious adverse events. Based on these trials, Roche stated that it intends to file in the first half of 1997 for regulatory approval to market Zenapax in the U.S., Canada and Europe.

In more recent findings, the pooled data from the two double-blind, controlled, randomized studies included a total of 535 evaluated patients, approximately half (267) of whom received Zenapax. There was one death within six months of transplant among patients receiving Zenapax as compared with 10 deaths that occurred among patients who did not receive Zenapax. Patient mortality at six months was 0.4% in Zenapax-treated patients and 3.7% in patients not receiving Zenapax. Graft loss at six months was 6.0% (16 grafts lost) in Zenapax-treated patients and 11.6% (31 grafts lost) in patients not receiving Zenapax.

In addition to the studies described above, Roche has completed enrollment in a controlled pharmacokinetics/safety study with 61 evaluable patients to assess Zenapax in combination with CellCept in kidney transplant patients. CellCept, marketed by Roche, is used to prevent kidney transplant rejection. Roche also plans to conduct a study of Zenapax in pediatric kidney transplantation.

According to industry sources, approximately 20,000 solid organs are transplanted into patients in the U.S. each year, with kidney transplants accounting for about 12,000 of the total. A comparable number of kidney transplants are performed outside of the U.S. The majority of kidney transplant patients receive cadaveric kidneys.

Roche previously evaluated Zenapax in a Phase II/III trial for the prevention of graft-versus-host disease ("GvHD"), a complication of bone marrow transplants. Analysis of the trial results led Roche to conclude that Zenapax was not effective in reducing the incidence of GvHD in the patient population studied. The reason for this lack of efficacy of Zenapax in GvHD despite its effectiveness in kidney transplantation is unknown. However, Roche stated that Zenapax was found to be safe and well-tolerated in the GvHD trial.

Autoimmune disease. Because of the ability of Zenapax to inhibit the proliferation of T cells, the Company believes that Zenapax may have potential for the treatment of certain autoimmune diseases. Investigators at the National Institutes of Health ("NIH") are evaluating Zenapax in a preliminary clinical trial in patients with tropical spastic paraparesis, a rare autoimmune disease of the nerves considered by these investigators to be a model for multiple sclerosis. In addition, proof-of-concept clinical trials of Zenapax have commenced for uveitis and are planned for psoriasis.

Cancer. The Company believes that Zenapax may also have potential for the treatment of certain blood cancers, because the IL-2 receptor is present on these types of cancer cells. The murine anti-Tac antibody has been tested at NIH in patients with adult T-cell leukemia, and several of the patients experienced remissions, especially when the antibody was linked to a radioisotope. A pilot Phase I clinical trial of Zenapax for the treatment of certain cancers was completed in 1993 at the National Cancer Institute ("NCI") of NIH, and a Phase II trial of a radiolabeled form of Zenapax for certain blood cancers is in progress at NCI.

There can be no assurance that Roche will file for or receive regulatory approval to market Zenapax for use in preventing kidney transplant rejections in a timely manner, if at all, or that it will pursue or continue clinical trials in autoimmune diseases or other indications.

SMART M195 ANTIBODY. The SMART M195 Antibody is a humanized antibody that binds to the cancer cells of most patients with myeloid leukemia. Myeloid leukemia, the major form of leukemia in adults, is classified into two types -- acute myelogenous leukemia ("AML") and chronic myelogenous leukemia ("CML"). There are at least 11,000 new cases of myeloid leukemia in the U.S. each year, of which more than half are AML. Currently, the survival rate of myeloid leukemia patients is very low, despite aggressive chemotherapy and multiple, expensive hospitalizations.

PDL has adopted strategies designed to achieve improved efficacy of antibodies in certain cancers. First, PDL's anti-cancer antibodies are humanized, which allows for longer term treatment by minimizing the HAMA response, and potentially makes the antibodies more effective in killing

cancer cells. Second, the Company is initially focusing on treatment of blood cancers, such as myeloid leukemia, which may be more susceptible to antibody therapy than solid tumors because the cancer cells are more readily accessible. Third, PDL will often conduct trials of its antibodies in combination with, or following, other chemotherapeutic agents.

PDL is conducting a randomized Phase II/III trial of the SMART M195 Antibody for AML, which was initiated in June 1994. Patients in the trial first receive a specific regimen of chemotherapy. Those patients entering clinical remission are randomized either to observation or to receive 20 doses of SMART M195 given over an eight month period. The primary clinical endpoint is the median duration of disease-free survival, which in the absence of SMART M195 therapy has historically been about eight months. The study is planned to evaluate 112 patients in remission, but a substantially larger number will need to receive chemotherapy in order to reach that number of patients in remission. The study is currently expected to require several additional years to complete. The Company is exploring the addition of other U.S. or foreign medical centers and other actions to accelerate patient accrual in the study. See "Risk Factors."

SMART M195 is also being studied in a Phase II trial under a physician-sponsored IND at the Memorial Sloan-Kettering Cancer Center ("Sloan-Kettering"), in patients with acute promyelocytic leukemia ("APL"), one of several types of AML. This trial is designed to examine whether SMART M195 alone can eliminate minimal residual leukemia that remains after treatment with retinoic acid, a drug recently approved to treat APL. The effectiveness is measured by elimination of cells having the characteristic genetic mutation found in APL to below detectable levels ("molecular remission"). Four of seven evaluable newly diagnosed patients have entered complete molecular as well as clinical remission after therapy with retinoic acid and SMART M195 prior to receiving chemotherapy. In the more difficult relapsed setting, one of seven APL patients entered molecular remission. Normally, one to three rounds of expensive and toxic chemotherapy are required to bring newly diagnosed APL patients into molecular remission after therapy with retinoic acid. More patients and longer-term follow-up are necessary to evaluate the significance of the observed remissions. While these results suggest that SMART M195 may be biologically active in APL, the Company currently has no plans to conduct pivotal clinical trials in this subpopulation of AML patients.

A Phase I clinical trial of the SMART M195 Antibody linked to Bismuth-213, an alpha particle-emitting isotope, was initiated in 1996 under a physician-sponsored IND at Sloan-Kettering in advanced myeloid leukemia patients. The Company is supporting this trial to obtain preliminary evidence of the safety and potential efficacy of SMART M195-Bismuth-213 used as a single agent to induce remissions of advanced myeloid leukemia. Generators to produce the Bismuth-213 isotope are being supplied by PharmActinium Inc. and associated companies. The Company believes that this study is the first clinical trial of an antibody combined with an alpha-emitting isotope. In previous clinical trials of radiolabeled antibodies, the antibodies have been linked to radioisotopes that emit beta or gamma particles. Alpha particles release more energy over a shorter path than beta or gamma particles and, therefore, may be more effective in destroying the targeted cancer cells without damaging nearby normal cells.

Exclusive development and marketing rights for therapeutic uses of SMART M195 in Asia have been licensed to PDL's collaborative partner, Kanebo, Ltd. ("Kanebo"), which is currently conducting a Phase I trial in Japan in patients with AML.

OST 577 (HUMAN ANTI-HEPATITIS B ANTIBODY). OST 577 is a human antibody, developed using the trioma technology and licensed by PDL from Sandoz Pharma, Sandoz Ltd. and Sandoz Pharmaceuticals Corporation (collectively, "Novartis"). OST 577 binds to the major protein present on hepatitis B virus ("HBV"), the hepatitis B surface antigen. Infection with HBV is a common cause of liver disease. In most cases of infection, the patient's immune response is sufficient to ultimately eliminate the virus. However, an estimated 2% to 10% of HBV-infected patients become chronic carriers of the virus, and about one-fourth of these patients develop chronic hepatitis B ("CHB"), which is characterized by progressive liver damage and often cirrhosis and liver cancer. In the U.S. there are an estimated one million chronic carriers of HBV, with 300,000 new HBV infections and more than 10,000 patients hospitalized due to HBV infections each year. While interferon-alpha is approved in the U.S. for treatment of CHB, only 30-40% of treated patients respond to this treatment, which must be given over four months and has significant side effects.

In patients receiving liver transplants due to end-stage CHB, the virus remaining after the transplant usually will rapidly infect and in many cases destroy the new liver. An initial Phase I/II clinical trial of OST 577 enrolled five patients receiving liver transplants due to end-stage CHB. In the clinical trial, each patient received doses of OST 577 for up to 18 months after transplantation. Three of the five treated patients showed no evidence of viral recurrence more than one year after transplantation. The other two patients did develop recurrence but remained asymptomatic for four years, after which one of them developed symptoms.

A Phase I/II clinical trial of OST 577 has also been completed in 12 patients with CHB. OST 577 was well tolerated by patients treated at the two lower dose levels, but some reversible side effects were seen at the highest level. Key markers for HBV infection decreased at least temporarily by 50% or more in many of the patients during treatment. Specifically, such reductions were seen in 5 of 10 patients for liver enzyme levels; in 10 of 12 for hepatitis B surface antigen; and in 5 of 9 for viral DNA levels. Results obtained in early clinical trials may not be predictive of results in larger, later-stage trials. See "Risk Factors."

PDL's development partner, Boehringer Mannheim GmbH ("Boehringer Mannheim"), which has development and marketing rights for therapeutic applications to OST 577 outside of North America, has primary clinical development responsibility for this potential product. In 1996, Boehringer Mannheim initiated a multinational, controlled Phase II trial in patients with CHB, and has stated that it is designing a Phase II/III trial in patients receiving liver transplants for end-stage liver disease due to CHB. The Phase II trial in CHB is planned to enroll 200 patients and will evaluate OST 577 both as a single agent and in combination with interferon-alpha. PDL is considering the possibility of conducting independent clinical trials with designs complementary to the Boehringer Mannheim trials. In addition, Novartis has certain rights to co-promote or co-market this antibody in North America or to receive royalties on product sales. See "--Collaborative and Licensing Arrangements."

PROTOVIR(TM) (HUMAN ANTI-CMV ANTIBODY). PROTOVIR is a human antibody, derived using the trioma technology, that binds to all tested strains of human cytomegalovirus ("CMV"). CMV is an important cause of morbidity and death in patients with suppressed immune systems, such as AIDS patients and recipients of solid organ and bone marrow transplants ("BMT").

Bone marrow transplantation. In BMT patients, CMV can cause often fatal infections, such as pneumonia. Many transplant centers treat patients with pooled human immunoglobulin preparations in an attempt to prevent CMV infection, despite the high cost and limited efficacy of this treatment. The Company has completed enrollment in a randomized, placebo-controlled, double-blinded Phase II trial to assess the potential safety and efficacy of PROTOVIR for the prevention of CMV infections in allogeneic (non-self) bone marrow transplant patients. The study is comparing two dose levels of PROTOVIR against placebo in approximately 168 evaluable patients. The primary endpoint of this study is the incidence of CMV infections during the 100 days following the BMT. Historically, such infections occur in 50-60% of these patients. Results of the study are expected to be available in the first half of 1997 but there can be no assurance that the results of the trial will be favorable. See "Risk Factors."

CMV retinitis. The potential safety and efficacy of PROTOVIR was evaluated in a Phase II/III clinical trial conducted by NEI SOCA for the treatment of CMV retinitis, a common ophthalmic condition in AIDS patients that often leads to blindness. In August 1996, the National Eye Institute Studies of Ocular Complications of AIDS ("NEI SOCA"), acting on the recommendation of an independent data and safety monitoring board, halted the study based on lack of evidence of efficacy. Concurrently with the NEI SOCA trial, PROTOVIR also was being evaluated in a Phase II clinical trial being conducted by National Institute of Allergy and Infectious Disease, Division of AIDS, AIDS Clinical Trials Group ("NIAID ACTG") for treatment of CMV retinitis. Based on the NEI SOCA findings and actions, enrollment in the Phase II trial had been suspended, and the trial was recently terminated.

Exclusive rights for the therapeutic application of this antibody outside of North America and Asia have been licensed to Boehringer Mannheim. In addition, Novartis, from whom PDL licensed the antibody, has certain rights to co-promote or co-market this antibody in North America and Asia or to receive royalties on product sales. See "--Collaborative and Licensing Arrangements."

#### PRECLINICAL PRODUCT CANDIDATES

The following table summarizes the potential therapeutic indications and commercial rights for certain of PDL's preclinical product candidates. "Preclinical" development includes in vitro testing, efficacy and toxicology testing in animals, process development and manufacturing scale-up prior to initiation of clinical trials. The Company has other compounds in development in addition to those described in the table below and is conducting research in other areas. The development and commercialization of the Company's preclinical product candidates are subject to numerous risks and uncertainties. See "Risk Factors."

PRODUCT	POTENTIAL THERAPEUTICS INDICATIONS	COMMERCIAL RIGHTS(1)
AUTOIMMUNE AND INFLAMMATORY CONDITIONS		
SMART Anti-L-Selectin Antibody	Trauma, adult respiratory distress syndrome ("ARDS"), reperfusion injury	PDL and Boehringer Mannheim
SMART Anti-E/P-	Stroke, trauma, certain autoimmune	PDL



Selectin Antibody	diseases (e.g. psoriasis), asthma	
SMART Anti-CD3 Antibody	Organ transplant rejection and certain autoimmune diseases	PDL
SMART Anti-Gamma Interferon Antibody	Certain autoimmune diseases (e.g. inflammatory bowel disease)	PDL
CANCER		
SMART ID10 Antibody	B-cell lymphoma	PDL
SMART ABL 364 Antibody	Certain epithelial cell cancers including breast, lung and colon	PDL and Novartis
VIRAL INFECTIONS		
Human Anti-Varicella Zoster Antibody	Shingles (herpes zoster)	PDL and Novartis
Human Anti-Herpes Antibody	Neonatal and genital herpes	PDL and Novartis

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(1) The development and marketing rights for each of these products differ. See "--Collaborative and Licensing Arrangements."

AUTOIMMUNE DISEASE AND INFLAMMATION. Recent discoveries in immunology have made possible a new therapeutic approach to inflammation resulting from such causes as injury or autoimmune disease. Certain proteins called adhesion molecules, located on the surface of various types of cells, play a key role in inflammation by directing the movement of white blood cells from the bloodstream into the sites of tissue inflammation. In laboratory experiments conducted by PDL and others, antibodies have been shown to block the function of these adhesion molecules, and in animal models these anti-adhesion antibodies have been shown to be effective at reducing many types of inflammation.

PDL has developed several SMART antibodies against adhesion molecules. One of these antibodies, the SMART Anti-L-Selectin Antibody, binds to L-selectin, an adhesion molecule on the surface of white blood cells. The Company believes that potential indications for this antibody may include trauma, ARDS, reperfusion injury (e.g., due to myocardial infarction or stroke) and possibly certain autoimmune diseases. In studies conducted by independent investigators, treatment with the SMART Anti-L-Selectin Antibody resulted in a statistically significant improvement in survival in a primate model that simulates severe trauma. Boehringer Mannheim, which has licensed rights to this antibody outside of North America and Asia from PDL, plans to begin clinical trials of the antibody in 1997, with an initial indication of trauma.

PDL's SMART Anti-E/P-Selectin Antibody binds to two different adhesion molecules, E and P-selectin, that occur on the surface of the cells on the inner lining of blood vessels. The Company believes that potential indications for such an antibody may include stroke, trauma, certain

autoimmune diseases, psoriasis and asthma. The Company is developing additional forms of the SMART Anti-E/P-Selectin Antibody, from which it intends to select the final form.

PDL's SMART Anti-CD3 Antibody binds to the CD3 antigen, a key receptor for stimulation of T cells. The Company believes that potential indications for this antibody may include treatment of organ transplant rejection and certain autoimmune diseases.

PDL's SMART Anti-Gamma-Interferon Antibody binds to and neutralizes gamma interferon, a lymphokine that stimulates several types of white blood cells. The Company believes that potential indications for this antibody may include inflammatory bowel disease, multiple sclerosis, and other autoimmune diseases.

CANCER. B-cell lymphomas, like leukemias, are a type of blood cancer that the Company believes may be accessible to antibody-based treatments. PDL has developed the SMART 1D10 Antibody, which binds to many malignant B cells, and is currently evaluating it in preclinical studies. The Company is also evaluating a bispecific antibody that incorporates the SMART 1D10 Antibody. To date bispecific antibodies developed by PDL have not been tested in humans.

PDL's SMART ABL 364 Antibody has potential for the treatment of many solid tumors, including colon, lung and breast cancer. Initial laboratory tests have shown that the SMART ABL 364 Antibody, in conjunction with other components of the immune system, can kill cancer cells.

VIRAL INFECTIONS. Varicella zoster virus ("VZV") is the virus responsible for causing chickenpox and shingles (herpes zoster). Shingles, a painful blistering condition of the skin, results from reactivation of the latent VZV that initially infected the patient years earlier. In the U.S., 10-20% of the population will develop shingles, with the incidence and severity increasing with age. A significant percentage of patients with shingles experience post-herpetic neuralgia, a very painful nerve condition which may last from weeks to years in some patients. Current anti-viral therapies are moderately effective in treating shingles, but have little or no effect on post-herpetic neuralgia. PDL's Human Anti-Varicella Zoster Antibody effectively neutralizes all tested strains of VZV in in vitro studies.

Herpes simplex virus ("HSV") causes a painful recurring genital infection. The virus also causes neonatal herpes, an uncommon but very serious disease of newborn infants. PDL's Human Anti-Herpes Antibody binds to and effectively neutralizes all strains of HSV tested, and is well-tolerated and non-immunogenic in primates. In animal studies sponsored by the National Institute of Allergy and Infectious Disease Collaborative Antiviral Studies Group ("NIAID-CASG"), the antibody effectively protected mice from a lethal herpes infection when administered up to 72 hours after the virus. The Company believes that competition from antiviral drugs and the present reimbursement environment may limit the market opportunities for the Human Anti-Herpes Antibody in treating genital herpes. The Company is currently exploring the possibility of providing the antibody to NIAID-CASG under a Cooperative Research and Development Agreement primarily for studies in neonatal herpes.

#### PDL TECHNOLOGIES

BACKGROUND ON ANTIBODIES. Antibodies are protective proteins released by the immune system's B cells, a type of white blood cell, in response to the presence of a foreign substance in the body, such as a virus. B cells produce millions of different kinds of antibodies, which have slightly

different shapes that enable them to bind to and thereby inactivate different targets. Antibodies of identical molecular structure that bind to a specific target are called monoclonal antibodies. Typically mice have been used to produce monoclonal antibodies to a wide variety of molecular targets, including targets to which the human body does not normally produce antibodies. In particular, many murine antibodies have been developed as potential therapeutics to neutralize viruses, destroy cancer cells or inhibit immune function.

Although murine monoclonal antibodies are relatively easy to generate, they have significant drawbacks as therapeutics. Murine antibodies have a relatively short half-life in human patients, requiring them to be administered frequently. Moreover, murine antibodies are not adapted to work effectively with the human immune system and therefore often have limited ability to destroy the target, such as cancer cells. Most importantly, when injected into human patients, a murine antibody is usually recognized by the body's immune system as being foreign. The immune system therefore responds with a HAMA response, which rapidly neutralizes the murine antibody and renders it ineffective for further therapy. These problems have largely prevented murine antibodies from fulfilling their promise as therapeutics.

More recently, improved forms of antibodies, such as humanized and chimeric antibodies, have been developed using recombinant DNA technology. These new antibodies can minimize or avoid many of the problems associated with murine antibodies and have led to a resurgence of interest in antibody therapeutics by the pharmaceutical and biotechnology industries. As a result of these advances, many recombinant antibodies are now progressing into clinical trials. In a list of biotechnology medicines under clinical development published in 1996 by the Pharmaceutical Research and Manufacturers of America, antibodies comprised the single largest category, representing 78 of 284 products listed. In particular, PDL is aware of more than twenty recombinant antibodies in clinical trials, including several antibodies addressing large markets that are being developed by major pharmaceutical companies. Furthermore, ReoPro, a recombinant antibody fragment developed by Centocor for reducing complications in patients undergoing angioplasty is being marketed by Eli Lilly and Company.

**PDL'S SMART ANTIBODY TECHNOLOGY.** PDL believes that its patented SMART antibody technology has positioned the Company as a leader in the development of therapeutic antibodies that overcome the problems associated with murine antibodies. PDL's SMART antibodies are human-like antibodies designed using structural information from promising murine antibodies to capture the benefits of such antibodies while overcoming many of their limitations in treating humans. Clinical trials and preclinical studies have shown that PDL's SMART antibodies generally avoid a HAMA response and have a longer half-life than murine antibodies.

Every antibody contains two regions, a variable domain that binds to the target and a constant domain that interacts with other portions of the immune system. The variable domain is composed of the complementarity determining regions ("CDRs") that directly bind to the target and the framework region that holds the CDRs in position and helps maintain their required shape. Researchers have used genetic engineering to construct "humanized" antibodies that consist of the CDRs from a murine antibody with the framework region and constant domain from a human antibody. However, when the CDRs from the murine antibody are combined with the framework of the human antibody, the human framework often distorts the shape of the CDRs so they no longer bind well to the target. Therefore, it is usually necessary to substitute one or more amino acids from the murine antibody into the framework of the humanized antibody for it to maintain the binding ability of the murine antibody.

A SMART antibody is a humanized antibody designed by using PDL's proprietary computer technology to guide the choice of substitutions of amino acids from the murine antibody into the human antibody framework, based on structural information derived from the murine antibody. The construction of a SMART antibody starts with the identification of a murine antibody that has demonstrated favorable results in laboratory, animal or human studies. A model of the murine antibody is generated using proprietary computer modeling software that predicts the shapes of antibodies and eliminates the need for more time-consuming laboratory techniques. The resulting model is carefully analyzed to identify the few key amino acids in the framework most responsible for maintaining the shape of the CDRs. Software developed at PDL as well as the experience of the Company's computational chemists is important in this analysis. These few key murine amino acids are substituted into the human framework of the SMART antibody along with the murine CDRs in order to maintain their ability to bind well to the target. The resulting SMART antibody retains most or all of the binding ability of the murine antibody, but is about 90% human.

In 1996, the Company was issued U.S. and European patents which cover, in most circumstances, humanized antibodies that contain amino acid substitutions from the murine antibody in their framework. The Company believes that most humanized antibodies require such amino acid substitutions in order to maintain high binding ability. The patents also cover pharmaceutical compositions containing such humanized antibodies and other aspects of PDL's SMART antibody technology. PDL has filed similar patent applications in Japan and other countries. See "--Patents and Proprietary Technology."

**OTHER PDL TECHNOLOGIES.** In addition to its SMART antibody technology, PDL employs additional antibody-based drug development technologies to overcome shortcomings of murine antibodies. The Company is also pursuing a rational drug design program that leverages its computer expertise to potentially develop new drug candidates.

**Human Antibodies.** The use of fully human monoclonal antibodies is another approach to avoiding many of the problems associated with murine antibodies. In April 1993, PDL exclusively licensed from Novartis its patented "trioma" technology to generate certain human antibodies, along with four human anti-viral antibodies. Two of these human antibodies, OST 577 and PROTOVIR, are in clinical development. The trioma technology is used to produce fully human antibodies against viruses and potentially other organisms which infect humans. A key aspect of the technology is the use of a mouse-human hybrid cell line as the fusion partner to immortalize human antibody-producing B cells. Trioma cell lines generated in this manner often stably produce human antibodies. As with SMART antibodies, clinical trials and preclinical studies have shown that PDL's human antibodies generally avoid a HAMA response and have a longer half-life than murine antibodies. See "--Collaborative and Licensing Arrangements."

**New Technologies.** The Company is pursuing a rational drug design program focusing on small molecules by extending the Company's computer modeling tools originally developed for its SMART antibody program. Rational drug design utilizes computer models of proteins and their interactions with smaller molecules in order to accelerate discovery and optimization of new drug compounds. Although PDL's technology is at an early stage, the Company believes that this application of its modeling algorithms may ultimately be used to develop non-antibody drug candidates. In addition, the Company plans to extend its research activities into other new areas, potentially including the development of novel classes of antibiotics for treating infections.

## BUSINESS STRATEGY

PDL's objective is to leverage its research expertise and intellectual property in the field of antibodies to become a profitable, research-based biopharmaceutical company that manufactures and, in North America, markets its own products. PDL's strategy to achieve this objective involves the following elements:

**Expand Product Portfolio.** The Company believes that its SMART antibody technology is capable of converting essentially any promising murine antibody into a humanized antibody better suited for therapeutic use. As a result, the Company has been able to rapidly develop a broad portfolio of product candidates with potential applications to the prevention and treatment of autoimmune and inflammatory conditions, cancers, viral infections, and other diseases. This diverse product pipeline enhances commercial opportunities and reduces the Company's reliance on individual products.

**Establish Collaborative Arrangements.** The Company actively seeks corporate partnerships with pharmaceutical companies, and to date has entered into partnerships with eight such companies. Typically, the Company receives a licensing fee, research funding and/or milestone payments, and royalties on potential product sales in return for certain marketing rights to one or more potential products developed at PDL. These revenues help to defray PDL's own product development expenses, while the partner typically bears significant direct responsibility for certain product development activities and expenses.

**Leverage Patent Position.** An important new aspect of PDL's business strategy is to obtain both near-term revenues and potential royalties by licensing limited rights under its issued humanized antibody patents and corresponding patent applications to other companies developing humanized antibodies. In December 1996 and February 1997, PDL entered into its first two such licensing agreements, with Sankyo Co., Ltd. ("Sankyo") and Biogen, Inc. ("Biogen"), respectively. The Company's patents are also helpful in inducing other companies to enter into collaborative relationships with the Company, in which PDL uses its proprietary technology to develop SMART antibodies based on promising murine antibodies developed by the other companies. PDL has entered into six such relationships, including four since December 1995. In addition to paying PDL license and other fees, in some cases the other companies have granted PDL options to obtain North American co-promotion rights.

**Retain and Obtain North American Marketing Rights.** Where appropriate, PDL retains and obtains North American marketing or co-promotion rights to many of its potential products. This strategy provides the Company with future opportunities to generate greater revenues.

## COLLABORATIVE AND LICENSING ARRANGEMENTS

**Roche.** In 1989, PDL entered into agreements with Roche to collaborate on the research and development of SMART antibodies against the IL-2 receptor, including Zenapax. Under these agreements, Roche has exclusive, worldwide rights to manufacture, market and sell Zenapax. The arrangement provides for research and development funding, milestone and bonus payments and future royalties that could be received by PDL under the agreements. Most of such milestone and bonus payments have already been received from Roche, and Roche has completed its research funding to PDL under these agreements, although Roche will continue to fund its own clinical development activities.

In October 1996, PDL entered into a collaborative agreement with Roche providing for the humanization by PDL of a murine antibody that has potential for treating rheumatoid arthritis. PDL received a licensing and signing fee and can earn milestone payments and royalties on potential product sales of this compound by Roche.

Corange/Boehringer Mannheim. In October 1993, PDL and Corange entered into a collaborative arrangement providing for the grant of exclusive marketing rights in certain territories for a number of products in development. In consideration for these rights, Corange paid to PDL a \$10 million licensing and signing fee and \$30 million in research and development funding over three years and agreed to certain milestone payments and the payment of royalties on future product sales. As part of this arrangement, PDL and Corange further committed to negotiate additional agreements under which each company would manufacture and supply the other with certain of the antibodies covered by the collaborative arrangement for use in clinical trials and potential future product sales. As part of this collaborative arrangement, PDL and Corange also entered into a stock purchase agreement, a standstill agreement and a registration rights agreement pursuant to which Corange invested an aggregate of \$75 million in PDL through the purchase of approximately 2.433 million newly issued shares of common stock in December 1993 and 1994. Product rights and duties under this arrangement were subsequently assigned and delegated to Corange's subsidiary, Boehringer Mannheim.

In 1994 and 1995, the parties amended certain of the agreements in this collaborative arrangement. As part of these amendments, the parties agreed to terminate Boehringer Mannheim's rights to certain preclinical products. As a result, Boehringer Mannheim currently has exclusive marketing rights outside of North America and Asia for PROTOVIR and the SMART Anti-L-Selectin Antibody, exclusive marketing rights outside of North America for OST 577, and North American co-promotion rights and exclusive marketing rights outside of North America for an additional antibody to an undisclosed cardiovascular target. The parties further agreed to allocate primary responsibility for clinical development and manufacturing of PDL's Human Anti-Hepatitis B Antibody to Boehringer Mannheim and for clinical development and manufacturing of PROTOVIR to PDL. In addition, as part of these amendments, Boehringer Mannheim agreed to provide certain clinical material manufactured by Boehringer Mannheim to PDL without charge for PDL's use in preclinical and clinical research. The amendment also provides that Boehringer Mannheim will assume the development and manufacturing expenses related to the OST 577 Human Anti-Hepatitis B Antibody, subject to reimbursement of certain clinical trial expenses by PDL of up to \$2 million toward Phase II studies and up to \$8.8 million for Phase III studies, if certain conditions are met. As a result of these amendments, PDL is no longer eligible to receive milestone payments with respect to OST 577 and PROTOVIR. In the first quarter of 1996, Boehringer Mannheim made a milestone payment to PDL with respect to the SMART Anti-L-Selectin Antibody.

Yamanouchi. In February 1991, PDL and Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi") entered into a collaborative agreement providing for the humanization of a murine anti-platelet (anti-gpIIb/IIIa) antibody developed by Yamanouchi for potentially treating certain cardiovascular disorders. PDL has completed humanization of the antibody and Yamanouchi is currently in the preclinical stage of development with this humanized antibody. Yamanouchi has exclusive, worldwide rights to the resulting SMART antibody and is responsible for all clinical trials and for obtaining necessary government regulatory approvals. The agreement provides for milestone payments, all of which have been received, and royalties on future product sales.

Kanebo. In February 1992, PDL and Kanebo entered into a product licensing agreement whereby Kanebo received an exclusive license to the SMART M195 Antibody for therapeutic uses in certain Asian countries including Japan in exchange for a licensing and signing fee, research funding, milestone payments and royalties on potential product sales. The research funding period under the agreement expired in September 1993. Also in September 1993 and May 1995, PDL entered into purchase agreements with Kanebo pursuant to which PDL sold Kanebo preclinical and clinical quantities of the SMART M195 Antibody. Kanebo is currently conducting a Phase I clinical trial of the SMART M195 Antibody in Japan.

Novartis. In April 1993, PDL and Novartis entered into agreements providing for the grant of exclusive licenses to PDL of four human anti-viral antibodies and other related technology and antibodies from Novartis. The human monoclonal antibodies target cytomegalovirus, the hepatitis B virus, herpes simplex viruses, and varicella zoster virus. In addition, PDL received an exclusive license to the SMART ABL 364 Antibody, an antibody previously humanized by PDL for Novartis, and the related murine antibody, ABL 364, of Novartis. This arrangement also included exclusive licenses to the Novartis trioma human antibody technology and patents as well as the purchase of certain antibody supplies and related manufacturing equipment. In consideration for the licenses and assets transferred, PDL initially paid Novartis \$5 million and agreed to provide up to an additional \$5 million in future milestone payments in the event of certain product approvals under the agreements.

Under the terms of the Novartis agreements, PDL has the right to manufacture and market the antibodies acquired from Novartis throughout the world. Novartis retained certain co-promotion and co-marketing rights, and rights to royalties on sales by PDL of licensed products in countries where Novartis does not sell these antibodies with PDL under the co-promotion and co-marketing arrangements. In November 1993, PDL paid Novartis an additional \$2.75 million to amend the April 1993 agreement relating to the human antibodies in order to terminate certain of Novartis' co-promotion and co-marketing rights in countries outside of the U.S., Canada and Asia and to reduce royalties Novartis may earn from the sale of human antibody products in countries outside of the U.S., Canada and Asia.

Mochida. In December 1995, PDL and Mochida Pharmaceutical Co., Ltd., ("Mochida") entered into a collaborative agreement providing for the humanization by PDL of a murine antibody that has potential for treating certain infectious diseases. To date, PDL has received a licensing and signing fee of \$1 million and a milestone payment and can earn a further milestone payment and royalties on potential product sales of this compound by Mochida. In addition, PDL has an option to co-promote the compound in North America.

Japanese Collaborator. In September 1996, PDL entered into a collaborative agreement with another Japanese company providing for the humanization by PDL of a murine antibody that has potential for treating cancer. PDL received a licensing and signing fee of \$1 million and can earn milestone payments and royalties on potential product sales of this compound by the Japanese company. PDL also has an option to co-promote the compound in North America. The name of the Japanese company has not been disclosed.

Sankyo. In December 1996, PDL entered into a patent license agreement with Sankyo pursuant to which PDL granted a worldwide, nonexclusive license under its humanized antibody patents to that company for an antibody to a specific target antigen. PDL received a \$1 million licensing and

signing fee and will receive royalties on potential product sales. The name of the antibody target has not been disclosed.

Genetics Institute. In December 1996, PDL and Genetics Institute, Inc. ("Genetics Institute"), a wholly-owned subsidiary of American Home Products Corporation, entered into a collaborative agreement pursuant to which PDL will initially develop three humanized monoclonal antibodies based on murine antibodies developed by Genetics Institute that modulate the immune co-stimulatory pathway. In addition, Genetics Institute received a worldwide, nonexclusive license for those antibodies under PDL's humanized antibody patents. PDL received a \$2.5 million licensing and signing fee and is entitled to receive milestone payments and royalties on potential product sales. In addition, PDL received an option to co-promote the products in North America (U.S. and Canada). The agreement contemplates that PDL may collaborate with Genetics Institute to humanize additional antibodies in the field.

Biogen. In February 1997, PDL entered into a patent license agreement with Biogen pursuant to which PDL granted a worldwide, nonexclusive license under its humanized antibody patents to that company for an antibody to a specific target antigen. PDL received a \$1 million licensing and signing fee and will receive royalties on potential product sales. The name of the antibody target has not been disclosed.

For a discussion of certain risks related to the Company's collaborations, see "Risk Factors."

Molecular Applications Group. PDL has licensed from Molecular Applications Group exclusive rights to certain protein modeling software. PDL uses this software in designing its SMART antibodies. PDL paid an initial license fee upon execution of this license and is obligated to pay an additional fixed fee each year, subject to certain adjustments.

Certain Patent Licenses. In July 1989, PDL obtained a nonexclusive license under certain patents from the Medical Research Council of the United Kingdom ("MRC License") to an antibody "reshaping" process, which allows the exchange of complementarity determining regions from different antibodies. PDL paid an initial license fee upon execution of the MRC License and is obligated to pay royalties on sales of products covered by the licensed patents. Each of PDL's SMART antibody products may be within the scope of the MRC License. In addition, the MRC License includes a sublicense to the Boss Patent held by Celltech relating to PDL's current process for producing SMART antibodies. In October 1994, PDL obtained a non-exclusive license from Celltech to the Boss Patent relating to PDL's current process for producing certain other PDL potential products, including OST 577 and PROTOVIR.

#### MANUFACTURING

PDL currently leases approximately 45,000 square feet housing its manufacturing facility in Plymouth, Minnesota. The Company intends to manufacture the SMART M195 Antibody, PROTOVIR, if clinical trials warrant continued development, and some of its other products in preclinical development. PDL intends to continue to manufacture potential products for use in preclinical studies and clinical trials using this manufacturing facility in accordance with standard procedures that comply with cGMP and appropriate regulatory standards. Roche is responsible for manufacturing Zenapax and Boehringer Mannheim is responsible for manufacturing OST 577.

In order to obtain regulatory approvals and to expand its capacity to produce its products for commercial sale at an acceptable cost, PDL will need to improve and expand its existing manufacturing capabilities and demonstrate to the FDA its ability to manufacture its products using controlled, reproducible processes. Accordingly, the Company is evaluating plans to improve and expand the capacity of its current facility. Such plans, if instituted, would result in substantial costs to the Company and may require a suspension of manufacturing operations during construction. See "Risk Factors."



## PATENTS AND PROPRIETARY TECHNOLOGY

The Company's success is significantly dependent on its ability to obtain patent protection for its products and technologies and to preserve its trade secrets and operate without infringing on the proprietary rights of third parties. PDL files and prosecutes patent applications to protect its inventions. No assurance can be given that the Company's pending patent applications will result in the issuance of patents or that any patents will provide competitive advantages or will not be invalidated or circumvented by its competitors. Moreover, no assurance can be given that patents are not issued to, or patent applications have not been filed by, other companies which would have an adverse effect on the Company's ability to use, manufacture or market its products or maintain its competitive position with respect to its products. Other companies obtaining patents claiming products or processes useful to the Company may bring infringement actions against the Company. As a result, the Company may be required to obtain licenses from others or not be able to use, manufacture or market its products. Such licenses may not be available on commercially reasonable terms, if at all.

Patents in the U.S. are issued to the party that is first to invent the claimed invention. Since patent applications in the U.S. are maintained in secrecy until patents issue, PDL cannot be certain that it was the first inventor of the invention covered by its pending patent applications or patents or that it was the first to file patent applications for such inventions.

The patent positions of biotechnology firms generally are highly uncertain and involve complex legal and factual questions. No consistent policy has emerged regarding the validity and scope of claims in biotechnology patents, and courts have issued varying interpretations in the recent past, and legal standards concerning validity, scope and interpretation of claims in biotechnology patents may continue to evolve. Even issued patents may later be modified or revoked by the PTO, EPO or the courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country, and claim interpretation and infringement laws vary among countries, so the extent of any patent protection is uncertain and may vary in different countries.

PDL has several patents and has exclusively licensed certain patents regarding the trioma technique and related antibodies from Novartis. In particular with respect to humanization technology, in June 1996, PDL was issued a U.S. patent covering Zenapax and certain related antibodies against the IL-2 receptor. In addition, PDL is currently prosecuting other patent applications with the U.S. Patent and Trademark Office ("PTO") and in other countries, including members of the European Patent Convention, Canada, Japan and Australia. The patent applications are directed to various aspects of PDL's SMART and human antibodies, antibody technology and other programs, and include claims relating to compositions of matter, methods of preparation and use of a number of PDL's compounds. However, PDL does not know whether any pending applications will result in the issuance of patents or whether such patents will provide protection of commercial significance. Further, there can be no assurance that PDL's patents will prevent others from developing competitive products using related technology.

In January and December 1996, PDL was issued patents by the European Patent Office ("EPO") and PTO, respectively. PDL believes the patent claims cover Zenapax and, based on its review of the scientific literature, most humanized antibodies. The terms of such patents continue until 2013 in the U.S. and 2009 in Europe, subject to possible patent term extensions. The EPO patent applies in the United Kingdom, Germany, France, Italy and eight other Western European countries. The EPO (but not PTO) procedures provide for a nine-month opposition period in which other parties may submit arguments as to why the patent was incorrectly granted and should be withdrawn or limited. The entire opposition process, including appeals, may take several years to complete, and during this

lengthy process, the validity of the EPO patent will be at issue, which may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on this patent. Eighteen notices of opposition to PDL's European patent were filed during the opposition period, including oppositions by major pharmaceutical and biotechnology companies, which cited references and made arguments not considered by the EPO and PTO before grant of the respective patents. The oppositions currently are being reviewed by the Company's patent counsel. PDL intends to vigorously defend the European and, if necessary, the U.S. patent; however there can be no assurance that the Company will prevail in the opposition proceedings or any litigation contesting the validity or scope of these patents. In addition, such proceedings or litigation, or any other proceedings or litigation to protect the Company's intellectual property rights or defend against infringement claims by others, could result in substantial costs and a diversion of management's time and attention, which could have a material adverse effect on the business and financial condition of the Company.

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to PDL's programs. Some of these applications or patents may be competitive with PDL's applications or contain claims that conflict with those made under PDL's patent applications or patents. Such conflict could prevent issuance of patents to PDL, provoke an interference with PDL's patents or result in a significant reduction in the scope or invalidation of PDL's patents, if issued. An interference is an administrative proceeding conducted by the PTO to determine the priority of invention and other matters relating to the decision to grant patents. Moreover, if patents are held by or issued to other parties that contain claims relating to PDL's products or processes, and such claims are ultimately determined to be valid, no assurance can be given that PDL would be able to obtain licenses to these patents at a reasonable cost, if at all, or to develop or obtain alternative technology.

The Company is aware that Celltech Limited ("Celltech") has been granted a patent by the EPO covering certain humanized antibodies, which PDL has opposed, and Celltech has announced that it has received a notice of allowance of a corresponding U.S. patent (the "U.S. Adair Patent") and expects the patent to issue in early 1997. Because U.S. patent applications are maintained in secrecy, PDL cannot review the scope of the claims in the U.S. Adair Patent. Accordingly, there can be no assurance that such claims would not cover any of PDL's SMART antibodies or be competitive with or conflict with claims in PDL's patents or patent applications. If the U.S. Adair Patent issues and if it is determined to be valid and to cover any of PDL's SMART antibodies, there can be no assurance that PDL would be able to obtain a license on commercially reasonable terms, if at all. If the claims of the U.S. Adair Patent conflict with claims in PDL's patents or patent applications, there can be no assurance that an interference would not be declared by the PTO, which could take several years to resolve and could involve significant expense to the Company. Also, such conflict could prevent issuance of patents to PDL relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of PDL's patents, if issued. Moreover, uncertainty as to the validity or scope of patents issued to PDL relating generally to humanization of antibodies may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on this patent.

PDL has obtained a nonexclusive license under a patent held by Celltech (the "Boss Patent") relating to PDL's current process for producing SMART and human antibodies. An interference proceeding was declared in early 1991 by the PTO between the Boss Patent and a patent application filed by Genentech to which PDL does not have a license. PDL is not a party to the

interference proceeding, and the timing and outcome of the proceeding or the scope of any patent that may be subsequently issued cannot be predicted. If the Genentech patent application were held to have priority over the Boss Patent, and if it were determined that PDL's processes and products were covered by a patent issuing from such patent application, PDL may be required to obtain a license under such patent or to significantly alter its processes or products. There can be no assurance that PDL would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on PDL.

The Company is aware that Lonza Biologics, Inc. has a patent issued in Europe to which PDL does not have a license (although Roche has advised the Company that it has a license covering Zenapax), which may cover the process the Company uses to produce its potential products. If it were determined that PDL's processes were covered by such patent, PDL may be required to obtain a license under such patent or to significantly alter its processes or products, if necessary to manufacture or import its products in Europe. There can be no assurance that PDL would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on the business and financial condition of the Company.

Also, Genentech has patents in the U.S. and Europe that relate to chimeric antibodies. The European patent is currently in the opposition process. If Genentech were to assert that the Company's SMART antibodies infringe these patents, PDL may have to choose whether to seek a license or to challenge in court the validity of such patents or Genentech's claim of infringement. There can be no assurance that PDL would be successful in either obtaining such a license on commercially reasonable terms, if at all, or that it would be successful in such a challenge of the Genentech patents, and the failure to do so would have a material adverse effect on the business and financial condition of the Company.

In addition to seeking the protection of patents and licenses, PDL also relies upon trade secrets, know-how and continuing technological innovation which it seeks to protect, in part, by confidentiality agreements with employees consultants, suppliers and licensees. There can be no assurance that these agreements will not be breached, that PDL would have adequate remedies for any breach or that PDL's trade secrets will not otherwise become known or independently developed by competitors.

#### GOVERNMENT REGULATION

The manufacturing, testing and marketing of PDL's products are subject to regulation by numerous governmental authorities in the U.S. and other countries based upon their safety and efficacy. In the U.S., pharmaceutical (biologic) products are subject to rigorous FDA regulation. The federal Food, Drug and Cosmetic Act ("FD&C Act"), Public Health Service Act ("PHS Act") and other federal, state and local regulations govern the manufacture, testing, labeling, storage, record keeping, clinical and nonclinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and the expenditure of substantial resources. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all.

In addition to the requirement for FDA approval of each pharmaceutical product, each pharmaceutical product manufacturing facility must be registered with, and approved by, the FDA. The manufacturing and quality control procedures must conform to cGMP in order to receive FDA approval. Pharmaceutical product manufacturing establishments are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the U.S., foreign manufacturing establishments must comply with cGMP and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in such countries under reciprocal agreements with the FDA. Moreover, pharmaceutical product manufacturing facilities may also be regulated by state, local and other authorities.

For marketing of pharmaceutical products outside the U.S., PDL is subject to foreign regulatory requirements governing marketing approval, and FDA and other U.S. export provisions should the pharmaceutical product be manufactured in the U.S. Requirements relating to the manufacturing, conduct of clinical trials, product licensing, promotion, pricing and reimbursement vary widely in different countries. Difficulties or unanticipated costs or price controls may be encountered by PDL or its licensees or its marketing partners in their respective efforts to secure necessary governmental approvals to market the potential pharmaceutical products, which could delay or preclude PDL or its licensees or its marketing partners from marketing their potential pharmaceutical products.

The basic steps required by the FDA before a new pharmaceutical product for human use may be marketed in the U.S. include (i) preclinical laboratory and animal tests, (ii) submission to the FDA of an application for an Investigational New Drug ("IND") which must be reviewed by the FDA before clinical trials may begin, (iii) completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the pharmaceutical product for its intended use, (iv) as of May 1996 for therapeutic monoclonal antibodies, submission of a Biologics License Application ("BLA") to the FDA, and (v) FDA approval of the BLA prior to any commercial sale or shipment of the pharmaceutical product.

Preclinical tests for safety are conducted in the laboratory and in animals in compliance with FDA good laboratory practices regulations and other additional tests are conducted to assess the potential safety and biological activity of the pharmaceutical product in order to support a sponsor's contention that it is reasonably safe to conduct proposed clinical investigations. The results of these studies are submitted to the FDA as part of an IND. Testing in humans may begin 30 days after filing an IND unless the FDA requests additional information or raises questions or concerns that must be resolved before the FDA will permit the study to proceed. In such cases, there can be no assurance that resolution will be achieved in a timely manner, if at all.

Clinical trials are conducted in accordance with good clinical practices based on regulations promulgated by the FDA and under protocols that include detail on the objectives of the trial, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of an IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB") at each of the medical institutions at which the trial will be conducted. There can be no assurance that submission of a protocol to an IRB or an IND to the FDA will result in the initiation or completion of a clinical investigation. Clinical trials are typically conducted in three sequential phases, although the phases may overlap. In Phase I, the pharmaceutical product is typically tested in a small number of healthy people or patients to initially determine safety, dose tolerance (including side effects associated with increasing doses), metabolism, distribution and excretion. Phase II usually involves studies in a

limited patient population to obtain a preliminary determination of efficacy, to identify an optimal dose and to further identify safety risks. Phase III trials are larger, multi-center trials undertaken to provide further confirmation of efficacy and provide additional safety information in a specific patient population. The FDA reviews the results of the trials and may discontinue them at any time for safety reasons or other reasons if they were deemed to be non-compliant with FDA regulations. There can be no assurance that Phase I, II or III clinical trials will be completed successfully within any specific time period, if at all, with respect to any of the Company's or its collaborators' pharmaceutical products, each of which is subject to such testing requirements.

Recently, the FDA has been engaged in regulatory reform efforts aimed at reducing the regulatory burden on manufacturers of certain biotechnology products. For example, in May 1996, the FDA issued regulations that eliminate the previous requirement of a separate establishment license application, in addition to the product license application, for certain categories of biotechnology products, including the pharmaceutical products of the Company. Furthermore, the FDA has announced its intention to adopt a single approval application for all pharmaceutical products. There can be no assurance, however, that implementation of these changes will benefit the Company or otherwise reduce the regulatory requirements applicable to the Company or that these changes will not result in the imposition of other, more burdensome obligations on the Company in connection with regulatory review of the Company's products. In any event, the results of the preclinical and clinical trials and a description of the manufacturing process and tests to control the quality of the pharmaceutical product must be submitted to the FDA in a BLA for approval. The approval process is likely to require substantial time and resource commitment by an applicant. Approval is influenced by a number of factors, including the severity of the disease being treated, availability of alternative treatments, and the risks and benefits of the proposed therapeutic as demonstrated in the clinical trials. Additional data or clinical trials may be requested by the FDA and may delay approval. There is no assurance that FDA approval will be granted on a timely basis, if at all. After FDA approval for the initial indications and dosage forms, further studies may be required by the FDA to gain approval for labeling of the pharmaceutical product for other disease indications or dosage forms, or to monitor for adverse effects. Both before and after approval is obtained, a pharmaceutical product, its manufacturer and the holder of the BLA for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny a BLA if applicable regulatory criteria are not satisfied, require additional testing or information or require postmarketing testing and surveillance to monitor the safety or efficacy of the pharmaceutical product. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which the pharmaceutical product may be marketed. Further, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. Among the conditions for BLA approval is the requirement that the manufacturer of the pharmaceutical product comply with cGMP. In addition, under a BLA, the manufacturer continues to be subject to facility inspection and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, including FDA refusal to accept a license application, total or partial suspension of licensure, delay in approving or refusal to approve the pharmaceutical product or pending marketing approval applications, warning letters, fines, injunctions, withdrawal of the previously approved pharmaceutical product or marketing approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holders. In addition, later discovery of previously unknown problems may result in new restrictions on such pharmaceutical product, manufacturer and/or BLA holders, including withdrawal of the pharmaceutical product or marketing approvals and pharmaceutical product recalls or seizures.

In addition to regulations enforced by the FDA, the Company is subject to federal, state and local laws and regulations governing the use, generation, manufacture, storage, discharge, handling and disposal of certain materials and wastes used in its operations, some of which are classified as "hazardous." There can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws, the Occupational Safety and Health Act, and state, local and foreign counterparts to such laws, rules and regulations as its manufacturing and research activities are increased or that the operations, business and future profitability of the Company will not be adversely affected by current or future laws, rules and regulations.

Although the Company believes that its safety processes and procedures and its handling and disposing of materials and wastes comply with applicable laws, rules and regulations, the risk of accidental contamination or injury from these materials cannot be 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. In addition, the Company cannot predict the extent of the adverse effect on its business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions. Compliance with such laws, rules and regulations does not have, nor is such compliance presently expected to have, a material adverse effect on its business. However, the Company cannot predict the extent of the adverse effect on its business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

#### COMPETITION

The Company's potential products are intended to address a wide variety of disease conditions, including autoimmune diseases, inflammatory conditions, cancers and viral infections. Competition with respect to these disease conditions is intense and is expected to increase. This competition involves, among other things, successful research and development efforts, obtaining appropriate regulatory approvals, establishing and defending intellectual property rights, successful product manufacturing, marketing, distribution, market and physician acceptance, patient compliance, price and potentially securing eligibility for reimbursement or payment for the use of the Company's product. The Company believes its most significant competitors may be fully integrated pharmaceutical companies with substantial expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and securing eligibility for reimbursement or payment, and substantially greater financial and other resources than the Company. Smaller companies also may prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies. Furthermore, academic institutions, governmental agencies and other public and private research organizations conduct research, seek patent protection, and establish collaborative arrangements for product development, clinical development and marketing. These companies and institutions also compete with the Company in recruiting and retaining highly qualified personnel. The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. The Company's competitors may develop and introduce other technologies or approaches to accomplishing the intended purposes of the Company's products which may render the Company's technologies and products noncompetitive and obsolete.

In addition to currently marketed competitive drugs, the Company is aware of potential products in research or development by its competitors that address all of the diseases being

targeted by the Company. These and other products may compete directly with the potential products being developed by the Company. In this regard, the Company is aware that potential competitors are developing antibodies or other compounds for treating autoimmune diseases, inflammatory conditions, cancers and viral infections. In particular, a number of other companies have developed and will continue to develop human antibodies and humanized antibodies. In addition, protein design is being actively pursued at a number of academic and commercial organizations, and several companies have developed or may develop technologies that can compete with the Company's SMART and human antibody technologies. There can be no assurance that competitors will not succeed in more rapidly developing and marketing technologies and products that are more effective than the products being developed by the Company or that would render the Company's products or technology obsolete or noncompetitive. Further, there can be no assurance that the Company's collaborative partners will not independently develop products competitive with those licensed to such partners by the Company, thereby reducing the likelihood that the Company will receive revenues under its agreements with such partners.

Any potential product that the Company succeeds in developing and for which it gains regulatory approval must then compete for market acceptance and market share. For certain of the Company's potential products, an important factor will be the timing of market introduction of competitive products. Accordingly, the relative speed with which the Company and competing companies can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market is expected to be an important determinant of market success. Other competitive factors include the capabilities of the Company's collaborative partners, product efficacy and safety, timing and scope of regulatory approval, product availability, marketing and sales capabilities, reimbursement coverage, the amount of clinical benefit of the Company's products relative to their cost, method of administration, price and patent protection. There can be no assurance that the Company's competitors will not develop more efficacious or more affordable products, or achieve earlier product development completion, patent protection, regulatory approval or product commercialization than the Company. The occurrence of any of these events by the Company's competitors could have a material adverse effect on the business and financial condition of the Company.

#### HUMAN RESOURCES

As of December 31, 1996, PDL had 208 full-time employees, of whom 25 hold Ph.D. or M.D. degrees. Of the total, 72 employees were engaged in research and development, 35 in quality assurance and compliance, 17 in clinical and regulatory, 55 in manufacturing and 29 in general and administrative functions. PDL's scientific staff members have diversified experience and expertise in molecular and cell biology, biochemistry, virology, immunology, protein chemistry, computational chemistry and computer modeling. PDL's success will depend in large part on its ability to attract and retain skilled and experienced employees. PDL has not entered into employment agreements with its executives or key employees and maintains limited amounts of insurance on the lives of only two of its executive officers. None of PDL's employees are covered by a collective bargaining agreement, and PDL considers its relations with its employees to be good.

#### ENVIRONMENT

PDL seeks to comply with environmental statutes and the regulations of federal, state and local governmental agencies. PDL has put into place processes and procedures and maintains records in order to monitor its environmental compliance. PDL may invest additional resources, if required, to comply with applicable regulations, and the cost of such compliance may increase significantly.

## RISK FACTORS

This Annual Report contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to those discussed in this section as well as those discussed elsewhere in this document.

**HISTORY OF LOSSES; FUTURE PROFITABILITY UNCERTAIN.** The Company has a history of operating losses and expects to incur substantial additional expenses with resulting quarterly losses over at least the next several years as it continues to develop its potential products and to devote significant resources to preclinical studies, clinical trials, and manufacturing. As of December 31, 1996, the Company had accumulated net losses of approximately \$35.5 million. To date, the Company has not received regulatory approval to distribute any products. The time and resource commitment required to achieve market success for any individual product is extensive and uncertain and in some cases controlled by the Company's collaborators. No assurance can be given that the Company's, or any of its collaborative partners', product development efforts will be successful, that required regulatory approvals can be obtained, that potential products can be manufactured at an acceptable cost and with appropriate quality, or that any approved products can be successfully marketed.

The Company has not generated any material revenues from product sales or royalties from licenses to the Company's technology, and potential products that may be marketed by the Company, if any, are not expected to be approved for marketing for at least the next several years. The Company's revenues to date have consisted, and for the near future are expected to consist, principally of research and development funding, licensing and signing fees and milestone payments from pharmaceutical companies under collaborative research and development agreements. These revenues may vary considerably from quarter to quarter and from year to year, and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. In particular, revenues for the fourth quarter of 1996, which included several non-recurring payments in connection with new licensing agreements, may not be indicative of revenues in future quarters. While the Company historically has received significant revenue pursuant to certain of its collaborations, the Company has recognized substantially all of the research and development and milestone revenue due under these collaborations. Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate realizing non-royalty revenue from its new and proposed collaborations at levels commensurate with the revenue historically recognized under its older collaborations. Moreover, the Company anticipates that its operating expenses will continue to increase significantly as the Company increases its research and development, manufacturing, preclinical, clinical, administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations, royalties on Zenapax sales or other sources, the Company expects to incur substantial and increased operating losses in the foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in additional manufacturing facilities or capacity, as the Company defends or prosecutes its patents and patent applications, and as the Company invests in research or acquires additional technologies, product candidates or businesses. The amount of net losses and the time required to reach sustained profitability are highly uncertain. To achieve sustained profitable operations, the Company, alone or with its collaborative partners, must



successfully discover, develop, manufacture, obtain regulatory approvals for and market its potential products. No assurances can be given that the Company will be able to achieve or sustain profitability, and results are expected to fluctuate from quarter to quarter.

**UNCERTAINTY OF CLINICAL TRIAL RESULTS.** Before obtaining regulatory approval for the commercial sale of any of its potential products, the Company must demonstrate through preclinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. There can be no assurance that the Company will be permitted to undertake or continue clinical trials for any of its potential products or, if permitted, that such products will be demonstrated to be safe and efficacious. Moreover, the results from preclinical studies and early clinical trials may not be predictive of results that will be obtained in later-stage clinical trials. Thus there can be no assurance that the Company's present or future clinical trials will demonstrate the safety and efficacy of any potential products or will result in approval to market products.

In advanced clinical development, numerous factors may be involved that may lead to different results in larger, later-stage trials from those obtained in earlier stage trials. For example, early stage trials usually involve a small number of patients and thus may not accurately predict the actual results regarding safety and efficacy that may be demonstrated with a large number of patients in a later-stage trial. Also, differences in the clinical trial design between an early-stage and late-stage trial may cause different results regarding the safety and efficacy of a product to be obtained. In addition, many early stage trials are unblinded and based on qualitative evaluations by clinicians involved in the performance of the trial, whereas later stage trials are generally required to be blinded in order to provide more objective data for assessing the safety and efficacy of the product. The Company may at times elect to aggressively enter potential products into Phase I/II trials to determine preliminary efficacy in specific indications. In addition, in certain cases the Company has commenced clinical trials without conducting preclinical animal testing where an appropriate animal model does not exist. Similarly, the Company or its partners at times will conduct potentially pivotal Phase II/III or Phase III trials based on limited Phase I or Phase I/II data. As a result of these and other factors, the Company anticipates that only some of its potential products will show efficacy in clinical trials and that the number of products that fail to show efficacy may be significant.

The Company is conducting a Phase II trial evaluating PROTOVIR for the prevention of CMV infections in bone marrow transplant recipients based on very limited and inconclusive data from Phase I trials primarily designed to obtain safety data. Thus, there can be no assurance that the results of this trial will be favorable.

The Company and a number of other companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier-stage trials. For example, in June 1995, Roche Holding Ltd and its subsidiary Hoffmann-La Roche Inc. ("Roche") and the Company announced the results of a Phase II/III clinical trial using the Company's SMART Anti-Tac Antibody, Zenapax, for the prevention of graft-versus-host disease ("GvHD"). The analysis of this data led Roche to conclude that Zenapax was not effective in reducing the incidence of GvHD in the patient population studied. In addition, in August 1996, the Company announced the halt of a Phase II/III clinical trial using PROTOVIR for treatment of CMV retinitis in AIDS patients conducted by the National Eye Institute ("NEI SOCA") due to lack of evidence of efficacy. Based on the findings and actions in the above study, enrollment in a Phase II clinical trial for treatment of CMV retinitis in AIDS patients conducted by the National Institute

of Allergy and Infectious Disease ("NIAID ACTG") had been suspended, and the trial was recently terminated.

**DEPENDENCE ON COLLABORATIVE PARTNERS.** The Company has collaborative agreements with several pharmaceutical companies to develop, manufacture and market certain potential products, which include the most advanced products under development by the Company. The Company granted to its collaborative partners certain exclusive rights to commercialize the products covered by these collaborative agreements. In some cases, the Company is relying on its collaborative partners to conduct clinical trials, to compile and analyze the data received from such trials, to obtain regulatory approvals and, if approved, to manufacture and market these licensed products, including Zenapax and the Company's Human Anti-Hepatitis B Virus Antibody (OST 577). As a result, the Company often has little or no control over the development of these potential products and little or no opportunity to review clinical data prior to or following public announcement.

The Company's collaborative research agreements are generally terminable by its partners on short notice. Suspension or termination of certain of the Company's current collaborative research agreements could have a material adverse effect on the Company's operations and could significantly delay the development of the affected products. Continued funding and participation by collaborative partners will depend not only on the timely achievement of research and development objectives by the Company and the successful achievement of clinical trial goals, neither of which can be assured, but also on each collaborative partner's own financial, competitive, marketing and strategic considerations. Such considerations include, among other things, the commitment of management of the collaborative partners to the continued development of the licensed products, the relationships among the individuals responsible for the implementation and maintenance of the collaborative efforts, the relative advantages of alternative products being marketed or developed by the collaborators or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully. In this regard, the Company has, at times, experienced difficulty in its continuing relationship with Boehringer Mannheim GmbH ("Boehringer Mannheim") due to a number of factors, including disagreements regarding the timing of the initiation and design of certain proposed clinical trials involving the development of certain products licensed to Boehringer Mannheim, particularly OST 577.

In addition, certain collaborative partners have developed and may be developing competitive products that may result in delay or a relatively smaller resource commitment to product launch and support efforts than might otherwise be obtained if the potentially competitive product were not under development or being marketed. For example, Roche controls the development of Zenapax, the most advanced of the Company's products in development, and the Company is dependent upon the resources and activities of Roche to pursue commercialization of Zenapax in order for the Company to achieve milestones or royalties from the development of this product. There can be no assurance that Roche will proceed to bring this product to market in a rapid and timely manner, if at all, or if marketed, that other independently developed products of Roche (including its recently introduced product CellCept) or others will not compete with or prevent Zenapax from achieving meaningful sales. Also Roche has stated that it plans to conduct or support other clinical trials of Zenapax in autoimmune indications. There can be no assurance that Roche will continue or pursue additional clinical trials in these indications or that, even if the additional clinical trials are completed, Zenapax will be shown to be safe and efficacious, or that the trials will result in approval to market Zenapax in these indications. Any adverse event or

announcement related to Zenapax would have a material adverse effect on the business and financial condition of the Company.

Further, because the Company expects, in some cases, to rely on its contractual rights to access data collected by its collaborative partners in various phases of its clinical development efforts, the Company is dependent on the continued satisfaction by such parties of their contractual obligations to provide such access and cooperate with the Company in the preparation and submission of appropriate filings with the FDA and equivalent foreign government regulatory agencies. The Company currently relies on Boehringer Mannheim for the manufacturing and clinical development of OST 577. Boehringer Mannheim has marketing rights to this antibody in countries outside of North America. There can be no assurance that Boehringer Mannheim will provide timely access to the manufacturing and clinical data, that the U.S. Food and Drug Administration ("FDA") will permit the Company to rely on that data or that the trials conducted by Boehringer Mannheim will produce data appropriate for approval by the FDA. If the Company were unable to rely on the clinical data collected by Boehringer Mannheim or its other collaborative partners, the Company may be required to repeat clinical trials or perform supplemental clinical trials in order to achieve regulatory approval in North America. Compliance with these requirements could significantly delay commercialization efforts and require substantially greater investment by the Company, either of which would have a material adverse effect on the business and financial condition of the Company.

The Company's ability to enter into new collaborations and the willingness of the Company's existing collaborators to continue development of the Company's potential products is dependent upon, among other things, the Company's patent position with respect to such products. In this regard, the Company recently was issued patents by the U.S. Patent and Trademark Office ("PTO") and European Patent Office ("EPO") with claims that the Company believes, based on its survey of the scientific literature, cover most humanized antibodies. Eighteen notices of opposition to the European patent have been filed with the EPO, and either or both patents may be further challenged through administrative or judicial proceedings. The Company has applied for similar patents in Japan and other countries. The Company recently entered into several new collaborations related to the humanization of certain antibodies whereby it granted nonexclusive licenses to its patent rights relating to such antibodies, and the Company anticipates entering into additional collaborations partially as a result of the Company's patent and patent applications with respect to humanized antibodies. As a result, the inability of the Company to successfully defend the opposition proceeding before the EPO or, if necessary, to defend patents granted by the PTO or EPO or to successfully prosecute the corresponding patent applications in Japan or other countries could adversely affect the ability of the Company to enter into additional collaborations and could therefore have a material adverse effect on the Company's business or financial condition.

LIMITED EXPERIENCE WITH CLINICAL TRIALS; RISK OF DELAY. The Company has conducted only a limited number of clinical trials to date. There can be no assurance that the Company will be able to successfully commence and complete all of its planned clinical trials without significant additional resources and expertise. In addition, there can be no assurance that the Company will meet its contemplated development schedule for any of its potential products. The inability of the Company or its collaborative partners to commence or continue clinical trials as currently planned, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of its potential products, would have a material adverse effect on the business and financial condition of the Company.

The rate of completion of the Company's or its collaborators' clinical trials is significantly dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including, among others, the size of the patient population, perceived risks and benefits of the drug under study, availability of competing therapies, access to reimbursement from insurance companies or government sources, design of the protocol, proximity of and access by patients to clinical sites, patient referral practices, eligibility criteria for the study in question and efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment in the trial. Delays in the planned rate of patient enrollment may result in increased costs and expenses in completion of the trial or may require the Company to undertake additional studies in order to obtain regulatory approval if the applicable standard of care changes in the therapeutic indication under study. For example, patient accrual in the Company's ongoing Phase II/III trial of the SMART M195 Antibody in myeloid leukemia has been negatively affected by changes in referral patterns, with such patients now more commonly being treated in local hospitals rather than being referred to tertiary care hospitals where the Company's trial is being conducted. There can be no assurance that any actions by the Company to accelerate accrual in this trial will be successful or, to the extent that they involve modifications in the design of the trial, will not cause that trial to be considered a Phase II clinical trial and thereby require one or more additional potentially pivotal trials to be conducted.

#### UNCERTAINTY OF PATENTS AND PROPRIETARY TECHNOLOGY; OPPOSITION PROCEEDINGS.

The Company's success is significantly dependent on its ability to obtain patent protection for its products and technologies and to preserve its trade secrets and operate without infringing on the proprietary rights of third parties. PDL files and prosecutes patent applications to protect its inventions. No assurance can be given that the Company's pending patent applications will result in the issuance of patents or that any patents will provide competitive advantages or will not be invalidated or circumvented by its competitors. Moreover, no assurance can be given that patents are not issued to, or patent applications have not been filed by, other companies which would have an adverse effect on the Company's ability to use, manufacture or market its products or maintain its competitive position with respect to its products. Other companies obtaining patents claiming products or processes useful to the Company may bring infringement actions against the Company. As a result, the Company may be required to obtain licenses from others or not be able to use, manufacture or market its products. Such licenses may not be available on commercially reasonable terms, if at all.

Patents in the U.S. are issued to the party that is first to invent the claimed invention. Since patent applications in the U.S. are maintained in secrecy until patents issue, PDL cannot be certain that it was the first inventor of the inventions covered by its pending patent applications or that it was the first to file patent applications for such inventions.

The patent positions of biotechnology firms generally are highly uncertain and involve complex legal and factual questions. No consistent policy has emerged regarding the validity and scope of claims in biotechnology patents, and courts have issued varying interpretations in the recent past, and legal standards concerning validity, scope and interpretation of claims in biotechnology patents may continue to evolve. Even issued patents may later be modified or revoked by the PTO, EPO or the courts in proceedings instituted by third parties. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country and claim interpretation and infringement laws vary among countries, so the extent of any patent protection is uncertain and may vary in different countries.

PDL has several patents and has exclusively licensed certain patents from Novartis Pharmaceuticals Corporation ("Novartis") (formerly known as Sandoz Pharmaceuticals Corporation). In particular with respect to humanization technology, in June 1996, PDL was

issued a U.S. patent covering Zenapax and certain related antibodies against the IL-2 receptor. In addition, PDL is currently prosecuting other patent applications with the PTO and in other countries, including members of the European Patent Convention, Canada, Japan and Australia. The patent applications are directed to various aspects of PDL's SMART and human antibodies, antibody technology and other programs, and include claims relating to compositions of matter, methods of preparation and use of a number of PDL's compounds. However, PDL does not know whether any pending applications will result in the issuance of patents or whether such patents will provide protection of commercial significance. Further, there can be no assurance that PDL's patents will prevent others from developing competitive products using related technology.

In January and December 1996, PDL was issued patents by the EPO and PTO, respectively. PDL believes the patent claims cover Zenapax and, based on its review of the scientific literature, most humanized antibodies. The EPO (but not PTO) procedures provide for a nine-month opposition period in which other parties may submit arguments as to why the patent was incorrectly granted and should be withdrawn or limited. The entire opposition process, including appeals, may take several years to complete, and during this lengthy process, the validity of the EPO patent will be at issue, which may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on this patent. Eighteen notices of opposition to PDL's European patent were filed during the opposition period, including oppositions by major pharmaceutical and biotechnology companies, which cited references and made arguments not considered by the EPO and PTO before grant of the respective patents. The oppositions currently are being reviewed by the Company's patent counsel. PDL intends to vigorously defend the European and, if necessary, the U.S. patent; however, there can be no assurance that the Company will prevail in the opposition proceedings or any litigation contesting the validity or scope of these patents. In addition, such proceedings or litigation, or any other proceedings or litigation to protect the Company's intellectual property rights or defend against infringement claims by others, could result in substantial costs and a diversion of management's time and attention, which could have a material adverse effect on the business and financial condition of the Company.

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to PDL's programs. Some of these applications or patents may be competitive with PDL's applications or contain claims that conflict with those made under PDL's patent applications or patents. Such conflict could prevent issuance of patents to PDL, provoke an interference with PDL's patents or result in a significant reduction in the scope or invalidation of PDL's patents, if issued. An interference is an administrative proceeding conducted by the PTO to determine the priority of invention and other matters relating to the decision to grant patents. Moreover, if patents are held by or issued to other parties that contain claims relating to PDL's products or processes, and such claims are ultimately determined to be valid, no assurance can be given that PDL would be able to obtain licenses to these patents at a reasonable cost, if at all, or to develop or obtain alternative technology.

The Company is aware that Celltech Limited ("Celltech") has been granted a patent by the EPO covering certain humanized antibodies, which PDL has opposed, and Celltech has announced that it has received a notice of allowance of a corresponding U.S. patent (the "U.S. Adair Patent") and expects the patent to issue in early 1997. Because U.S. patent applications are maintained in secrecy, PDL cannot review the scope of the claims in the U.S. Adair Patent. Accordingly, there can be no assurance that such claims would not cover any of PDL's SMART antibodies or be competitive with or conflict with claims in PDL's patents or patent applications. If the U.S. Adair

Patent issues and if it is determined to be valid and to cover any of PDL's SMART antibodies, there can be no assurance that PDL would be able to obtain a license on commercially reasonable terms, if at all. If the claims of the U.S. Adair Patent conflict with claims in PDL's patents or patent applications, there can be no assurance that an interference would not be declared by the PTO, which could take several years to resolve and could involve significant expense to the Company. Also, such conflict could prevent issuance of patents to PDL relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of PDL's patents, if issued. Moreover, uncertainty as to the validity or scope of patents issued to PDL relating generally to humanization of antibodies may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

PDL has obtained a nonexclusive license under a patent held by Celltech (the "Boss Patent") relating to PDL's current process for producing SMART and human antibodies. An interference proceeding was declared in early 1991 by the PTO between the Boss Patent and a patent application filed by Genentech, Inc. ("Genentech") to which PDL does not have a license. PDL is not a party to this proceeding, and the timing and outcome of the proceeding or the scope of any patent that may be subsequently issued cannot be predicted. If the Genentech patent application were held to have priority over the Boss Patent, and if it were determined that PDL's processes and products were covered by a patent issuing from such patent application, PDL may be required to obtain a license under such patent or to significantly alter its processes or products. There can be no assurance that PDL would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on PDL.

The Company is aware that Lonza Biologics, Inc. has a patent issued in Europe to which PDL does not have a license (although Roche has advised the Company that it has a license covering Zenapax), which may cover the process the Company uses to produce its potential products. If it were determined that PDL's processes were covered by such patent, PDL may be required to obtain a license under such patent or to significantly alter its processes or products, if necessary to manufacture or import its products in Europe. There can be no assurance that PDL would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on the business and financial condition of the Company.

Also, Genentech has patents in the U.S. and Europe that relate to chimeric antibodies. The European patent is currently in the opposition process. If Genentech were to assert that the Company's SMART antibodies infringe these patents, PDL may have to choose whether to seek a license or to challenge in court the validity of such patents or Genentech's claim of infringement. There can be no assurance that PDL would be successful in either obtaining such a license on commercially reasonable terms, if at all, or that it would be successful in such a challenge of the Genentech patents, and the failure to do so would have a material adverse effect on the business and financial condition of the Company.

In addition to seeking the protection of patents and licenses, PDL also relies upon trade secrets, know-how and continuing technological innovation which it seeks to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. There can be no assurance that these agreements will not be breached, that PDL would have adequate remedies for

any breach or that PDL's trade secrets will not otherwise become known or independently developed by competitors.

ABSENCE OF MANUFACTURING EXPERIENCE; DEPENDENCE ON MANUFACTURING BY BOEHRINGER MANNHEIM. Of the products developed by the Company which are currently in clinical development, Roche is responsible for manufacturing Zenapax and Boehringer Mannheim is responsible for manufacturing OST 577. The Company intends to manufacture the SMART M195 Antibody, PROTOVIR and some of its other products in preclinical development. PDL currently leases approximately 45,000 square feet housing its manufacturing facility in Plymouth, Minnesota. PDL intends to continue to manufacture potential products for use in preclinical and clinical trials using this manufacturing facility in accordance with standard procedures that comply with current Good Manufacturing Practices ("cGMP") and appropriate regulatory standards. The manufacture of sufficient quantities of antibody products in accordance with such standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays. For example, PDL has experienced some difficulties in the past in manufacturing certain potential products on a consistent basis. Production interruptions, if they occur, could significantly delay clinical development of potential products, reduce third party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization of such products and impair their competitive position, which would have a material adverse effect on the business and financial condition of the Company.

PDL has no experience in manufacturing commercial quantities of its potential products and currently does not have sufficient capacity to manufacture its potential products on a commercial scale. In order to obtain regulatory approvals and to expand its capacity to produce its products for commercial sale at an acceptable cost, PDL will need to improve and expand its existing manufacturing capabilities, including demonstration to the FDA of its ability to manufacture its products using controlled, reproducible processes. Accordingly, the Company is evaluating plans to improve and expand the capacity of its current manufacturing facility. Such plans, if instituted, would result in substantial costs to the Company and may require a suspension of manufacturing operations during construction. There can be no assurance that construction delays would not occur, and any such delays could impair the Company's ability to produce adequate supplies of its potential products for clinical use or commercial sale on a timely basis. There can be no assurance that PDL will successfully improve and expand its manufacturing capability sufficiently to obtain necessary regulatory approvals and to produce adequate commercial supplies of its potential products on a timely basis. Failure to do so could delay commercialization of such products and impair their competitive position, which could have a material adverse effect on the business or financial condition of the Company.

In addition, PDL and Boehringer Mannheim have agreed to negotiate additional agreements under which each company could manufacture and supply the other with certain of the antibodies covered by the agreement. There can be no assurance that the parties will enter into an agreement that will provide for the Company's potential product requirements to be met in a consistent, timely and cost effective manner. Specifically, with respect to OST 577, the Company currently does not manufacture this product and has no alternative manufacturing sources for this product. In the event that Boehringer Mannheim and the Company are unable to reach an acceptable agreement, or if material is not supplied in accordance with such an agreement, there can be no assurance that the Company could make alternative manufacturing arrangements on a timely basis, if at all, and the inability to do so could have a material adverse effect on the business and financial condition of the Company.

UNCERTAINTIES RESULTING FROM MANUFACTURING CHANGES. Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. When certain changes are made in the manufacturing process, it is necessary to demonstrate to the FDA that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced, if results of prior preclinical studies and clinical trials performed using the previously produced drug material are to be relied upon in regulatory filings. Such changes could include, for example, changing the cell line used to produce the antibody, changing the fermentation or purification process or moving the production process to a new manufacturing plant. Depending upon the type and degree of differences between the newer and older drug material, various studies could be required to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material, possibly requiring additional animal studies or human clinical trials. Manufacturing changes have been made or are likely to be made for the production of PDL's products currently in clinical development. There can be no assurance that such changes will not result in delays in development or regulatory approvals or, if occurring after regulatory approval, in reduction or interruption of commercial sales. Such delays could have an adverse effect on the competitive position of those products and could have a material adverse effect on the business and financial condition of the Company.

Roche has equipped a manufacturing facility that is expected to be used to produce Zenapax. Phase III trials of Zenapax in kidney transplantation were conducted using material produced for Roche by a third party contract manufacturer at a different facility using a different cell line and a different manufacturing process. Roche has produced Zenapax at its facility using the new cell line and process and has produced data indicating that the newly produced material is substantially similar to the material used in the Phase III clinical trials. However, there can be no assurance that changes in the manufacturing site or any other manufacturing changes by Roche will not cause delays in the development or commercialization of Zenapax. Such delays could have an adverse effect on the competitive position of Zenapax and could have a material adverse effect on the business and financial condition of the Company.

In addition, with respect to two of the antibodies in clinical development licensed from Novartis, PROTOVIR and OST 577, the cell lines developed by PDL for both antibodies and the production processes developed by PDL for PROTOVIR and Boehringer Mannheim for OST 577 are different from those utilized by Novartis for the manufacture of the antibody supplies used in earlier clinical trials. There can be no assurance that this new material, when used in humans, will have the same characteristics or produce results similar to the antibody material originally developed and used by Novartis in earlier clinical trials. Accordingly, Boehringer Mannheim or the Company may be required to conduct additional laboratory or clinical testing, which could result in significant delays and/or additional expenses and could have a material adverse effect on the competitive position of these potential products and on the business and financial condition of the Company.

DEPENDENCE ON SUPPLIERS. The Company is dependent on outside vendors for the supply of raw materials used to produce its product candidates. The Company currently qualifies only one or a few vendors for its source of certain raw materials. Therefore, once a supplier's materials have been selected for use in the Company's manufacturing process, the supplier in effect becomes a sole or limited source of such raw materials to the Company due to the extensive regulatory compliance procedures governing changes in manufacturing processes. Although the Company



believes it could qualify alternative suppliers, there can be no assurance that the Company would not experience a disruption in manufacturing if it experienced a disruption in supply from any of these sources. Any significant interruption in the supply of any of the raw materials currently obtained from such sources, or the time and expense necessary to transition a replacement supplier's product into the Company's manufacturing process, could disrupt its operations and have a material adverse effect on the business and financial condition of the Company. A problem or suspected problem with the quality of raw materials supplied could result in a suspension of clinical trials, notification of patients treated with products or product candidates produced using such materials, potential product liability claims, a recall of products or product candidates produced using such materials, and an interruption of supplies, any of which could have a material adverse effect on the business or financial condition of the Company.

**COMPETITION; RAPID TECHNOLOGICAL CHANGE.** The Company's potential products are intended to address a wide variety of disease conditions, including autoimmune diseases, inflammatory conditions, cancers and viral infections. Competition with respect to these disease conditions is intense and is expected to increase. This competition involves, among other things, successful research and development efforts, obtaining appropriate regulatory approvals, establishing and defending intellectual property rights, successful product manufacturing, marketing, distribution, market and physician acceptance, patient compliance, price and potentially securing eligibility for reimbursement or payment for the use of the Company's product. The Company believes its most significant competitors may be fully integrated pharmaceutical companies with substantial expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and securing eligibility for reimbursement or payment, and substantially greater financial and other resources than the Company. Smaller companies also may prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies. Furthermore, academic institutions, governmental agencies and other public and private research organizations conduct research, seek patent protection, and establish collaborative arrangements for product development, clinical development and marketing. These companies and institutions also compete with the Company in recruiting and retaining highly qualified personnel. The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. The Company's competitors may develop and introduce other technologies or approaches to accomplishing the intended purposes of the Company's products which may render the Company's technologies and products noncompetitive and obsolete.

In addition to currently marketed competitive drugs, the Company is aware of potential products in research or development by its competitors that address all of the diseases being targeted by the Company. These and other products may compete directly with the potential products being developed by the Company. In this regard, the Company is aware that potential competitors are developing antibodies or other compounds for treating autoimmune diseases, inflammatory conditions, cancers and viral infections. In particular, a number of other companies have developed and will continue to develop human anti-viral antibodies and humanized antibodies. In addition, protein design is being actively pursued at a number of academic and commercial organizations, and several companies have developed or may develop technologies that can compete with the Company's SMART and human antibody technologies. There can be no assurance that competitors will not succeed in more rapidly developing and marketing technologies and products that are more effective than the products being developed by the Company or that would render the Company's products or technology obsolete or noncompetitive. Further, there can be no assurance that the Company's collaborative partners will not independently develop products

competitive with those licensed to such partners by the Company, thereby reducing the likelihood that the Company will receive revenues under its agreements with such partners.

Any potential product that the Company succeeds in developing and for which it gains regulatory approval must then compete for market acceptance and market share. For certain of the Company's potential products, an important factor will be the timing of market introduction of competitive products. Accordingly, the relative speed with which the Company and competing companies can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market is expected to be an important determinant of market success. Other competitive factors include the capabilities of the Company's collaborative partners, product efficacy and safety, timing and scope of regulatory approval, product availability, marketing and sales capabilities, reimbursement coverage, the amount of clinical benefit of the Company's products relative to their cost, method of administration, price and patent protection. There can be no assurance that the Company's competitors will not develop more efficacious or more affordable products, or achieve earlier product development completion, patent protection, regulatory approval or product commercialization than the Company. The occurrence of any of these events by the Company's competitors could have a material adverse effect on the business and financial condition of the Company.

**NO ASSURANCE OF REGULATORY APPROVAL; GOVERNMENT REGULATION.** The manufacturing, testing and marketing of PDL's products are subject to regulation by numerous governmental authorities in the U.S. and other countries based upon their safety and efficacy. In the U.S., pharmaceutical products are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act ("FD&C Act"), Public Health Service Act ("PHS Act") and other federal, state and local regulations govern the manufacture, testing, labeling, storage, record keeping, clinical and nonclinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and the expenditure of substantial resources. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all.

In addition to the requirement for FDA approval of each pharmaceutical product, each pharmaceutical product manufacturing facility must be registered with, and approved by, the FDA. The manufacturing and quality control procedures must conform to cGMP in order to receive FDA approval. Pharmaceutical product manufacturing establishments are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the U.S., foreign manufacturing establishments must comply with cGMP and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in such countries under reciprocal agreements with the FDA. Moreover, pharmaceutical product manufacturing facilities may also be regulated by state, local and other authorities.

For marketing of pharmaceutical products outside the U.S., PDL is subject to foreign regulatory requirements governing marketing approval, and FDA and other U.S. export provisions should the pharmaceutical product be manufactured in the U.S. Requirements relating to the manufacturing, conduct of clinical trials, product licensing, promotion, pricing and reimbursement vary widely in different countries. Difficulties or unanticipated costs or price controls may be encountered by PDL or its licensees or marketing partners in their respective efforts to secure necessary governmental approvals to market the potential pharmaceutical products, which could

delay or preclude PDL or its licensees or its marketing partners from marketing their potential pharmaceutical products.

The basic steps required by the FDA before a new pharmaceutical product for human use may be marketed in the U.S. include (i) preclinical laboratory and animal tests, (ii) submission to the FDA of an application for an Investigational New Drug ("IND") which must be reviewed by the FDA before clinical trials may begin, (iii) completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the pharmaceutical product for its intended use, (iv) as of May 1996 for therapeutic monoclonal antibodies, submission of a Biologics License Application ("BLA") to the FDA, and (v) FDA approval of the BLA prior to any commercial sale or shipment of the pharmaceutical product.

The FDA reviews the results of the trials and may discontinue them at any time for safety reasons or other reasons if they were deemed to be non-compliant with FDA regulations. There can be no assurance that Phase I, II or III clinical trials will be completed successfully within any specific time period, if at all, with respect to any of the Company's or its collaborators' pharmaceutical products, each of which is subject to such testing requirements.

Both before and after approval is obtained, a pharmaceutical product, its manufacturer and the holder of the BLA for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny a BLA if applicable regulatory criteria are not satisfied, require additional testing or information or require postmarketing testing and surveillance to monitor the safety or efficacy of the pharmaceutical product. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which the pharmaceutical product may be marketed. Further, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. Among the conditions for BLA approval is the requirement that the manufacturer of the pharmaceutical product comply with cGMP. In addition, under a BLA, the manufacturer continues to be subject to facility inspection and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, including FDA refusal to accept a license application, total or partial suspension of licensure, delay in approving or refusal to approve the pharmaceutical product or pending marketing approval applications, warning letters, fines, injunctions, withdrawal of the previously approved pharmaceutical product or marketing approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holders. In addition, later discovery of previously unknown problems may result in new restrictions on such pharmaceutical product, manufacturer and/or BLA holders, including withdrawal of the pharmaceutical product or marketing approvals and pharmaceutical product recalls or seizures.

**LIMITED SALES AND MARKETING EXPERIENCE.** The Company intends to market and sell certain of its products, if successfully developed and approved, through a direct sales force in the U.S. and through sales and marketing partnership arrangements outside the U.S. However, PDL does not expect to establish a direct sales capability for at least the next few years. The Company has no history or experience in sales, marketing or distribution. To market its products directly, the Company must either establish a marketing group and direct sales force or obtain the assistance of another company. There can be no assurance that the Company will be able to establish sales and distribution capabilities or succeed in gaining market acceptance for its products. If the Company enters into co-promotion or other marketing or licensing arrangements with established

pharmaceutical companies, the Company's revenues will be subject to the payment provisions of such arrangements and dependent on the efforts of third parties. There can be no assurance that the Company will be able to successfully establish a direct sales force or that its collaborators will effectively market any of the Company's potential products, and the inability of the Company or its collaborators to do so could have a material adverse effect on the business and financial condition of the Company.

**DEPENDENCE ON KEY PERSONNEL.** The Company's success is dependent to a significant degree on its key management personnel. To be successful, the Company will have to retain its qualified clinical, manufacturing, scientific and management personnel. The Company does not have employment agreements with its key personnel and only maintains limited amounts of insurance on the lives of two of its executive officers. The Company faces competition for personnel from other companies, academic institutions, government entities and other organizations. There can be no assurance that the Company will be successful in hiring or retaining qualified personnel, and its failure to do so could have a material adverse effect on the business and financial condition of the Company.

**PRODUCT LIABILITY AND INSURANCE.** The Company faces an inherent business risk of exposure to product liability claims in the event that the use of products during research and development efforts or after commercialization results in adverse effects. There can be no assurance that the Company will avoid significant product liability exposure. The Company maintains product liability insurance for clinical trials. However, there can be no assurance that such coverage will be adequate or that adequate insurance coverage for future clinical trials or commercial activities will be available at an acceptable cost, if at all, or that a product liability claim would not materially adversely affect the business or financial condition of the Company.

**POTENTIAL VOLATILITY OF STOCK PRICE.** The market for the Company's securities is volatile and investment in these securities involves substantial risk. The market prices for securities of biotechnology companies (including the Company) have been highly volatile, and the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. Factors such as results of clinical trials, delays in manufacturing or clinical trial plans, fluctuations in the Company's operating results, disputes or disagreements with collaborative partners, market reaction to announcements by other biotechnology or pharmaceutical companies, announcements of technological innovations or new commercial therapeutic products by the Company or its competitors, initiation, termination or modification of agreements with collaborative partners, failures or unexpected delays in manufacturing or in obtaining regulatory approvals or FDA advisory panel recommendations, developments or disputes as to patent or other proprietary rights, loss of key personnel, litigation, public concern as to the safety of drugs developed by the Company, regulatory developments in either the U.S. or foreign countries (such as opinions, recommendations or statements by the FDA or FDA advisory panels, health care reform measures or proposals), and general market conditions could result in the Company's failure to meet the expectations of securities analysts or investors. In such event, or in the event that adverse conditions prevail or are perceived to prevail with respect to the Company's business, the price of PDL's common stock would likely drop significantly. In the past, following significant drops in the price of a company's common stock, securities class action litigation has often been instituted against such a company. Such litigation against the Company could result in substantial costs and a diversion of management's attention and resources, which would have a material adverse effect on the Company's business and financial condition.

**FUTURE REQUIREMENTS FOR SIGNIFICANT ADDITIONAL CAPITAL.** The Company's operations to date have consumed substantial amounts of cash. Negative cash flow from operations is expected to increase significantly beyond current levels over at least the next two years as the Company expects to spend substantial funds in conducting clinical trials, to expand its research and development programs and to develop and expand its manufacturing capability. The Company's future capital requirements will depend on numerous factors, including, among others, the progress of the Company's product candidates in clinical trials; the continued or additional support by collaborative partners or other third parties of research and clinical trials; enhancement of research and development programs; the time required to gain regulatory approvals; the resources the Company devotes to self-funded products, manufacturing methods and advanced technologies; third party manufacturing commitments; the ability of the Company to obtain and retain funding from third parties under collaborative agreements; the development of internal marketing and sales capabilities; the demand for the Company's potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by the Company; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect the Company's proprietary technology. In order to develop and commercialize its potential products, the Company may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders. The inability of the Company to secure adequate funds on a timely basis could result in the delay or cancellation of programs that the Company might otherwise pursue and, in any event, could have a material adverse effect on the business and financial condition of the Company.

**ENVIRONMENTAL REGULATION.** The Company is subject to federal, state and local laws and regulations governing the use, generation, manufacture, storage, discharge, handling and disposal of certain materials and wastes used in its operations, some of which are classified as "hazardous." There can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws, the Occupational Safety and Health Act, and state, local and foreign counterparts to such laws, rules and regulations as its manufacturing and research activities are increased or that the operations, business and future profitability of the Company will not be adversely affected by current or future laws, rules and regulations. The risk of accidental contamination or injury from hazardous materials cannot be 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. In any event, the cost of defending claims arising from such contamination or injury could be substantial. In addition, the Company cannot predict the extent of the adverse effect on its business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

**UNCERTAINTY RELATED TO HEALTH CARE INDUSTRY.** The health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of human therapeutics. Cost containment measures, whether instituted by health care providers or enacted as a result of government health administration regulators or new regulations, such as pricing limitations or formulary eligibility for dispensation by medical providers, could result in greater selectivity in the availability of treatments. Such selectivity could have an adverse effect on the Company's ability to sell its products and there can be no assurance that adequate third-party coverage will be available for the Company to maintain price levels sufficient to generate an appropriate return on its investment in product development. Third-party payors are increasingly focusing on the cost-benefit profile of alternative therapies and prescription drugs and

challenging the prices charged for such products and services. Also, the trend towards managed health care in the U.S. and the concurrent growth of organizations such as health maintenance organizations, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices or reduced markets for the Company's products. The cost containment measures that health care providers and payors are instituting and the effect of any health care reform could adversely affect the Company's ability to sell its products and may have a material adverse effect on the Company. To date, the Company has conducted limited marketing studies on certain of its potential products and has not undertaken any pharmacoeconomic analysis with respect to its products under development. The cost containment measures and reforms that government institutions and third party payors are considering instituting could result in significant and unpredictable changes to the marketing, pricing and reimbursement practices of biopharmaceutical companies such as the Company. The adoption of any such measures or reforms could have a material adverse effect on the business and financial condition of the Company.

## ITEM 2. PROPERTIES

The Company leases approximately 43,000 square feet of laboratory and office space in Mountain View, California. The Company's lease will terminate on December 31, 2000. The Company has also leased an additional 10,000 square feet of office space located adjacent to its current facility in Mountain View, California through May 31, 1998. The Company believes that it will need to obtain additional laboratory and office space in 1997 to supplement or replace the facilities at its Mountain View site.

The Company also leases approximately 45,000 square feet of manufacturing, laboratory and office space in Plymouth, Minnesota. The Company's lease will terminate on February 29, 2004, subject to the Company's options to extend the lease for two additional five year terms. Although these facilities currently leased by the Company are sufficient for its present manufacturing operations, the Company believes that it may have to obtain additional manufacturing space in the future and may lease or acquire additional space as required.

The Company owns substantially all of the equipment used in its facilities. See Note 4 to the financial statements.

## ITEM 3. LEGAL PROCEEDINGS

The Company is involved in administrative opposition proceedings being conducted by the EPO with respect to its European patent relating to humanized antibodies. Eighteen oppositions have been filed with respect to the issuance of the patent to the Company in January 1996. The oppositions argue that the patent was incorrectly granted and should be withdrawn or limited. See "Business--Patents and Proprietary Technology" and "Risk Factors--Uncertainty of Patents and Proprietary Technology; Opposition Proceedings." Other than such administrative proceedings, the Company is not a party to any material administrative or legal proceedings.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITYHOLDERS

Not applicable.

## PART II

## ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

## MARKET INFORMATION AND DIVIDEND POLICY (\$)

1995 ----	High ----	Low ---
First Quarter	22.25	13.88
Second Quarter	26.75	19.25
Third Quarter	20.63	13.13
Fourth Quarter	24.00	14.63
1996 ----	High ----	Low ---
First Quarter	28.38	20.38
Second Quarter	30.00	22.00
Third Quarter	27.25	12.00
Fourth Quarter	38.38	21.75

The Company's common stock trades on the Nasdaq National Market under the symbol "PDLI". Prices indicated above are the sale prices as reported by the Nasdaq National Market for the periods indicated. The Company has never paid any cash dividends on its capital stock and does not anticipate paying any cash dividends in the foreseeable future.

As of December 31, 1996, the approximate number of common stockholders of record was 224. The market for the Company's securities is volatile. See "Risk Factors."

In October 1993, the Company entered into a Stock Purchase Agreement with Corange International Limited ("Corange") pursuant to which the Company sold 1.2 million and 1.233 million newly issued shares of Common Stock of the Company in December 1993 and 1994 at a price of \$25 per share and \$36.50 per share, respectively. The Company offered and sold the shares to Corange, a sophisticated investor who purchased such shares for investment purposes, as transactions not involving a public offering pursuant to the exemption from registration provisions of Section 4(2) of the Securities Act of 1933, as amended.



## ITEM 6. SELECTED FINANCIAL DATA

(In thousands, except per share and number of employees data)

	YEARS ENDED DECEMBER 31,				
	1996	1995	1994	1993	1992
STATEMENTS OF OPERATIONS DATA:					
Revenues:					
Research and development revenue under collaborative agreements-related parties	\$ 11,500	\$ 10,408	\$ 10,233	\$ 14,233	\$ 3,400
Research and development revenue-other	5,000	1,000	1,627	456	2,746
Interest and other income	6,100	6,205	3,349	2,111	2,239
Total revenues	22,600	17,613	15,209	16,800	8,385
Costs and expenses:					
Research and development	28,795	20,803	16,367	12,329	7,264
Purchase of in-process technology	--	--	--	7,725	--
General and administrative	5,601	5,163	4,051	2,653	1,997
Interest expense	--	1	7	25	44
Total costs and expenses	34,396	25,967	20,425	22,732	9,305
Net loss	\$ (11,796)	\$ (8,354)	\$ (5,216)	\$ (5,932)	\$ (920)
Net loss per share(1)	\$ (0.76)	\$ (0.54)	\$ (0.37)	\$ (0.47)	\$ (0.07)
Shares used in computation of net loss per share	15,604	15,343	14,060	12,747	12,491

	DECEMBER 31,				
	1996	1995	1994	1993	1992
BALANCE SHEET DATA:					
Cash, cash equivalents and investments	\$ 99,667	\$ 107,065	\$ 113,245	\$ 72,732	\$ 50,904
Working capital	74,221	43,522	95,450	29,843	18,188
Total assets	110,331	116,412	121,054	80,294	55,623
Capital lease obligations, less current portion	--	--	--	25	93
Accumulated deficit	(35,507)	(23,711)	(15,357)	(10,141)	(4,209)
Total stockholders' equity	105,112	112,856	117,783	77,921	53,534
Number of employees	208	181	145	112	86

(1) For a description of the computation of net loss per share, see Note 1 to the Financial Statements.

**ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This Annual Report contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to those discussed in "Risk Factors" as well as those discussed elsewhere in this document.

**OVERVIEW**

Since the Company's founding in 1986, a primary focus of its operations has been research and development. Achievement of successful research and development and commercialization of products derived from such efforts is subject to high levels of risk and significant resource commitments. The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next few years, as it continues to develop its proprietary products and devote significant resources to preclinical studies, clinical trials, and manufacturing. The Company's revenues to date have consisted, and for the near future are expected to consist, principally of research and development funding, licensing and signing fees and milestone payments from pharmaceutical companies under collaborative research and development and licensing agreements. These revenues may vary considerably from quarter to quarter and from year to year and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. In particular, revenues for the fourth quarter of 1996, which included several non-recurring payments in connection with new licensing agreements, may not be indicative of revenues in future quarters.

While the Company historically has received significant revenue pursuant to certain of its research and development agreements, the Company has recognized substantially all of the research and development and milestone revenue due under these collaborations. Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate realizing non-royalty revenue from its new and proposed collaborations at levels commensurate with the non-royalty revenue historically recognized under its older collaborations. Moreover, the Company anticipates that its operating expenses will continue to increase significantly as the Company increases its research and development, manufacturing, preclinical and clinical activity, and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or licensing agreements, royalties on Zenapax sales, if any, or other sources, the Company expects to incur substantial and increased operating losses in the foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in additional manufacturing facilities or capacity, as the Company defends or prosecutes its patents and patent applications and as the Company invests in research or acquires additional technologies or businesses.

The preparation of financial statements in conformity with generally accepted accounting principles requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, the Company has a policy of accruing expenses for clinical trials based upon pro rating estimated total costs of a clinical trial over the estimated length of the clinical trial and the number of patients anticipated to be enrolled in the trial. Expenses are accrued as patients meeting the entry criteria in the clinical trial protocol are enrolled in and progress through the trial. In the event of early termination of a clinical trial, management accrues an amount based on its estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial.

These estimates and assumptions could differ significantly from the amounts which may actually be realized.

Nonrefundable signing or licensing fee payments that are not dependent on future performance under collaborative agreements are recognized as revenue when received. Payments for research and development performed by the Company under contractual arrangements are recognized as revenue ratably over the quarter in which the payment is received and the related work is performed. Revenue from achievement of milestone events is recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met. Deferred revenue arises principally due to timing of cash payments received under research and development contracts.

#### RESULTS OF OPERATIONS

Years ended December 31, 1996, 1995 and 1994

The Company's total revenues were \$22.6 million in 1996 as compared to \$17.6 million in 1995 and \$15.2 million in 1994. Total research and development revenues represented \$16.5 million, \$11.4 million and \$11.9 million of total revenues in 1996, 1995 and 1994, respectively. Interest and other income were \$6.1 million in 1996, \$6.2 million in 1995, and \$3.3 million in 1994.

The increase in total research and development revenues in 1996 over the prior years was primarily attributable to an increase in up-front licensing and signing fees, and receipt of a milestone payment from Boehringer Mannheim in January 1996. Increased funding during 1995 and 1994 from Boehringer Mannheim was partially offset by reduced funding from Roche, whose funding arrangement ended in January 1995. Reimbursement funding under the agreement with Boehringer Mannheim ended in October 1996. The Company received \$6.5 million in up-front licensing and signing fees and milestone payments in 1996, compared to \$1.0 million and \$2.5 million in 1995 and 1994 respectively. Of the amounts spent by the Company for research and development, \$10.0 million in 1996, \$10.4 million in 1995 and \$9.2 million in 1994 represented third-party funded research and development activities (not including licensing fees, milestone payments and product sales).

Interest and other income of \$6.1 million in 1996 was comparable to \$6.2 million in 1995. The increase in 1995 from \$3.3 million in 1994 was attributable primarily to higher cash and investment balances in 1995 resulting from the sale of stock to Corange, an affiliate of Boehringer Mannheim, in December 1994.

Total costs and expenses increased to \$34.4 million in 1996 from \$26.0 million in 1995 and \$20.4 million in 1994. The increase in costs and expenses in 1996 compared to 1995 and 1994 was due primarily to increases in research and development expenses in each of those periods.

Research and development expenses in 1996 increased to \$28.8 million from \$20.8 million in 1995 and \$16.4 million in 1994, primarily as a result of the Company's conducting additional development efforts independently and under its agreements with its collaborative partner, Boehringer Mannheim. These expenses included the addition of staff, the initiation and continuation of clinical trials, costs of conducting preclinical tests, expansion of pharmaceutical development capabilities including support for both clinical development and manufacturing process development, and higher costs in the expanded operation of the manufacturing facility.

General and administrative expenses for 1996 increased to \$5.6 million from \$5.2 million in 1995 and \$4.1 million in 1994. These increases were primarily the result of increased staffing and associated expenses necessary to manage and support the Company's expanding operations.

#### LIQUIDITY AND CAPITAL RESOURCES

To date the Company has financed its operations primarily through public and private placements of equity, research and development revenue, capital lease financing and interest income on invested capital. At December 31, 1996, the Company had cash, cash equivalents and investments in the aggregate of \$99.7 million, compared to \$107.1 million at December 31, 1995 and \$113.2 million at December 31, 1994. Pursuant to the agreement with Boehringer Mannheim, the Company may be required to reimburse Boehringer Mannheim up to \$2.0 million for Phase II studies and up to \$8.8 million for Phase III studies of OST 577 in the event certain conditions are met.

Net cash used in operating activities was approximately \$7.0 million for the year ended December 31, 1996 compared to approximately \$7.1 million in 1995 and \$1.9 million in 1994.

The Company's future capital requirements will depend on numerous factors, including, among others, the progress of the Company's product candidates in clinical trials; the continued or additional support by collaborative partners or other third parties of research and clinical trials; enhancement of research and development programs; the time required to gain regulatory approvals; the resources the Company devotes to self-funded products, manufacturing methods and advanced technologies; third party manufacturing commitments; the ability of the Company to obtain and retain funding from third parties under collaborative agreements; the development of internal marketing and sales capabilities; the demand for the Company's potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by the Company; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect the Company's proprietary technology. In order to develop and commercialize its potential products the Company may need to raise substantial additional funds following this offering through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders. The Company believes that existing capital resources will be adequate to satisfy its capital needs through 1999.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PROTEIN DESIGN LABS, INC.  
BALANCE SHEETS

	DECEMBER 31,	
	1996	1995
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,141,184	\$ 4,686,259
Short-term investments	64,050,165	41,743,675
Other current assets	1,249,772	648,536
	-----	-----
Total current assets	79,441,121	47,078,470
Property and equipment, net	8,589,555	7,850,485
Long-term investments	21,475,483	60,635,550
Other assets	825,246	847,891
	-----	-----
	\$ 110,331,405	\$ 116,412,396
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,029,157	\$ 637,637
Accrued compensation	635,729	605,127
Other accrued liabilities	3,554,869	1,313,805
Deferred revenue	--	1,000,000
	-----	-----
Total current liabilities	5,219,755	3,556,569
Commitments		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 10,000,000 shares authorized; no shares issued and outstanding	--	--
Common stock, par value \$0.01 per share, 40,000,000 shares authorized; 15,759,089 and 15,405,761 issued and outstanding at December 31, 1996 and December 31, 1995, respectively	157,591	154,058
Additional paid-in capital	140,328,297	135,616,420
Accumulated deficit	(35,507,154)	(23,711,056)
Unrealized gain on investments	132,916	796,405
	-----	-----
Total stockholders' equity	105,111,650	112,855,827
	-----	-----
	\$ 110,331,405	\$ 116,412,396
	=====	=====

See accompanying notes

PROTEIN DESIGN LABS, INC.  
STATEMENTS OF OPERATIONS

	YEARS ENDED DECEMBER 31,		
	1996	1995	1994
Revenues:			
Research and development revenue under collaborative agreements - related parties	\$ 11,500,000	\$ 10,408,333	\$ 10,233,333
Research and development revenue - other	5,000,000	1,000,000	1,626,500
Interest and other income	6,099,519	6,204,663	3,349,237
Total revenues	22,599,519	17,612,996	15,209,070
Costs and expenses:			
Research and development	28,794,355	20,802,661	16,366,746
General and administrative	5,601,262	5,162,738	4,050,895
Interest expense	--	1,366	7,479
Total costs and expenses	34,395,617	25,966,765	20,425,120
Net loss	\$(11,796,098)	\$ (8,353,769)	\$ (5,216,050)
Net loss per share	\$ (0.76)	\$ (0.54)	\$ (0.37)
Shares used in computation of net loss per share	15,604,000	15,343,000	14,060,000

See accompanying notes

PROTEIN DESIGN LABS, INC.  
STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital				
	Shares	Amount		Accumulated Deficit	Deferred Compensation	Unrealized Gain (Loss) on Investments	Total Stockholders' Equity
Balance at December 31, 1993	13,925,172	\$ 139,252				\$ 88,168,082	
Repurchase of common stock from officers, employees and consultants at \$0.05 to \$0.125 per share for cash	(755)	(8)				(63)	
Issuance of common stock to employees for cash	90,622	906				977,256	
Issuance of common stock to investor at \$36.50 per share	1,232,877	12,329				44,987,682	
Amortization of deferred compensation						150,000	
Change in unrealized gain (loss) on investments					(1,049,656)	(1,049,656)	
Net loss			(5,216,050)			(5,216,050)	
Balance at December 31, 1994	15,247,916	152,479		(94,641)	(1,049,656)	117,782,954	
Issuance of common stock to employees and outside directors for cash	157,845	1,579				1,485,940	
Amortization of deferred compensation				96,641		96,641	
Change in unrealized gain (loss) on investments					1,846,061	1,846,061	
Net loss			(8,353,769)			(8,353,769)	
Balance at December 31, 1995	15,405,761	154,058			796,405	112,855,827	
Issuance of common stock to employees and outside directors for cash	353,328	3,533				4,715,410	
Change in unrealized gain (loss) on investments					(663,489)	(663,489)	
Net loss			(11,796,098)			(11,796,098)	
Balance at December 31, 1996	15,759,089	\$ 157,591	\$ (35,507,154)	\$ --	\$ 132,916	\$ 105,111,650	

See accompanying notes

PROTEIN DESIGN LABS, INC.  
STATEMENTS OF CASH FLOWS  
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

	YEARS ENDED DECEMBER 31,		
	1996	1995	1994
Cash flows from operating activities:			
Net loss	\$(11,796,098)	\$ (8,353,769)	\$ (5,216,050)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	3,241,775	2,533,448	2,164,512
Other	466,496	(1,923,950)	(189,602)
Changes in assets and liabilities:			
Other current assets	(601,236)	377,090	373,163
Accounts payable	391,520	(120,315)	(1,156)
Accrued liabilities	2,271,666	339,257	781,894
Deferred revenue	(1,000,000)	91,667	166,666
Total adjustments	4,770,221	1,297,197	3,295,477
Net cash used in operating activities	(7,025,877)	(7,056,572)	(1,920,573)
Cash flows from investing activities:			
Purchases of short and long term investments	(24,458,022)	(74,161,730)	(76,249,102)
Maturities of short and long term investments	39,900,000	46,900,000	34,008,428
Proceeds from sales of short and long term investments	--	36,348,806	--
Capital expenditures	(3,669,231)	(3,585,812)	(2,378,737)
(Increase) decrease in other assets	22,645	(659,467)	53,138
Net cash provided by investing activities	11,765,392	4,841,797	(44,566,273)
Cash flows from financing activities:			
Principal payments on capital lease obligations	--	(24,971)	(49,469)
Proceeds from issuance of capital stock	4,715,410	1,485,940	45,977,267
Payments for repurchases of common stock	--	--	(63)
Net cash provided by financing activities	4,715,410	1,460,969	45,927,735
Net increase (decrease) in cash and cash equivalents	9,454,925	(753,806)	(559,111)
Cash and cash equivalents at beginning of year	4,686,259	5,440,065	5,999,176
Cash and cash equivalents at end of year	\$ 14,141,184	\$ 4,686,259	\$ 5,440,065
Supplemental disclosure of cash flow information			
Interest paid	\$ --	\$ 1,366	\$ 7,479

See accompanying notes



PROTEIN DESIGN LABS, INC.  
NOTES TO FINANCIAL STATEMENTS  
December 31, 1996

1. Summary of Significant Accounting Policies

Organization and Business

Since the Company's founding in 1986, a primary focus of its operations has been research and development. Achievement of successful research and development and commercialization of products derived from such efforts is subject to high levels of risk and significant resource commitments. The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next few years, as it continues to develop its proprietary products and devote significant resources to preclinical studies, clinical trials, and manufacturing. The Company's revenues to date have consisted, and for the near future are expected to consist, principally of research and development funding, licensing and signing fees and milestone payments from pharmaceutical companies under collaborative research and development and licensing agreements. These revenues may vary considerably from quarter to quarter and from year to year and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. For example, revenues for the fourth quarter of 1996, which included several non-recurring payments in connection with new licensing agreements, may not be indicative of revenues in future quarters.

While the Company historically has received significant revenue pursuant to certain of its research and development agreements, the Company has recognized substantially all of the research and development and milestone revenue due under these collaborations. Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate realizing non-royalty revenue from its new and proposed collaborations at levels commensurate with the non-royalty revenue historically recognized under its older collaborations. Moreover, the Company anticipates that its operating expenses will continue to increase significantly as the Company increases its research and development, manufacturing, preclinical and clinical activity, and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or licensing agreements, royalties on Zenapax sales, if any, or other sources, the Company expects to incur substantial and increased operating losses in the foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in additional manufacturing facilities or capacity, as the Company defends or prosecutes its patents and patent applications and as the Company invests in research or acquires additional technologies or businesses.

Cash Equivalents, Investments and Concentration of Credit Risk

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of acquisition to be cash equivalents. The Company places its cash and short-term and long-term investments with high-credit-quality financial

institutions and in securities of the U.S. government and U.S. government agencies, and by policy, limits the amount of credit exposure in any one financial instrument. To date, the Company has not experienced credit losses on investments in these instruments.

#### Revenue Recognition Under Development Contracts

Nonrefundable signing or licensing fee payments that are not dependent on future performance under collaborative agreements are recognized as revenue when received. Payments for research and development performed by the Company under contractual arrangements are recognized as revenue ratably over the quarters in which the related work is performed. Revenue from achievement of milestone events is recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met. Deferred revenue arises principally due to timing of cash payments received under research and development contracts.

#### Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Common equivalent shares from options are included in the computation (using the treasury stock method) when their effect is dilutive.

#### New Accounting Standards

Effective on January 1, 1996, the Company adopted Statement of Financial Accounting Standards 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" ("FAS 121"), which required the Company to review for impairment long-lived assets, certain identifiable intangibles and goodwill related to those assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In certain situations, an impairment loss would be recognized. The adoption of FAS 121 did not have a material impact on the financial position, results of operations or cash flows of the Company.

In 1996, the Company implemented the disclosure requirements of Financial Accounting Standards 123, "Accounting for Stock-Based Compensation" ("FAS 123"). Under FAS 123, the Company will continue to account for stock-based compensation under the intrinsic value method prescribed by Accounting Principles Board Opinion 25, "Accounting for Stock Issued to Employees," and will provide pro forma disclosures of net income and earnings per share as if the fair value basis method prescribed in FAS 123 had been applied in measuring compensation expense.

#### Management Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, the Company has a policy of accruing expenses for clinical trials based upon pro rating estimated total costs of a clinical trial over the estimated length of the clinical trial and the number of patients anticipated to be enrolled in the trial. Expenses are accrued as patients meeting the entry criteria in the clinical trial protocol are enrolled in and progress through the trial. In the event of early termination of a clinical trial, management accrues an amount based on its estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial. These estimates and assumptions could differ significantly from the amounts which may actually be realized.

## Property and Equipment

Property and equipment are stated at cost less accumulated straight-line depreciation and amortization and consist of the following:

	December 31,	
	----- 1996	1995 -----
Laboratory and manufacturing equipment	\$ 10,170,750	\$ 7,910,701
Office equipment	3,237,572	2,405,900
Furniture and fixtures	4,351,269	3,743,759
	-----	-----
	17,759,591	14,060,360
Less accumulated depreciation and amortization	(9,170,036)	(6,209,875)
	-----	-----
	\$ 8,589,555	\$ 7,850,485
	=====	=====

Laboratory, manufacturing, office equipment and furniture and fixtures are depreciated over the estimated useful lives of the assets, generally three to five years.

## 2. Collaborative Research and Development Arrangements

## Roche

In March 1989, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche & Co. Limited Company, subsidiaries of Roche Holding Ltd (collectively, "Roche") entered into a stock purchase agreement and a product licensing agreement with the Company. Under the product licensing agreement, the Company received a licensing and signing fee in exchange for exclusive worldwide manufacturing and marketing rights to the product which is under development. Revenues related to the achievement of milestones under this agreement were \$2 million in 1993. In 1994 and 1993, Roche provided quarterly payments to fund additional research and development associated with the product. This funding arrangement ended in January 1995. Related costs under this arrangement approximated the related revenues and are included in research and development expenses in the accompanying financial statements. The Company will receive further payments if additional milestones are achieved. The product licensing agreement provides for royalty payments to the Company on net sales of the licensed product. The royalty rate is subject to reduction upon the occurrence of certain events. The product licensing agreement may be terminated by Roche upon 90 days notice, in which event rights licensed to Roche will revert to the Company.

In October 1996, Roche entered into a humanization agreement with the Company. Under this agreement, the Company received a nonrefundable signing fee and can earn additional payments upon the achievement of certain milestones. The agreement also provides for royalty payments to the Company on net sales of licensed product.

## Corange/Boehringer Mannheim

In October 1993, Corange International Limited ("Corange") entered into a strategic alliance with the Company pursuant to a stock purchase agreement, standstill agreement, registration rights agreement and a joint development, marketing and licensing agreement. Under the equity agreement, Corange invested \$30 million through the purchase of 1.2 million newly issued shares of common stock at a price of \$25 per share in December 1993, and an additional \$45 million through the purchase of approximately 1.233 million newly issued shares of common stock at a price of \$36.50 per share in December 1994. Under the license agreement, Corange acquired exclusive marketing and co-promotion rights to certain of the Company's potential products for certain territories. Corange and the Company have also agreed to negotiate future agreements under which each party would manufacture and supply to the other certain of these potential products. In 1994 and 1995, Corange and the Company agreed to amend certain of these agreements to provide for, among other matters, the termination of Corange's rights to certain of the Company's preclinical products, the assignment of the joint development, marketing and license agreement to Corange's affiliate, Boehringer Mannheim, the assumption by each party of primary responsibility for clinical development and manufacturing for specific products, the termination of certain milestone payments to the Company with respect to particular products, the reimbursement to Boehringer Mannheim by the Company up to a limited amount of certain costs with respect to clinical trials to be conducted by Boehringer Mannheim, if certain conditions are met, and the termination of certain restrictions on Corange's ability to sell its equity investment in the Company.

The Company recorded as contract revenue under the license agreement a milestone payment of \$1 million in each of 1996 and 1994, respectively. In addition, the Company received research and development funding of approximately \$10.0 million, \$10.3 million and \$8.3 million in 1996, 1995 and 1994, respectively. Related costs under the license agreement approximated the related research and development funding revenue and are included in research and development expenses in the accompanying financial statements. The research and development funding ended in October 1996. The license agreement provides for additional payments to the Company upon the achievement of certain milestones related to certain remaining licensed products under this agreement, as well as the payment of royalties to the Company on net sales of licensed products. The royalty rate is subject to reduction upon the occurrence of certain events.

#### Novartis

In April 1993, the Company entered into agreements with Sandoz Pharma, Sandoz, Ltd. and Sandoz Pharmaceuticals Corporation (collectively, "Novartis") to acquire certain licenses and rights to certain human, humanized and mouse monoclonal antibodies and certain related know-how, patent rights, equipment and materials. The Company is pursuing development of these products with the intent of producing treatments for certain diseases, and has obtained from Novartis worldwide manufacturing and marketing rights to these products. The agreements called for upfront payment to Novartis of \$5 million, substantially all of which was expensed in April 1993 for the acquisition of exclusive rights to in-process technology. Additional milestone payments of up to \$5 million will be made to Novartis in the event of certain product approvals. The agreements specify that Novartis has certain co-promotion and co-marketing rights and will earn royalties on the Company's sales of certain products in countries where

Novartis does not sell such products. In November 1993, the Company paid Novartis an additional \$2.75 million to amend the April 1993 agreement relating to the human antibodies in order to terminate certain of Novartis's co-promotion and co-marketing rights to the products covered by that agreement and to reduce royalties Novartis may earn from the sale of such antibodies in countries outside of the U.S., Canada and Asia.

#### Yamanouchi

In February 1991, Yamanouchi Pharmaceutical Co., Ltd. entered into a humanization agreement with the Company. Under this agreement, the Company received a licensing and signing fee in exchange for exclusive worldwide rights to the product under development. The agreement also provides for royalty payments to the Company on net sales of licensed products. The Company has received all of the additional payments for achieving milestones under this agreement.

#### Kanebo

In February 1992, Kanebo, Ltd. ("Kanebo") entered into a product licensing agreement with the Company. Under this agreement, the Company received a licensing and signing fee in exchange for a license to the potential product in certain Asian countries. The Company has received additional payments for achieving milestones under this agreement. The agreement also provides for royalty payments to the Company on net sales of licensed products. Kanebo provided annual payments to fund additional research and development work associated with the development of the product. The research and development funding period ended in September 1993. Related costs under this arrangement approximated the related revenue and are included in research and development expenses in the accompanying financial statements. During 1993 and 1994, the Company signed separate agreements to supply Kanebo with drug substance in order for Kanebo to conduct preclinical and clinical studies in Japan. The Company received payments for delivery of manufactured drug substance under these agreements in 1995, 1994 and 1993, respectively. These amounts were not material.

#### Mochida

In December 1995, the Company entered into a humanization agreement with Mochida Pharmaceutical Co., Ltd., a Japanese pharmaceutical company. Under this agreement, the Company received a \$1 million licensing and signing fee and can earn additional payments upon the achievement of certain milestones. The agreement also provides for royalty payments to the Company on net sales of licensed product. In addition, the Company has an option for co-promotion of the product in North America.

#### Unnamed Japanese Collaborator

In September 1996, the Company entered into a humanization agreement with another Japanese company. Under this agreement, the Company received a \$1 million licensing and signing fee and can earn additional payments upon the achievement of certain milestones. The agreement also provides for royalty payments to the Company on net sales of licensed product. In addition, the Company has an option for co-promotion of

the product in North America. The name of the Japanese company has not been disclosed.

#### Sankyo

In December 1996, the Company entered into a licensing agreement with Sankyo Co., Ltd. Under this agreement, the Company received a \$1 million licensing and signing fee. The agreement also provides for royalty payments to the Company on net sales of licensed product.

#### Genetics Institute (American Home Products)

In December 1996, the Company entered into a humanization agreement with Genetics Institute, Inc., a wholly-owned subsidiary of American Home Products Corporation. Under this agreement, the Company received a \$2.5 million licensing and signing fee and can earn additional payments upon the achievement of certain milestones. The agreement also provides for royalty payments to the Company on net sales of licensed products. In addition, the Company has an option to co-promote the products in North America (U.S. and Canada).

### 3. Other Accrued Liabilities

At December 31, other accrued liabilities consisted of the following:

	1996	1995
	-----	-----
Employee stock purchase plan	\$ 333,872	\$ 277,874
Clinical trials	1,843,206	182,766
Accrued rent	281,614	306,793
Other accrued liabilities	1,096,177	546,372
	-----	-----
	\$ 3,554,869	\$1,313,805
	=====	=====

The Company has a policy of accruing expenses for clinical trials based upon pro rating estimated total costs of a clinical trial over the estimated length of the clinical trial and the number of patients anticipated to be enrolled in the trial. Expenses are accrued as patients meeting the entry criteria in the clinical trial protocol are enrolled in and progress through the trial. In the event of early termination of a clinical trial, management accrues an amount based on its estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial.

### 4. Commitments

The Company occupies leased facilities under agreements that expire in 1998, 2000 and 2004. The Company also has leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately \$1,343,000, \$1,328,000 and \$1,200,000 for the years ended December 31, 1996, 1995 and 1994, respectively.

At December 31, 1996 the total future minimum non-cancelable payments under these agreements are approximately as follows:

1997	\$1,359,000
1998	1,214,000
1999	1,297,000
2000	1,309,000
2001	383,000
Thereafter	830,000
	-----

Total \$6,392,000

## 5. Short-and Long-Term Investments

The Company invests its excess cash balances in short-term and long-term marketable securities and U.S. government and government agency notes. These securities are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. The cost of securities sold is based on the specific identification method, when applicable.

The following is a summary of available-for-sale securities. Estimated fair value is based upon quoted market prices for these or similar instruments.

Available-for-Sale Securities				
Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	
December 31, 1996				
Securities of the U.S. Government and its agencies	\$ 85,392,700	\$ 132,900	\$ --	\$ 85,525,600
December 31, 1995				
Securities of the U.S. Government and its agencies	\$101,582,800	\$ 796,400	\$ --	\$102,379,200
December 31, 1994				
Securities of the U.S. Government and its agencies	\$107,902,900	\$ 166,600	\$ (1,216,300)	\$106,853,300

During 1996, there were no realized gains or losses on the sale of available-for-sale securities, as all securities liquidated in 1996 were held to maturity. During 1995, certain available-for-sale securities were sold before maturity resulting in a realized gain of approximately \$53,000. During 1994, there were no realized gains or losses on the sale of available-for-sale securities, as all securities liquidated in 1994 were held to maturity. As of December 31, 1996, the maturities of short-term investments ranged from 1 month to 12 months, and maturities of long-term investments ranged from 13 months to 20 months.

## 6. Stockholders' Equity

### Stock Purchase Plan

The Company has reserved 1,820,000 shares of its common stock for sale to employees, consultants and scientific advisors under the 1986 Stock Purchase Plan (the "Stock Purchase Plan"), which was adopted in November 1986. Shares issued pursuant to the Plan are issued at the fair value of such shares (as determined by the Company's Board of Directors) and are subject to stock purchase agreements which enable the Company to repurchase unvested shares at the original issuance price upon termination of employment or services. Shares generally vest at the rate of 25 percent at the end of the first year, with the remaining balance vesting monthly over the next three years in the

case of employees, and ratably over five years in the case of scientific advisors and consultants.

Through December 31, 1996, 1,081,227 shares had been issued under the Plan, of which none remain subject to repurchase. For certain shares sold under the Stock Purchase Plan, the Company has recorded compensation expense for the difference between the purchase and the deemed value for financial statement presentation purposes of the Company's common stock. This compensation expense has been amortized over the vesting period of each share sold and this amortization was completed during 1995.

#### 1991 Stock Option Plan

In December 1991, the Board of Directors adopted the 1991 Stock Option Plan (the "Option Plan"). During 1995, the stockholders approved an increase in the number of shares reserved under the Option Plan from 2,000,000 to 4,000,000 shares of common stock for the grant of options under the Option Plan.

At December 31, 1996, options to purchase 752,311 shares were exercisable at prices ranging from \$6.25 to \$25.75. Options granted under the Option Plan generally vest at the rate of 25 percent at the end of the first year, with the remaining balance vesting monthly over the next three years in the case of employees, and ratably over five years in the case of advisors and consultants.

#### 1992 Outside Directors' Stock Option Plan

In February 1992 the Board of Directors adopted the 1992 Outside Directors' Stock Option Plan (the "Directors' Plan"). The Company has reserved 200,000 shares of common stock for the grant of options under the Directors' Plan. Through December 31, 1996, the Company granted options to purchase 75,000 shares at exercise prices ranging from \$7.25 to \$27.00 per share, of which 22,500 were exercisable at December 31, 1996. Options granted pursuant to the Directors' Plan vest ratably over five years. A total of 11,666 and 4,167 options were exercised in 1996 and in 1995, respectively.

#### 1993 Employee Stock Purchase Plan

In February 1993, the Board of Directors adopted the 1993 Employee Stock Purchase Plan (the "Employee Purchase Plan"). The Company has reserved 300,000 shares of common stock for the purchase of shares by employees under the Employee Purchase Plan. Eligibility to participate in the Employee Purchase Plan is essentially limited to full time employees of the Company who own less than 5% of the outstanding shares of the Company. Under the Employee Purchase Plan, eligible employees can purchase shares of the Company's common stock based on a percentage of their compensation, up to certain limits. The purchase price per share must equal at least the lower of 85% of the market value on the date offered or on the date purchased. During 1996, an aggregate of 38,399 shares was purchased by employees under the Employee Purchase Plan at prices ranging from \$17.74 to \$19.13 per share.

#### Accounting for Stock-Based Compensation



The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting of Stock Issued to Employees" ("APB 25") and related interpretations, in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. Pro forma information regarding net income and earnings per share in 1996 and 1995 has been determined as if the Company had accounted for its employee stock options under the fair value method prescribed by FAS 123. The resulting effect on pro forma net income and earnings per share on a pro forma basis disclosed for 1996 and 1995 is not likely to be representative of the effects on net income and earnings per share on a pro forma basis in future years, because 1996 and 1995 pro forma results include the impact of only one and two years, respectively, of options vesting, while subsequent years will include additional years of vesting.

		1996 ----	1995 ----
Net loss	As reported	\$ (11,796,098)	\$ (8,353,796)
	Pro forma	(14,399,292)	(9,219,776)
Loss per share	As reported	\$ (0.76)	\$ (0.54)
	Pro forma	(0.92)	(0.60)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes options pricing model with the following weighted-average assumptions used for grants in 1996 and 1995, respectively: (a) no dividends; (b) expected volatility of 55%; (c) risk-free interest rates ranging from 5.25% to 7.5%; and (d) expected lives of 6 years.

A summary of the status of the Company's stock option plans as of December 31, 1996 and 1995, and changes during the years ending those dates is presented below.

	1996 -----		1995 -----	
	Shares -----	Weighted Average Exercise Price -----	Shares -----	Weighted Average Exercise Price -----
Outstanding at beginning of year	1,756,317	\$ 15.61	1,412,030	\$ 13.72
Granted	608,405	24.90	544,350	18.99
Exercised	(309,167)	13.23	(137,250)	9.41
Forfeited	(114,123)	21.32	(62,813)	16.75
	-----		-----	
Outstanding at end of year	1,941,432	18.44	1,756,317	15.61
	=====		=====	

Weighted average fair value of

options granted during the year	\$ 14.23 =====	\$ 11.01 =====
---------------------------------	-------------------	-------------------

The following information applies to all stock options outstanding under the Company's stock option plans at December 31, 1996:

Options exercisable	774,811
Range of exercise prices	\$6.25 to \$34.25
Weighted average remaining contractual life	8 years

## 7. Income Taxes

As of December 31, 1996, the Company had federal and state net operating loss carryforwards of approximately \$33.2 million and \$2.9 million, respectively. Federal net operating loss carryforwards will expire at various dates beginning in 2002 through 2011, if not utilized.

The federal net operating loss carryforward differs from the accumulated deficit principally due to temporary differences in the recognition of certain revenue and expense items for financial and federal tax reporting purposes, consisting primarily of in-process technology capitalized for federal tax purposes.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amount used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes as of December 31 are as follows:

(In thousands)

	1996 -----	1995 -----
Deferred tax assets:		
Net operating loss carryforwards	\$ 11,400	\$ 6,100
Research credits	2,400	1,700
Deferred revenue	--	400
Capitalized research and development	2,800	2,400
Other	500	(400)
	-----	-----
Total deferred tax assets	17,100	10,200
Valuation allowance for deferred tax asset	(17,100)	(10,200)
	-----	-----
Net deferred tax assets	\$ --	\$ --
	=====	=====

Because of the Company's lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$3 million during the year ended December 31, 1995.

Utilization of the net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the

Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

#### 8. Legal Proceedings

The Company is involved in administrative opposition proceedings being conducted by the EPO with respect to its European patent relating to humanized antibodies. Eighteen oppositions have been filed with respect to the issuance of the patent to the Company in January 1996. The oppositions argue that the patent was incorrectly granted and should be withdrawn or limited. Other than such administrative proceedings, the Company is not a party to any material administrative or legal proceedings.

#### 9. Subsequent Event

On February 3, 1997, the Company filed a Registration Statement on Form S-3 for the sale of 2,000,000 shares of Common Stock by the Company and 750,000 shares of Common Stock by Corange.

## Report of Ernst &amp; Young LLP, Independent Auditors

Board of Directors and Stockholders  
Protein Design Labs, Inc.

We have audited the accompanying balance sheets of Protein Design Labs, Inc., as of December 31, 1996 and 1995, and the related statements of operations, stockholders' equity and cash flows for each of three years in the period ended December 31, 1996. 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 Protein Design Labs, Inc. at December 31, 1996 and 1995, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1996 in conformity with generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
January 27, 1997

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON  
ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

PART III

ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS

Information with respect to the executive officers and directors of the Company as of December 31, 1996 is set forth below:

Name -----	Age ---	Positions -----
Laurence Jay Korn, Ph.D. . . . .	47	Chief Executive Officer and Chairperson of the Board of Directors
Jon S. Saxe . . . . .	60	President and Director
Cary L. Queen, Ph. D. . . . .	46	Senior Vice President, Vice President, Research and Director
Christine Booker . . . . .	55	Vice President, Quality and Compliance
Douglas O. Ebersole . . . . .	40	Vice President, Licensing and Corporate Services, General Counsel and Secretary
Fred Kurland . . . . .	46	Vice President and Chief Financial Officer
Daniel J. Levitt, M.D., Ph.D. . .	49	Senior Vice President, Clinical and Regulatory Affairs
Mark D. Young, Ph.D. . . . .	46	Vice President, Technical Operations
Stanley Falkow, Ph.D.(1) . . . . .	62	Distinguished Investigator (consultant) and Director
Jurgen Drews, M.D.(2) . . . . .	63	Director
George M. Gould(1)(3) . . . . .	59	Director
Max Link, Ph.D.(3) . . . . .	56	Director

- - - - -

- (1) Member of the Audit Committee.  
 (2) Dr. Drews joined the Board in February 1997.  
 (3) Member of the Compensation Committee.

Laurence Jay Korn, Ph.D., has served as a director and Chairperson of the Board since July 1986 and Chief Executive Officer since January 1987. Previously, Dr. Korn headed a research laboratory and served on the faculty of the Department of Genetics at the Stanford University School of Medicine from March 1981 to December 1986. Dr. Korn received his Ph.D. from Stanford University and was a Helen Hay Whitney Postdoctoral Fellow at the Carnegie Institution of Washington and a Staff Scientist at the MRC Laboratory of Molecular Biology in Cambridge, England, before becoming an Assistant Professor at Stanford.

Jon S. Saxe has been a director of the Company since March 1989 and has served as President of the Company since January 1995. Mr. Saxe was a consultant to the Company from June 1993 to December 1994. He has served as President of Saxe Associates, a biotechnology consulting firm, since May 1993. Mr. Saxe served as the President, Chief Executive Officer and a director of Synergen, Inc., a biopharmaceutical company, from October 1989 to April 1993. Mr. Saxe served as Vice President, Licensing & Corporate Development for Roche from August 1984 through September 1989, and Head Patent Law from September 1978 through September 1989. Mr. Saxe is also a director of InSite Vision Incorporated, Microcide Pharmaceuticals, Inc., Incyte Pharmaceuticals Inc. and ID Biomedical Corporation. Mr. Saxe received his J.D. from George Washington University School of Law and his LL.M. from New York University School of Law.

Cary L. Queen, Ph.D., has served as a director since January 1987, as Vice President, Research, since April 1989 and as Senior Vice President since June 1993. Previously, Dr. Queen held positions at the National Institutes of Health from 1983 to 1986, where he studied the regulation of genes involved in the synthesis of antibodies. Dr. Queen received his Ph.D. in Mathematics from the University of California at Berkeley and subsequently served as an Assistant Professor of Mathematics at Cornell University.

Christine Booker has served as the Company's Vice President, Quality and Compliance since February 1996. Prior to joining the Company, from February 1995 through January 1996, Ms. Booker served as a consultant to the Company. Since August 1994, Ms. Booker has served as the principal consultant for Booker Associates. From March 1992 to October 1994, Ms. Booker served as Director, Quality Assurance for Synergen, Inc. From October 1980 to February 1992, Ms. Booker served in various positions at Genentech, Inc., including Associate Director, Technical Operations. Ms. Booker received her B.S. in Chemistry from DePaul University.

Douglas O. Ebersole has served as the Company's Vice President, Licensing, General Counsel and Secretary since July 1992 and in April 1996 was appointed to the additional position of Vice President, Corporate Services. Prior to joining the Company, he served first as Associate General Counsel and later as General Counsel at NeXT Computer, Inc. Prior to joining NeXT in 1989, he was a partner in the corporate department of the law firm Ware & Freidenrich (now known as Gray Cary Ware & Freidenrich). Mr. Ebersole received his J.D. from Stanford Law School.

Fred Kurland has served as the Company's Vice President and Chief Financial Officer since February 1996. Prior to joining the Company, from May 1995 to January 1996, Mr. Kurland served as the Vice President, Chief Financial Officer and Secretary of Applied Immune Sciences, Inc., a biotechnology company. From February 1991 to April 1995, Mr. Kurland served as Vice President and Controller of Syntex Corporation, a pharmaceutical company ("Syntex"). From 1981 to February 1991, Mr. Kurland served in various senior financial positions in corporate and operations functions at Syntex. Mr. Kurland received his J.D. and M.B.A. degrees from the University of Chicago.

Daniel J. Levitt, M.D., Ph.D., has served as Senior Vice President, Clinical and Regulatory Affairs of the Company since November 1996. From February 1995 to October 1996 he served as Vice President of Drug Development and Chief Medical Officer of Geron Corporation, a biotechnology company. From 1990 until January 1995, Dr. Levitt held various positions at Sandoz Pharma Ltd. (now known as Novartis Pharma Ltd.), a pharmaceutical company, most recently as Worldwide Head of Oncology Clinical Research and Development. From 1986 to 1990, Dr. Levitt held various positions with Roche, including Director of Clinical Oncology and Immunology. He received post-graduate training at Yale-New Haven Hospital and the University of Chicago Pritzker School of Medicine. Dr. Levitt holds an M.D. and Ph.D. from the University of Chicago Pritzker School of Medicine.

Mark D. Young, Ph.D., has served as the Company's Vice President, Technical Operations since September 1995. From February 1995 through August 1995, Dr. Young served as acting Head of Manufacturing of the Company. From 1989 through January 1995, Dr. Young served in various senior management positions at Synergen Inc. and its successor Amgen, a biotechnology company, including Vice President, Process Development and Executive Vice President, Technical Operations. Dr. Young has over 20 years experience in fermentation and biotechnology-based pharmaceutical process development and manufacturing. Dr. Young received his Ph.D. in Chemical Engineering from the University of Michigan and his M.S. in Chemical Engineering from Columbia University.

Stanley Falkow, Ph.D., has been a director of the Company since December 1991, a consultant to the Company since 1987 and a Distinguished Investigator for the Company since 1991. Dr. Falkow has served as a Professor of Microbiology, Immunology and Medicine at the Stanford University School of Medicine since 1981. Dr. Falkow is a recipient of the Paul Erlich Prize from the German Federal Republic and the Squibb Award of the Infectious Diseases Society of America and is a member of the U.S. National Academy of Sciences and the American Academy of Arts and Sciences. Dr. Falkow is also a director of GalaGen Inc.

Jurgen Drews, M.D. has been a director of the Company since February 1997. Dr. Drews has been President, Global Research for Roche since January 1996, and also serves as a member of the Executive Committee of the Roche Group. From January 1991 to December 1995, Dr. Drews served as President, International Research and Development and as a Member of the Executive Committee for Roche. Prior to that time Dr. Drews served as Chairman of the Research Board and Member of the Executive Committee for Roche from April 1986 to December 1990. Dr. Drews served as Head of International Pharmaceutical Research and Development for Sandoz Ltd. (now known as Novartis Ltd.) from January 1982 to July 1985. Dr. Drews is also a director of Genentech, Inc.

George M. Gould has been a director of the Company since October 1989. Mr. Gould is of counsel to the law firm Crummy, Del Deo, Dolan, Griffinger & Vecchione. From May 1996 to December 1996, Mr. Gould was a Senior Vice President of PharmaGenics, Inc., a biotechnology company. Prior to that time Mr. Gould served as Vice President of Licensing & Corporate Development and Chief Patent Counsel for Roche from October 1989 to May 1996.

Max Link, Ph.D., has been a director of the Company since June 1993. Dr. Link served as the Chief Executive Officer of Boehringer Mannheim -- Therapeutics from October 1993 to May 1994 and as the Chief Executive Officer of Corange Ltd. from May 1993 to May 1994. Dr. Link served as the Chairman of Sandoz Pharma Ltd. (now known as Novartis Pharma Ltd.) from April 1992 to April 1993. Dr. Link served in various management positions at Sandoz Ltd. (now known as Novartis Ltd.) and Sandoz Pharmaceuticals Corporation (now known as Novartis Pharmaceuticals Corporation) from October 1971 to April 1992. Dr. Link is also a director of Access Pharmaceuticals, Inc., Alexion Pharmaceutical Inc., CytRx Corp., Human Genome Sciences, Inc. and Procept, Inc.

#### SECTION 16(A) REPORTING

Each director and each executive officer of the Company who is subject to Section 16 of the Securities Exchange Act of 1934 is required by Section 16(a) of such act to report to the Securities and Exchange Commission by a specified date his or her transactions in the Company's securities. To the best of the Company's knowledge, all reports relating to stock ownership and such other reports required to be filed during 1996 under Section 16(a) by the Company's directors and executive officers were timely filed, with the exception of the Initial Statement of Beneficial Ownership of Securities on Form 3 for Dr. Levitt, which form was filed late.



## ITEM 11. EXECUTIVE COMPENSATION

## COMPENSATION OF EXECUTIVE OFFICERS

The following table sets forth information concerning the compensation of the Chief Executive Officer of the Company and the four other most highly compensated executive officers of the Company as of December 31, 1996 as well as a former executive officer who is required to be identified herein ("Named Executive Officers"), whose salary and bonus exceeded \$100,000 for the fiscal year ended December 31, 1996, during the fiscal years ended December 31, 1996, 1995 and 1994:

## SUMMARY COMPENSATION TABLE

Name and Principal Positions	Year	Annual Compensation(1)		Long Term Compensation	
		Salary (\$)	Other Annual Compensation(\$)	Restricted Stock (\$)	Securities Underlying Options (#)
Laurence Jay Korn(2) Chief Executive Officer	1996	356,220	--	--	50,000
	1995	320,300	--	--	--
	1994	300,000	--	--	150,000
Jon S. Saxe President	1996	339,915	--	--	35,000
	1995	307,610	32,270(3)	--	150,000(4)
	1994	--	--	--	--
Paul I. Nadler(5) Vice President, Medical and Regulatory Affairs	1996	281,575	--	--	50,000
	1995	275,675	--	--	--
	1994	265,760	--	--	--
Cary L. Queen(6) Senior Vice President and Vice President, Research	1996	256,220	--	--	30,000
	1995	240,785	--	--	--
	1994	225,000	--	--	120,000
Douglas O. Ebersole(7) Vice President, Corporate Services and Licensing, General Counsel and Secretary	1996	224,255	--	--	--
	1995	201,905	--	--	70,000
	1994	182,500	--	--	--
Mark D. Young(8) Vice President, Technical Operations	1996	218,720	--	--	--
	1995	167,640	--	--	70,000
	1994	--	--	--	--

(1) Compensation deferred at the election of the executive officer under the Company's 401(k) Plan is included in the year earned. No bonuses were paid in 1994, 1995 or 1996 to the named individuals and the bonus column is omitted from the table.

(2) Stock options granted in 1996 and 1994 to Dr. Korn were granted based on his reaching his tenth and eighth anniversary dates of employment with the Company in January 1997 and 1995, respectively.

(3) Amounts received as compensation in connection with Mr. Saxe's relocation to the Company's headquarters office.

(4) Stock options were granted in 1994 to Mr. Saxe in connection with his joining the Company as President in January 1995.

(5) Dr. Nadler resigned as an officer and employee of the Company in November 1996. Stock options granted to Dr. Nadler in 1996 did not vest.

(6) Stock options granted in 1996 and 1994 to Dr. Queen were granted based on his reaching his tenth and eighth anniversary dates of employment with the Company in January 1997 and 1995, respectively.

(7) Stock options granted in 1995 to Mr. Ebersole were granted based on his reaching his third anniversary date of employment with the Company in July 1995.

(8) Stock options were granted in 1995 to Dr. Young in connection with his joining the Company as Acting Head of Manufacturing in February 1995.

#### STOCK OPTIONS GRANTED IN FISCAL 1996

The following table provides the specified information concerning grants of options to purchase the Company's Common Stock made during the fiscal year ended December 31, 1996 to the persons named in the Summary Compensation Table:

#### OPTION GRANTS IN THE LAST FISCAL YEAR

Name	Number of Securities Underlying Options(1,2) Granted (#)	% of Total Options Granted to Employees in Fiscal Year(%)	Exercise Or Base Price (\$/Sh)(3)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(4)	
					5% (\$)	10% (\$)
Laurence Jay Korn	50,000	8.57	26.50	12/14/06	833,285	2,111,709
Jon S. Saxe	35,000	6.00	26.50	12/14/06	583,300	1,478,196
Paul I. Nadler	--	--	--	--	--	--
Cary L. Queen	30,000	5.14	26.50	12/14/06	499,971	1,267,025
Douglas O. Ebersole	--	--	--	--	--	--
Mark D. Young	--	--	--	--	--	--

(1) Options granted vest over a four year period at the rate of one-fourth one year after the date specified at the time of grant (typically the hire date or an anniversary of the hire date) and 1/48 per month thereafter for each full month of the optionee's continuous employment with the Company. Only vested shares are exercisable. Options granted to date have had terms of either six or ten years. The Company has never granted any Stock Appreciation Rights and references to this security are omitted.

(2) Under the Option Plan, the Board retains some discretion to modify the terms of outstanding options; see "Change of Control Arrangements."

(3) All options granted to employees were granted at market value on the date of grant.

(4) Potential gains are net of exercise price, but before taxes associated with exercise. These amounts represent certain assumed rates of appreciation only, based on the Securities and Exchange Commission's rules. Actual gains, if any, on stock option exercises are dependent on the future performance of the Common Stock, overall market conditions and the optionholder's continued employment through the vesting period. Any amounts reflected in this table may not necessarily be achieved. As an example of the effects such assumed appreciation would have on a stockholder's investment, one share of stock purchased at \$36.50 (December 31, 1996 closing price) in 1996 would yield profits of \$28.16 per share at 5% appreciation per year over ten years or \$58.17 per share at 10% appreciation per year over the same period. The "potential realizable values" in this table are calculated using the exercise price of the stock options and assuming 5% or 10% appreciation per year from that price over the term of the options granted.

#### OPTION EXERCISES AND FISCAL 1996 YEAR-END VALUES

The following table provides the specified information concerning exercises of options to purchase the Company's Common Stock in the fiscal year ended December 31, 1996, and unexercised options held as of December 31, 1996, by the persons named in the Summary Compensation Table:

#### AGGREGATE OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END VALUES(1)

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options at 12/31/96(2)		Value of Unexercised In-the-Money Options at 12/31/96(3)	
			Unexercisable	Exercisable	Unexercisable	Exercisable
Laurence Jay Korn	--	--	128,125	171,875	2,101,562	3,723,437
Jon S. Saxe	--	--	113,125	101,625	1,863,672	2,236,078
Paul I. Nadler	51,083	674,165	--	--	--	--
Cary L. Queen Douglas O.	--	--	92,500	137,500	1,581,250	2,978,750
Ebersole	13,000	232,375	45,208	59,792	695,078	1,396,172
Mark D. Young	--	--	37,917	32,083	782,031	661,719

(1) The Company has never granted any Stock Appreciation Rights and references to this security are omitted.

(2) See footnote 1 of the "OPTION GRANTS IN THE LAST FISCAL YEAR" table for information concerning the vesting provisions of these stock options.

(3) Based on a value of \$36.50 which was the closing price of the Company's Common Stock as of December 31, 1996.

## COMPENSATION OF DIRECTORS

As of December 31, 1996, each director who is not an employee of the Company was authorized to receive cash compensation in the amount of \$2,500 each fiscal quarter, or such other amount as the Board may approve, and may be reimbursed for expenses incurred in attending each Board and committee meeting.

As of December 31, 1996, the Company's Outside Directors Stock Option Plan (the "Directors Plan") provided for the initial automatic grant of an option to purchase 25,000 shares of the Company's Common Stock to each director of the Company who is not an employee of the Company ("Outside Directors"). The Directors Plan also provides for a subsequent grant to Outside Directors to purchase 25,000 shares of Common Stock on the date five years from the date of the initial grant; provided, however, that if the director was granted an option under the Option Plan prior to February 14, 1992 (the date of adoption of the Directors Plan), the subsequent grant shall be on the date five years from the date of such grant. Options under the Directors Plan are granted at the fair market value of the Company's Common Stock on the date of grant and vest as to 1/60 of the shares subject to the option per month until such time as the optionee ceases to be a director for any reason. Options granted under the Directors Plan to date had terms of either 6 or 10 years from the date of grant.

## CHANGE OF CONTROL ARRANGEMENTS, TERMINATION OF EMPLOYMENT ARRANGEMENTS

Stock options issued to full-time employees under the Company's Option Plan contain provisions pursuant to which an additional twenty five percent (25%) of the total number of options subject to vesting under any outstanding employee stock option agreement will vest if either (a) in connection with a "transfer of control," an acquiring corporation fails to assume the outstanding option or to substitute a substantially equivalent option for the acquiring corporation's stock, or (b) within one year following a "transfer of control," the option holder is either terminated by the Company or its successor without cause or resigns from employment within a reasonable time following "constructive termination."

Under the terms of the Directors Plan, in the event of the sale, dissolution, or liquidation of the Company, or a merger or consolidation in which the Company is not the surviving or resulting corporation or in which the stockholders of the Company immediately before such event beneficially own, directly or indirectly, less than 50% of the voting securities of the surviving corporation immediately after such event, and if the surviving corporation does not assume or substitute new options for the outstanding options, the Company's Board may, but is not obligated to, provide that any unexercisable and/or unvested portion of the outstanding options shall be immediately exercisable and vested. Any options which are neither assumed nor substituted for by the acquiring corporation nor exercised as of the date of the transfer of control shall terminate effective as of the date of the transfer of control.

## COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

George M. Gould served as a member of the Board's Compensation Committee during the entire year ended December 31, 1996. Mr. Gould, a director of the Company, was a member of the management of Hoffmann-La Roche Inc. until May 1996. In 1989, Roche entered into a stock purchase agreement and licensing agreement with the Company for certain potential products. In addition, during 1996 the Company retained the law firm of Crummy, Del Deo, Dolan, Griffinger

& Vecchione, a law firm in which Mr. Gould is of counsel, to provide representation on a small patent matter on behalf of the Company.

Laurence Jay Korn and Cary L. Queen, executive officers and directors of the Company during the entire year ended December 31, 1996, were both also executive officers and directors of Advanced Software of California, Inc. (formerly Advanced Software, Inc.). During 1996, Advanced Software of California, Inc. was a privately held company in which the Board of Directors performed the same function as a compensation committee. Drs. Korn and Queen are the only officers and directors of the Company who served as officers or directors of Advanced Software of California, Inc. during the fiscal year ended December 31, 1996. Neither Dr. Korn nor Dr. Queen served on the Compensation Committee of the Board of Directors of the Company.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of the Company's Common Stock as of December 31, 1996 by (i) each person who is known by the Company, based on the records of the Company's transfer agent and relevant documents filed with the U.S. Securities and Exchange Commission ("SEC"), to own beneficially more than 5% of the outstanding shares of the Company's Common Stock, (ii) each member of the Company's Board of Directors, (iii) the Named Executive Officers, and (iv) all members of the Board of Directors and executive officers of the Company as a group. Except as set forth below, the address of each named individual is the address of the Company.

Name of Beneficial Owner or Group and Nature of Beneficial Ownership(1)	Amount of Beneficial Ownership	Percent of Common Stock Outstanding
Corange International Limited 22 Church Street P.O. Box HM2026 Hamilton HM HX Bermuda	2,432,877	15.44%
LGT Asset Management, Inc.(2) Chancellor LGT Asset Management, Inc. Chancellor LGT Trust Company 50 California St., 27th Floor San Francisco, CA 94111	1,989,500	12.62
Hoffmann-La Roche Inc. 340 Kingsland Street Nutley, NJ 07110	1,321,418	8.39
FMR Corp.(2) 82 Devonshire Street Boston, MA 02109	860,300	5.46
Jurgen Drews, M.D.(3)	1,321,418	8.39
Cary L. Queen, Ph.D.(4)	881,750	5.54

Laurence Jay Korn, Ph.D.(5)	853,949	5.36
Jon S. Saxe(6)	127,688	*
Stanley Falkow, Ph.D.(7)	70,167	*
Douglas O. Ebersole(8)	64,069	*
Mark D. Young, Ph.D.(9)	36,228	*
George M. Gould(10)	22,666	*
Max Link, Ph.D.(11)	18,333	*
Paul I. Nadler, M.D.(12)	250	*
All directors and executive officers as a group (11 persons)(3,4,5,6,7,8,9,10,11,13)	2,089,642	12.76%

- - - - -  
\* Less than 1%

(1) Except as indicated in the footnotes to this table, the persons named in the table have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them, subject to community property laws where applicable.

(2) Based solely on information provided in Schedule 13G as filed with the SEC.

(3) Includes 1,321,418 shares held by Hoffmann-La Roche Inc. with respect to which Dr. Drews disclaims beneficial ownership.

(4) Includes 145,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996. Also includes 1,600 shares held in trusts for the benefit of certain of Dr. Queen's relatives with respect to which Dr. Queen disclaims beneficial ownership.

(5) Includes 181,250 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996. Also includes 12,067 shares held as separate property by Dr. Korn's spouse with respect to which Dr. Korn disclaims beneficial ownership.

(6) Includes 111,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996.

(7) Includes 25,167 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996.

(8) Includes 62,708 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996.

(9) Includes 35,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996.

(10) Includes 21,666 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996. Also includes 1,000 shares held for the benefit of Mr. Gould's daughter, with respect to which Mr. Gould disclaims beneficial ownership.

(11) Includes 2,500 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 1996.

(12) Dr. Nadler resigned as an officer and employee of the Company effective as of November 1, 1996.

(13) Includes all directors and officers who served in that capacity as of December 31, 1996 and includes 611,791 shares issuable upon the exercise of options beneficially owned by directors and officers which are currently, or which will become, exercisable within 60 days after December 31, 1996.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

During 1996, the Company paid Dr. Falkow, a director of the Company, a total of approximately \$60,800 in connection with his providing scientific consulting services to the Company, which services included, among other matters, assistance in establishing development priorities for the research efforts of the Company and identifying the most promising clinical candidates for advancement out of research and into development. In addition, the Company has entered into negotiations with Dr. Falkow to increase his consulting commitment to the Company and with Stanford University to provide funding for up to three years for Dr. Falkow's laboratory at Stanford. The Company expects that the funding commitment will involve financial support in an aggregate amount of up to approximately \$3 million over the three-year period.

In November 1996, the Company loaned to Dr. Levitt, an officer of the Company, an aggregate of \$90,000 at an annual interest rate of 6.60% pursuant to a three-year promissory note. The terms of Dr. Levitt's note provide for, among other matters, payment of accrued interest annually and forgiveness of one-third of the principal amount on each anniversary date of his full-time employment with the Company.

Dr. Drews, an executive officer of Roche, joined the Company's Board of Directors in February 1997. The Company and Roche are parties to a number of agreements that had been entered into prior to the election of Dr. Drews to the Board of Directors. See "Business -- Collaborative and Licensing Arrangements."

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS  
ON FORM 8-K

(a) The following documents are filed as part of this report:

(1) Index to financial statements

The following financial statements of the Company and the Report of the Independent Auditors are included in Part II, Item 8.

Item	Page
Balance Sheets	45
Statements of Operations	46
Statements of Stockholders' Equity	47
Statements of Cash Flows	48
Report of Ernst & Young LLP, Independent Auditors	58

(2) No financial statement schedules are required to be filed as part of this Form 10-K by Regulation S-X. All other financial statement schedules are omitted because the information is inapplicable or presented in the Financial Statements or notes.

(3) The items listed on the Index to Exhibits on page 74 are incorporated herein by reference.

(b) Reports on Form 8-K.

None.

(c) See (a)(3) above.

(d) See (a)(3) above.



## SIGNATURES

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

PROTEIN DESIGN LABS, INC.  
(Registrant)

By: /s/ LAURENCE JAY KORN

-----  
Laurence Jay Korn,  
Chief Executive Officer  
and Chairperson of the Board  
of Directors

March 7, 1997

-----  
Date

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 and in the capacities and on the dates indicated.

Signature -----	Title -----	Date ----
/s/ LAURENCE JAY KORN ----- (Laurence Jay Korn)	Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)	March 7, 1997
/s/ FRED KURLAND ----- (Fred Kurland)	Vice President and Chief Financial Officer (Principal Accounting Officer)	March 7, 1997
/s/ CARY L. QUEEN ----- (Cary L. Queen)	Director	March 7, 1997
----- (George M. Gould)	Director	, 1997
/s/ JON S. SAXE ----- (Jon S. Saxe)	Director	March 7, 1997
/s/ STANLEY FALKOW ----- (Stanley Falkow)	Director	March 7, 1997
----- (Max Link)	Director	, 1997
----- (Jurgen Drews)	Director	, 1997

## INDEX TO EXHIBITS

Exhibit Number -----	Exhibit Title -----	Page No. -----
3.1	Restated Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K filed March 31, 1993.)	
3.2	Amended and Restated Bylaws. (Incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K filed March 31, 1995.)	
4.1	Registration Rights Agreement between the Company and certain holders of Preferred Stock and Common Stock, dated August 21, 1986. (Incorporated by reference to Exhibit 4.1 to Registration Statement No. 33-44562 effective January 28, 1992.)	
4.2	Amendment to Registration Rights Agreement between the Company and certain holders of Preferred Stock and Common Stock, dated March 16, 1989. (Incorporated by reference to Exhibit 4.2 to Registration Statement No. 33-44562 effective January 28, 1992.)	
4.3	Registration Rights Agreement between the Company and Hoffmann-La Roche Inc., dated March 16, 1989. (Incorporated by reference to Exhibit 4.3 to Registration Statement No. 33-44562 effective January 28, 1992.)	
4.4	Standstill Agreement between the Company and Hoffmann-La Roche Inc., dated March 16, 1989. (Incorporated by reference to Exhibit 4.4 to Registration Statement No. 33-44562 effective January 28, 1992.)	
4.5	Registration Rights Agreement between the Company and Corange International Limited, dated October 28, 1993. (Incorporated by Reference to Exhibit 4.5 to Annual Report on Form 10-K filed March 31, 1994.)	
4.6	Standstill Agreement between the Company and Corange International Limited, dated October 28, 1993. (Incorporated by Reference to Exhibit 4.5 to Annual Report on Form 10-K filed March 31, 1994.)	
4.7	Amendment No. 1 to Stock Purchase Agreement, Registration Rights Agreement and Joint Development, Marketing and Licensing Agreement. (Incorporated by Reference to Exhibit 5.2 to Current Report on Form 8-K filed December 15, 1994.)	
*10.1	1991 Stock Option Plan, as amended on October 20, 1992 and June 15, 1995, together with forms of Incentive Stock Option Agreement and Nonqualified Stock Option Agreements. (Incorporated by reference to Exhibit 10.1 to Annual Report on Form 10-K filed March 31, 1996.)	
*10.2	Founder Stock Purchase Agreement between the Company and Dr. Laurence Jay Korn, dated August 21, 1986. (Incorporated by reference to Exhibit 10.3 to Registration Statement No. 33-44562 effective January 28, 1992.)	
*10.3	Founder Stock Purchase Agreement between the Company and Dr. Cary Queen, dated January 1, 1987. (Incorporated by reference to Exhibit 10.4 to Registration Statement No. 33-44562 effective January 28, 1992.)	

Exhibit Number -----	Exhibit Title -----	Page No. -----
*10.4	1986 Stock Purchase Plan. (Incorporated by reference to Exhibit 10.18 to Registration Statement No. 33-44562 effective January 28, 1992.)	
*10.5	Forms of Stock Purchase Agreement under the 1986 Stock Purchase Plan. (Incorporated by reference to Exhibit 10.19 to Registration Statement No. 33-44562 effective January 28, 1992.)	
*10.6	Outside Directors Stock Option Plan, together with form of Nonqualified Stock Option Agreements. (Incorporated by reference to Exhibit 10.31 to Annual Report on Form 10-K filed March 31, 1993.)	
*10.7	1993 Employee Stock Purchase Plan. (Incorporated by reference to Exhibit 10.32 to Annual Report on Form 10-K filed March 31, 1993.)	
*10.8	Letter Agreement between the Company and Saxe Associates, dated June 14, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.9 to Annual Report on Form 10-K filed March 31, 1994.)	
10.9	Lease Agreement between the Company and Charleston Properties, a California general partnership, dated December 22, 1989. (Incorporated by reference to Exhibit 10.5 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.10	First Amendment of Lease between the Company and Charleston Properties, a California general partnership, dated August 31, 1992. (Incorporated by reference to Exhibit 10.26 to Annual Report on Form 10-K filed March 31, 1993.)	
10.11	Lease Agreement between the Company and Plymouth Business Center I Partnership, a Minnesota general partnership, dated February 10, 1992. (Incorporated by reference to Exhibit 10.28 to Annual Report on Form 10-K filed March 31, 1993.)	
10.12	Amendment No. 1 to Lease Agreement between the Company and Plymouth Business Center I Partnership, a Minnesota general partnership, dated July 8, 1993. (Incorporated by reference to Exhibit 10.14 to Annual Report on Form 10-K filed March 31, 1994.)	
10.13	License Agreement between the Company and the National Technical Information Service effective as of October 31, 1988 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.7 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.14	License Agreement between the Company and Hoffmann-La Roche Inc. effective January 31, 1989 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.8 to Registration Statement No. 33-44562 effective January 28, 1992.)	

Exhibit Number -----	Exhibit Title -----	Page No. -----
10.15	License Agreement between the Company and F. Hoffmann-La Roche & Co. effective January 31, 1989 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.9 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.16	License Agreement between the Company and the Medical Research Council of the United Kingdom dated July 1, 1989, as amended on January 30, 1990 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.10 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.17	Software License Agreement among the Company, Molecular Applications Group and Michael Levitt effective September 1, 1990 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.14 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.18	Development and License Agreement between the Company and Yamanouchi Pharmaceutical Company, Ltd. effective February 12, 1991, as amended on February 12, 1991 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.16 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.19	Form of Director and Officer Indemnification Agreement. (Incorporated by reference to Exhibit 10.1 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.20	Stock Purchase Agreement between the Company and certain holders of Preferred Stock and Common Stock dated August 21, 1986. (Incorporated by reference to Exhibit 10.22 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.21	Stock Purchase Agreement between the Company and Hoffmann-La Roche Inc. dated March 16, 1989. (Incorporated by reference to Exhibit 10.25 to Registration Statement No. 33-44562 effective January 28, 1992.)	
10.22	Agreement for Purchase and Sale of Assets between the Company and Helix BioCore, Inc., a Minnesota corporation, dated February 10, 1992. (Incorporated by reference to Exhibit 10.27 to Annual Report on Form 10-K filed March 31, 1993.)	
10.23	Agreement between the Company and Kanebo, Ltd., a Japanese corporation, dated February 29, 1992. (Incorporated by reference to Exhibit 10.29 to Annual Report on Form 10-K filed March 31, 1993.)	
10.24	Letter dated November 4, 1992 amending the License Agreement between the Company and Hoffmann-La Roche Inc. effective January 21, 1989. (Incorporated by reference to Exhibit 10.30 to Annual Report on Form 10-K filed March 31, 1993.)	
10.25	Asset Purchase and License Agreement among the Company, Sandoz Pharma Ltd. and Sandoz Pharmaceuticals Corporation, dated April 13, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted	

information). (Incorporated by reference to Exhibit 5.1 to Current Report on Form 8-K filed April 28, 1993.)

Exhibit Number	Exhibit Title	Page No.
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10.26	License Agreement among the Company, Sandoz Pharma Ltd. and Sandoz Ltd., dated April 13, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 5.2 to Current Report on Form 8-K filed April 28, 1993.)	
10.27	Letter dated October 21, 1993 amending the Asset Purchase and License Agreement among the Company, Sandoz Pharma Ltd. and Sandoz Pharmaceuticals Corporation, dated April 13, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.31 to Annual Report on Form 10-K filed March 31, 1994.)	
10.28	Amended and Restated Agreement between the Company and Sloan-Kettering Institute for Cancer Research, dated April 1, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.32 to Annual Report on Form 10-K filed March 31, 1994.)	
10.29	Stock Purchase Agreement between the Company and Corange International Limited, dated October 28, 1993. (Incorporated by reference to Exhibit 5.1 to Current Report on Form 8-K filed November 12, 1993.)	
10.30	Joint Development, Marketing and License Agreement between the Company and Corange International Limited, dated October 28, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 5.2 to Current Report on Form 8-K filed November 12, 1993.)	
10.31	License Agreement between the Company and The Board of Trustees of Leland Stanford Junior University effective as of June 30, 1993 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.35 to Annual Report on Form 10-K filed March 31, 1994.)	
10.32	Lease Agreement between the Company and Bio-Shore Holdings, Ltd. dated as of May 16, 1994 (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 2, 1994.)	
10.33	Amendment No. 2 to Lease Agreement between the Company and St. Paul Properties, effective as of October 25, 1994. (Incorporated by reference to Exhibit 10.36 to Annual Report on Form 10-K filed March 31, 1995.)	
10.34	Amendment No.1 to Lease Agreement between the Company and Bio-Shore Holdings, Ltd. dated as of October 17, 1994. (Incorporated by reference to Exhibit 10.38 to Annual Report on Form 10-K filed March 31, 1995.)	
10.35	Patent License Agreement between the Company and Celltech Limited dated as of September 30, 1994 (with certain confidential information deleted and marked by a	

box surrounding the deleted information). (Incorporated by reference to Exhibit 10.39 to Annual Report on Form 10-K filed March 31, 1995.)

- 10.36 Amendment No. 2 to Joint Development, Marketing and Licensing Agreement between the Company and Boehringer Mannheim GmbH dated and effective as of November 7, 1995 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.37 to Annual Report on Form 10-K filed March 31, 1996.)

Exhibit Number -----	Exhibit Title -----	Page No. -----
10.37	Development and License Agreement between the Company and an Unnamed Japanese Pharmaceutical Company dated December 28, 1995 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by Reference to Exhibit 10.38 to Annual Report on Form 10-K filed March 31, 1996.)	
10.38	Amendment No. 3 to Joint Development, Marketing and Licensing Agreement between the Company and Boehringer Mannheim GmbH dated and effective as of May 31, 1996 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by Reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 14, 1996.)	
10.39	Amendment No. 3 to Lease Agreement between the Company and St. Paul Properties, effective as of November 27, 1996.	
24.1	Consent of Ernst & Young LLP, Independent Auditors.	
27.1	Financial Data Schedule.	

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\*Management contract or compensatory plan or arrangement.

AMENDMENT NO. 3  
TO LEASE AGREEMENT

This Amendment No. 3 to Lease Agreement made and entered into this 27th day of November, 1996, by and between St. Paul Properties, Inc., a Delaware corporation ("Landlord") and Protein Design Labs, Inc., a Delaware corporation ("Tenant").

WITNESSETH:

WHEREAS, Landlord and Tenant are the parties to that certain Lease Agreement dated February 10, 1992 (the "Original Lease") and amended July 8, 1995, (the "Amendment No. 1") with regard to the leasing of approximately 38,270 square feet, and amended October 25, 1994 (the "Amendment No. 2") for the leasing of an additional 4,005 square feet in the building owned by Landlord and located in 3955 Annapolis Lane, Plymouth, Minnesota as more particularly described in Exhibit "A" to the Original Lease, (the Original Lease, Amendment No. 1 and Amendment No. 2 are referred to collectively as the "Lease"); and

WHEREAS, Landlord and Tenant desire to amend the Lease in order to provide for the extension of the Lease and the expansion of the building and other terms and conditions in said building, as more particularly described in Exhibit "A" attached to this Amendment No. 3 (the "Building Expansion").

NOW, THEREFORE, in consideration of the foregoing, and the following covenants and agreements, and for the good and valuable consideration, the receipt and adequacy whereof is hereby acknowledged by the parties, Landlord and Tenant hereby agrees as follows:

1. Unless otherwise indicated, capitalized terms shall be defined as set forth in the Lease.
2. Landlord hereby leases to Tenant and Tenant hereby takes from Landlord the Leased Premises (consisting of 42,475 square feet as demised under the Original Lease and Amendment No. 2) for an additional period of sixty (60) months commencing March 1, 1999 through February 29, 2004 (the "Lease Extension Period") and in all other respects subject to the terms and conditions of the Lease, except as otherwise expressly provided herein.
3. The Base Rent for the Lease Extension Period shall be \$9.02 per square foot or \$31,927.00 per month.
4. Tenant shall have a first option to renew the Lease for a period of five (5) years (for the period March 1, 2004 through February 28, 2009). Tenant may, through the delivery of written notice to Landlord (the "First Notice of Exercise"), delivered not later than August 31, 2002, renew this Lease for five (5) years, upon all the same terms and conditions as set forth in this Lease; provided, however, that (a) the square footage of the Leased Premises during the option granted pursuant to this Paragraph 4 shall be 44,788 square feet; and (b) the rental rate shall be at the then current market rates; and (c) in no event shall the Base Rent in the option term be less than the Base Rent paid in the year immediately preceding the first option period.

Upon delivery of the First Notice of Exercise, the parties shall proceed in good faith to negotiate the market rental for Tenant's occupancy of the Premises. If no agreement is reached as to such rental within twenty (20) days after the delivery of the First Notice of Exercise, such rent shall be determined in accordance with the appraisal procedure (the "Appraisal Procedure") outlined in Paragraph 44 of the Original Lease.

Notwithstanding the provision of the preceding paragraphs, Tenant shall have said option rights provided that Tenant has not been in default of any of the terms, covenants and conditions of the Lease.

5. Tenant shall have a second option to renew the Lease for five (5) years (for the period March 1, 2009 through February 28, 2014) in the event Tenant exercises its first option as outlined in Article 4 of this Amendment (the "Second Renewal Option"). In the event there has been no default by Tenant, Tenant may, through the delivery of written notice to Landlord (the "Second Notice of Exercise"), delivered not later than August 31, 2007, renew this Lease for five (5) years, upon all the same terms and conditions as set forth in this Lease; provided, however, that (a) the square footage of the Leased Premises during the option granted pursuant to this Paragraph 5 shall be 44,788 square feet; and (b) the rental rate shall be at the then current market rates; and (c) in no event shall the Base Rent in the option term be less than the Base Rent paid in the year immediately preceding the second renewal option period.

Upon delivery of the Second Notice of Exercise, the parties shall proceed in good faith to negotiate the market rental for Tenant's occupancy of the Premises. If no agreement is reached as to such rental within twenty (20) days after the delivery of the Second Notice of Exercise, such rent shall be determined in accordance with the appraisal procedure (the "Appraisal Procedure") outlined in Paragraph 44 of the Original Lease.

Notwithstanding the provision of the preceding paragraphs, Tenant shall have said option rights provided that Tenant has not been in default of any of the terms, covenants and conditions of the Lease.

Notwithstanding the foregoing, the Second Renewal Option contemplated by this Paragraph 5 shall automatically terminate and become null and void and of no further force and effect upon the earlier to occur of (i) the expiration or termination of this Lease, (ii) the termination of Tenant's right to possession of the Premises in accordance with the terms of the Lease, or (iii) the failure of Tenant to timely or properly exercise the rights granted by this Paragraph 5 or the rights granted by Paragraph 4 hereof. The right contemplated by this Paragraph 5 shall not survive the expiration or termination of this Lease, and shall not be available to any assignee, sublessee or successor to Tenant's interests hereunder.

- 6. Landlord and Tenant agree that the building shall be expanded in accordance with plans and specifications dated as follows: Site 1, dated October 25, 1996
  - A-1, Floor Plan dated October 25, 1996
  - A-2, Ref. Ceiling & Roof Plan dated October 25, 1996
  - A-3, Elevations & Details dated October 25, 1996
  - A-4, Wall Sections dated October 25, 1996
  - D-1, Demo Plan dated October 25, 1996as prepared by Genesis Architecture and marked Exhibit "A" the "Building Expansion" attached hereto.

All work and other associated costs, as provided in Article 6 above, for the interior and exterior "Building Expansion" improvements to be completed by Welsh Construction at Tenant's sole cost and expense.

Landlord reserves the right, upon written notice to Tenant, at the expiration of this Lease, as the same may be extended, to require Tenant to remove the "Building Expansion" corridor portion only; if Landlord deems, in its sole judgment, it wants the corridor removed. Such removal shall be completed at Tenant's sole cost and all building exterior conditions shall be restored consistent with the then existing conditions of the exterior of the building.

- 7. Article 43 of the Rider to the original Lease Agreement and Article 7 of Amendment No. 1 and Articles 5 and 6 of Amendment No. 2 shall be deleted and of no further force and effect.

- 8. Reference to an Effect on the Lease:
  - a. Upon the effectiveness of this Amendment No. 3, each reference in the Lease to "this Lease", "hereunder", "hereof", "herein" or words of like import referring to the Lease shall mean and be a reference to the Lease as amended hereby.
  - b. Except as specifically set forth above, the Lease remains in full force and effect and is hereby ratified and confirmed; provided, however, that the parties agree that the rights and obligations of each of them occurring prior to the Extension Commencement Date shall survive the execution and delivery of this Amendment.
  - c. Wherever there exists a conflict between this Amendment and the Lease, the provisions of this Amendment shall control.

- 9. Governing Law. This Amendment No. 3 shall be governed by and construed in accordance with the laws of the State of Minnesota.

- 10. Headings. Section headings in this Amendment No. 3 are included herein for convenience of reference only and shall not constitute a part of this Amendment for any other purpose

IN WITNESS WHEREOF, the parties have executed this Amendment No. 3 to Lease Agreement as of the year and date first above written.

Tenant:  
PROTEIN DESIGN LABS, INC.  
a Delaware corporation

Landlord:  
ST. PAUL PROPERTIES, INC.  
a Delaware corporation

By: /s/ Laurence Jay Korn  
-----  
Dr. Laurence Korn

By: /s/ R. William Inserra  
-----  
R. William Inserra

Its: \_\_\_\_\_  
Chief Executive Officer

Its: \_\_\_\_\_  
Vice President

Date: \_\_\_\_\_

Date: \_\_\_\_\_



## CONSENT OF ERNST &amp; YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Forms S-8 Nos. 33-65224, 33-50116, 33-50114, and 33-96318) pertaining to the Employee Stock Purchase Plan, Outside Directors Stock Option Plan and 1991 Stock Option Plan of Protein Design Labs, Inc., and to the incorporation by reference in the Registration Statement (Form S-3 No. 333-20941) of Protein Design Labs, Inc. and in the related prospectus, of our report dated January 27, 1997, with respect to the financial statements of Protein Design Labs, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 1996.

ERNST &amp; YOUNG LLP

Palo Alto, California  
February 13, 1997

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM (A)  
STATEMENT OF OPERATIONS AND BALANCE SHEET AND IS QUALIFIED IN ITS ENTIRETY BY  
REFERENCE TO SUCH (B) 10K

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