

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000

OR

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

Commission file number 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 Number)

**34801 Campus Drive**

**Fremont, California, 94555**

(Address of Principal Executive Offices including Zip Code)

**(510) 574-1400**

(Registrant's Telephone Number, Including Area Code)

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

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

**Common Stock, Par value \$.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 the 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 December 31, 2000, as reported on the NASDAQ National Market System, was approximately \$3,111,000,000.

As of January 31, 2001, registrant had outstanding 43,604,123 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

**PROTEIN DESIGN LABS, INC.**

**FORM 10-K**  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000

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**PART I**

of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this Annual Report. All forward-looking statements and reasons why results may differ included in this Annual Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

As used in this Annual Report, the terms "we," "us," "our," the "Company" and "PDL" mean Protein Design Labs, Inc. and its subsidiaries (unless the context indicates a different meaning).

Protein Design Labs, our logo and SMART are registered U.S. trademarks and Nuvion is a trademark of Protein Design Labs, Inc. Zenapax is a registered U.S. trademark of Roche. All other company names and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

## ITEM 1. BUSINESS

### OVERVIEW

We are a leader in the development of humanized monoclonal antibodies for the prevention and treatment of disease. We have licensed certain rights to our first humanized antibody product, Zenapax, to Hoffmann-La Roche Inc. and its affiliates (Roche), which markets it for the prevention of kidney transplant rejection. We are also testing Zenapax for the treatment of autoimmune disease. In addition, we have several other humanized antibodies in clinical development for autoimmune and inflammatory conditions, asthma and cancer.

We have fundamental patents in the U.S., Europe and Japan, which we believe cover most humanized antibodies. Eleven companies have licenses under these patents for humanized antibodies that they have developed. We receive royalties on sales of the three humanized antibodies developed by other companies that are currently being marketed.

### PRODUCTS IN DEVELOPMENT

The following table summarizes the potential therapeutic applications and development status for our approved product and clinical product candidates. Not all clinical trials being conducted are listed. The development and commercialization of our product candidates is subject to numerous risks and uncertainties.

Antibody Product	Indication(s)	Status
Zenapax	Kidney transplant rejection	Marketed
	Heart transplant rejection	Phase III
	Psoriasis	Phase II
	Type I diabetes mellitus	Phase II
	Uveitis	Phase I/II
	Multiple sclerosis	Phase I/II
SMART M195	Acute myeloid leukemia	Phase III
SMART 1D10	Non-Hodgkins B-cell lymphoma	Phase II
SMART Anti-L-Selectin	Trauma	Phase IIa
Nuvion	Psoriasis	Phase I/II
	Graft-versus-host disease	Phase I
Humanized Anti-IL-4	Asthma	Phase I/II
SMART Anti-Gamma Interferon	Crohn's disease	Phase I/II

**Zenapax.** The FDA approved Zenapax in December 1997 for the prevention of kidney transplant rejection. It has since been approved in Europe and other countries. Zenapax was the first humanized antibody to be approved anywhere in the world. The Zenapax approvals are based on two Phase III clinical trials, both of which demonstrated that Zenapax-treated patients had a statistically significant reduction in acute rejection episodes compared to patients who did not receive Zenapax. Also, Zenapax treatment was not associated with any observed side effects in addition to those typically seen in the transplant setting. Our licensee Roche sells Zenapax in the U.S., Europe and other territories for the transplant indication and we receive royalties on Zenapax sales.

Roche has sponsored or authorized several additional Zenapax clinical trials in other transplant settings, including liver transplants, pediatric kidney transplants, in combination with Roche's drug CellCept with and without certain other immunosuppressive drugs in kidney transplants, and for the treatment of graft-versus-host disease in donor bone marrow transplants. Roche is currently

conducting a Phase III trial in heart transplant patients. In addition, we are aware of numerous independent clinical studies using Zenapax in settings including heart, lung, pancreas and combined intestinal and liver transplants.

Zenapax binds to the interleukin-2 (IL-2) receptor on immune system cells known as T cells. IL-2 is a lymphokine, one of the substances released by cells as part of the immune response that occurs in autoimmune diseases and often following organ transplants. IL-2 stimulates T cells to divide and participate in an immune response. Zenapax blocks the binding of IL-2 to its receptor on T cells, suppressing an immune response by inhibiting the proliferation of activated T cells.

Zenapax is the first effective immunosuppressive drug without significant side effects. For example, Zenapax is more specific and less toxic than other immunosuppressive drugs such as cyclosporine or ORTHOCLONE OKT3 which suppress essentially all T cells and possibly other cells. As a result, we believe Zenapax may be useful for the long-term treatment of autoimmune and inflammatory diseases such as psoriasis, multiple sclerosis and asthma.

In 1999, we reacquired from Roche specific development and marketing rights to Zenapax for autoimmune diseases. We will fund costs of clinical trials for Zenapax in autoimmune diseases. In return, we have the right to market Zenapax for approved autoimmune indications in the U.S. and Canada, and will receive a major portion of the revenues from sales for these diseases. Roche will continue to manufacture Zenapax and pay for the cost of goods from its share of the revenues. In Europe and other countries, Roche can elect to market Zenapax for approved autoimmune indications or to allow us to market it, and revenues will be shared.

Zenapax is currently in a PDL-sponsored Phase II trial in psoriasis, a common autoimmune disease of the skin, and in trials for uveitis, multiple sclerosis, type I diabetes, aplastic anemia, and the ocular manifestations of Behcet's disease. We plan to conduct additional trials for other autoimmune diseases and asthma. In the early stage clinical trial for uveitis, an autoimmune disease of the eye, Zenapax was safely administered to patients for one year and was effective in controlling the disease in most patients, some of whom have continued to receive Zenapax for up to three years.

**SMART M195 Antibody.** SMART M195 binds to the cancer cells of most patients with myeloid leukemias. Myeloid leukemia is the major form of adult leukemia. It is classified into two types: acute myeloid leukemia, or AML, and chronic myelogenous leukemia. At least 14,000 new cases of myeloid leukemia occur each year in the U.S. and 10,000 or more of these cases are AML. The current survival rate from myeloid leukemia is very low, despite aggressive chemotherapy and multiple, expensive hospitalizations.

Several clinical trials using the SMART M195 Antibody have been conducted, including:

- a multicenter Phase II/III trial designed to evaluate the antibody for prolonging remission in AML patients
- a Phase II trial to evaluate whether the antibody could induce remission in patients whose AML had relapsed
- a physician-sponsored Phase II trial of the antibody in patients with newly diagnosed acute promyelocytic leukemia, a subtype of AML, and
- physician-sponsored trials using the antibody linked to the radioisotopes 90-Yttrium or 213-Bismuth.

In general, these trials have demonstrated that SMART M195 has some biological activity and potential for efficacy. In November 1999, we began a randomized, multicenter, international Phase III study of the antibody in patients with refractory or first-relapsed AML. Patients receive a regimen of either SMART M195 plus standard chemotherapy or standard chemotherapy alone. Up to 200 patients may be enrolled in the trial, which is designed to evaluate the frequency of complete remission and other endpoints. An interim review of the trial results by an independent data safety monitoring board was conducted in the fourth quarter of 2000, and the board recommended that the trial continue. If the final results of the trial are positive, we expect to file for marketing approval.

In addition to the Phase III trial, in 1999 a Phase II trial began to test the safety and efficacy of SMART M195 in patients with high risk myelodysplastic syndrome, a precancerous condition. The study is being conducted by the European Organization for the Research and Treatment of Cancer.

**Nuvion (SMART Anti-CD3 Antibody).** We are developing this antibody for the treatment of autoimmune diseases. It binds to the CD3 antigen, a key receptor for stimulating T cells. A mouse anti-CD3 antibody, ORTHOCLONE OKT3, from Johnson & Johnson, is marketed as an immunosuppressive drug for the treatment of acute kidney, liver and heart transplantation rejection. While highly effective, OKT3 use is often limited by serious toxicity as well as formation of anti-OKT3 antibodies because it is a mouse antibody. In contrast, Nuvion is humanized and also has been specifically engineered to reduce certain immune system interactions that we believe contribute to the toxicity of OKT3.

Although both Nuvion and Zenapax may target some of the same diseases, we believe they may have complementary roles in medical treatment. Nuvion may be more potent than Zenapax, but may not be suitable for chronic administration, so it may be most useful to treat acute episodes of autoimmune disease and to induce remissions. Zenapax may be useful to maintain the remissions for longer periods.

Nuvion is currently in a Phase I/II clinical trial for psoriasis. It is also in a Phase I trial for steroid-refractory graft-versus-host-disease, in which the response rate in the first 15 patients was 100%. We expect to initiate additional trials in psoriasis, inflammatory bowel disease and graft-versus-host disease in 2001. We have retained worldwide rights to Nuvion.

**SMART Anti-L-Selectin Antibody.** This antibody inhibits the process of neutrophil binding to the lining of blood vessels. It may be useful for preventing multiple organ failure and mortality that often follows severe trauma. In primate studies carried out by independent investigators, SMART Anti-L-Selectin treatment resulted in a statistically significant improvement in survival in a model that simulates severe trauma. We believe this antibody also may be useful to treat adult respiratory distress syndrome and reperfusion injury due to heart attacks.

In May 1999, we licensed European marketing rights for this antibody to Scil Biomedicals GmbH, a European biotechnology company. Scil paid us a licensing fee and agreed to conduct and pay for clinical trials in Europe and to provide us with the data; in return, we are making milestone payments to Scil, at our election, on the achievement of defined clinical and regulatory goals. Scil has completed a Phase I trial of SMART Anti-L-Selectin and is now conducting a Phase IIa trial for treatment of trauma. If the results from that Phase IIa trial are encouraging, we may initiate clinical development in the U.S.

**SMART 1D10 Antibody.** The National Cancer Institute sponsored a Phase I trial of this antibody for non-Hodgkins B-cell lymphoma. Clinical responses were observed in five of the patients in this trial, and we have initiated a Phase II trial. SMART 1D10 is directed to a different target on B cells than Rituxan, the antibody currently marketed for non-Hodgkins lymphoma, and thus may provide an alternative therapy. In the U.S., approximately 290,000 patients have this disease and 55,000 new cases occur annually. We have retained worldwide rights to SMART 1D10.

**Humanized Anti-IL-4 Antibody.** We licensed this antibody, for the potential treatment of asthma and allergy, from SmithKline Beecham, now GlaxoSmithKline plc, in 1999. The humanized anti-IL-4 antibody blocks the effects of interleukin 4, which is believed to play a key role in initiating the series of biological processes that lead to allergy and asthma. GlaxoSmithKline began a Phase I trial of the humanized anti-IL-4 antibody, which we have now completed. We have initiated a Phase I/II multiple dose study and plan to initiate a Phase II trial in moderate to severe asthma patients.

We will conduct and pay for initial clinical trials of the humanized anti-IL-4 antibody and pay GlaxoSmithKline to manufacture the antibody. GlaxoSmithKline has agreed to make a milestone payment to us upon the achievement of a specified clinical goal. At the completion of a specified Phase II trial, GlaxoSmithKline may choose to pay us a fee to acquire marketing rights. In that case, we and GlaxoSmithKline will share future development costs and profits from any product sales. If GlaxoSmithKline elects not to pay this fee, we will have the right to develop and market the antibody.

Concurrently, we granted GlaxoSmithKline an exclusive license under our humanization patents for a humanized anti-IL-5 antibody that they are developing, for which GlaxoSmithKline paid us a licensing fee. We also granted GlaxoSmithKline options to obtain non-exclusive licenses under these patents for up to three additional antibodies. These arrangements with GlaxoSmithKline illustrate our ability to leverage our patent portfolio to obtain rights to a potentially important product.

**SMART Anti-Gamma Interferon Antibody.** This antibody targets gamma interferon, a protein that stimulates several types of white blood cells and that may be involved in some autoimmune diseases. We have completed a Phase I trial of SMART Anti-Gamma Interferon in normal volunteers, which showed the antibody is well-tolerated and has biological activity. We have initiated a Phase I/II trial in patients with Crohn's disease, a form of inflammatory bowel disease. In the future, we may initiate clinical trials in other autoimmune diseases. We have retained worldwide rights to SMART Anti-Gamma Interferon.

## OUR TECHNOLOGY

### *Antibody Background Information*

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, or due to an aberrant autoimmune response. B cells produce millions of different kinds of antibodies, which have slightly different shapes that enable them to bind and, as a result, inactivate different targets. Antibodies that have 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 range of targets, including targets to which the human body does not normally produce antibodies. Specifically, many mouse, or murine, antibodies have been developed as potential therapeutics to inhibit immune function, destroy cancer cells or neutralize viruses.

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. In addition, 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 humans, a murine antibody is usually recognized by the body's immune system as foreign. The immune system therefore responds with a human anti-mouse antibody, or 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, human and chimeric antibodies, have been developed using recombinant DNA and other technologies. 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 monoclonal antibodies are now progressing into clinical trials. In a list of biotechnology medicines under clinical development in the U.S. published in 1999 by the Pharmaceutical Research and Manufacturers of America, antibodies comprised the single largest category (excluding vaccines), representing 22% of the products listed. In particular, we are aware of at least 40 humanized antibodies in clinical trials, including several antibodies addressing large

markets that are being developed by major pharmaceutical companies. Eight humanized or chimeric antibodies have already been approved for marketing by the FDA.

### *Our SMART Antibody Technology*

Our patented SMART antibody technology has positioned us as a leader in the development of therapeutic antibodies that overcome the problems associated with murine antibodies. Our 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 our 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 antigen 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 antigen 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 our 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 we developed as well as the experience of our 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.

### **BUSINESS STRATEGY**

Our objective is to leverage our product pipeline and patent portfolio in the field of antibodies to become a fully-integrated, profitable, research-based biopharmaceutical company. We derive revenues, and expect to derive revenues in the future, from three major sources:

- Sales of products that we have developed. We receive royalties on sales of Zenapax by our licensee, Roche. We have several other humanized antibodies in clinical development. We plan to market some of our products, once approved, in North America, especially for specialty markets such as cancer that we believe can be effectively serviced with a relatively small sales force. We may license marketing rights for some antibodies or some geographic areas to other pharmaceutical companies.
- Royalties from the sale of humanized antibodies developed by other companies. We license our patents covering humanized antibodies in return for license fees, annual maintenance payments and royalties on product sales. The three humanized antibodies currently approved by the FDA in addition to Zenapax are licensed under our patents, Genentech's Herceptin, MedImmune's Synagis and American Home Products' Mylotarg. Combined sales of these products exceeded \$700 million in 2000. We have patent license or patent rights agreements with eleven other companies for humanized antibodies they are developing.
- Research and development contracts with other companies. We humanize antibodies for other companies in return for upfront fees, milestone payments and royalties on any product sales. In some cases we also receive the right to co-promote these products in designated territories. We also sometimes license out marketing rights to a humanized antibody that we are developing, and then typically receive upfront fees and milestone payments and/or research funding, in addition to royalties on any product sales by our licensee.

### **COLLABORATIVE, HUMANIZATION AND PATENT LICENSING ARRANGEMENTS**

#### *Collaborative Arrangements*

**Roche.** In 1989, we entered into agreements with Roche to collaborate on the research and development of antibodies which bind to the IL-2 receptor, including Zenapax. Under these agreements, Roche has exclusive, worldwide rights to manufacture, market and sell Zenapax. We began receiving royalties on sales of Zenapax in 1998. Our royalties are subject to offsets for milestones, third party license fees and royalties, and patent expenses paid by Roche.

In October 1999, we agreed with Roche to replace the 1989 agreements with new agreements under which we assumed worldwide responsibility for the clinical development of Zenapax for the potential treatment of autoimmune diseases. Roche retained exclusive worldwide rights to Zenapax for non-autoimmune diseases and is continuing to market Zenapax for the prevention of kidney transplant rejection. In return for undertaking clinical development in autoimmune indications, we will receive a significant share

of Zenapax revenues from sales for autoimmune indications, either from our own marketing efforts or from revenue sharing with Roche.

In the U.S. and Canada, we will have the right to market Zenapax in autoimmune indications and will pay for these activities from our share of revenues. Outside the U.S. and Canada, Roche may choose to market Zenapax in autoimmune indications. In this case, we will receive a substantial portion of Zenapax revenue from these indications. For countries and indications for which Roche elects not to market, we will receive an exclusive license to market Zenapax and pay Roche a small royalty.

**Scil Biomedicals GmbH.** In March 1999, we entered into an agreement with Scil for rights to develop and market SMART Anti-L-Selectin in Europe. Scil paid us a \$3.0 million signing and licensing fee for these rights, and we will be entitled to royalties on any product sales. We agreed to make milestone payments to Scil, at our election, upon the achievement of specified clinical and regulatory goals.

**GlaxoSmithKline plc.** In September 1999, we signed agreements with SmithKline Beecham, now GlaxoSmithKline, involving two humanized antibodies for the possible treatment of asthma. We obtained a license to GlaxoSmithKline's humanized anti-IL-4 antibody and granted an exclusive license under our antibody humanization patents to GlaxoSmithKline for its humanized anti-IL-5 antibody. We have completed the Phase I clinical program for the humanized anti-IL-4 antibody, are conducting a Phase I/II trial and plan to conduct a Phase II trial in asthma patients. We will be entitled to exclusive, worldwide development, marketing and sales rights to the anti-IL-4 antibody unless GlaxoSmithKline pays a fee to acquire marketing rights at the end of a specified Phase II trial. If GlaxoSmithKline decides to participate in the further development of the antibody, we will share future development costs and profits at a pre-agreed ratio. We also may receive co-promotion rights in the U.S.

**Toagosei Co., Ltd.** In July 1999, we signed a licensing and joint development agreement with Toagosei for an antibody developed by Toagosei and humanized by us. The antibody, SMART Anti-VEGF, binds to vascular endothelial growth factor, a protein that regulates new blood vessel formation in certain tissues and in tumors. Due to competitive factors and the need to devote greater resources to more advanced programs, we have recently notified Toagosei that we are withdrawing from this joint development agreement. Toagosei has also announced that it is terminating development of SMART Anti-VEGF.

**Eli Lilly and Company.** In December 1997, we signed a collaborative agreement with Lilly to discover and develop new small molecule drugs for the treatment of some types of infections, including those caused by organisms that are resistant to available antibiotics. The agreement involves a program to identify microbial genes that are differentially expressed when an infectious agent, such as a bacteria, infects a host. Lilly terminated the research program under this agreement on November 30, 2000. We received an initial \$3.0 million payment under the agreement and have received research funding totaling \$4.8 million over the three-year term. PDL retains all rights to discoveries made by PDL in this program.

#### *Humanization and Patent Licensing Arrangements.*

**Yamanouchi Pharmaceutical Co., Ltd.** In February 1991, we entered into an agreement with Yamanouchi to humanize a mouse anti-platelet (anti-gpIIb/IIIa) antibody developed by Yamanouchi for cardiovascular disorders. Yamanouchi is conducting a Phase II clinical trial with the antibody we humanized for them. Yamanouchi has exclusive, worldwide rights to the antibody and is responsible for all development activities. We have received milestone payments and will be entitled to royalties on any sales of the antibody.

**Mochida Pharmaceutical Co., Ltd.** In December 1995, we entered into an agreement with Mochida to humanize a mouse antibody for use in infectious disease. We received a licensing and signing fee and milestone payments and can earn royalties on any product sales. In addition, we have an option to co-promote the antibody in North America.

**Toagosei Co., Ltd.** In September 1996, we entered into an agreement with Toagosei to humanize a mouse antibody for treating cancer. We received a licensing and signing fee and milestone payments. Development of this antibody has been terminated.

**American Home Products Corporation.** In December 1996, we entered into an agreement with Genetics Institute, now a wholly-owned subsidiary of American Home Products, to initially humanize three mouse antibodies that regulate an immune system pathway. To date, we have received a \$2.5 million licensing and signing fee and three milestone payments. We are entitled to royalties on any product sales. We also received an option to co-promote the products in North America under certain conditions. Two of the three antibodies are in Phase II trials.

**Teijin Limited.** In March 1997, we entered into an agreement with Teijin to humanize a mouse antibody to a toxin produced by the E. coli O157 bacteria that can cause serious illness or death from the consumption of contaminated food. We have received a licensing and signing fee and milestone payment and are entitled to royalties on any product sales.

**Ajinomoto Co., Inc.** In July 1997, we entered into an agreement with Ajinomoto to humanize a mouse antibody directed at cardiovascular conditions. We have received a licensing and signing fee and milestone payments and are entitled to royalties on any product sales. In addition, we received the right to obtain co-promotion rights to the antibody in North America.

**Genentech, Inc.** In September 1998, we entered into an agreement covering patent rights under our humanization patents and under Genentech patents relating to antibody engineering. Genentech paid us a \$6.0 million fee, and we paid Genentech a \$1.0 million fee. Each company can obtain up to six licenses for humanized antibodies upon payment of an additional fee of at least \$1.0 million per antibody, as well as royalties on any product sales. The number of licensed antibodies may be increased and the term of the agreement extended upon payment of additional fees. In November 1998, Genentech exercised certain of its rights under the

agreement and obtained a nonexclusive license for Herceptin. Genentech paid us a \$1.0 million licensing and signing fee and we currently receive royalties on Herceptin sales.

**Progenics Pharmaceuticals, Inc.** In April 1999, we entered into an agreement to humanize PRO 140, Progenics' novel anti-CCR5 monoclonal antibody that inhibits HIV replication in the laboratory. Progenics paid us a licensing and signing fee, has paid a milestone payment, and has agreed to make additional payments upon the achievement of specified milestones and to pay royalties on any sales of the antibody.

**Fujisawa Pharmaceuticals Co.** In June 1999, we entered into a research agreement with Fujisawa to engineer certain antibodies targeted to the treatment of inflammatory and immunologically-based disorders. The engineering included the use of our patented modification of the constant region of certain types of antibodies. In February 2000, we entered into an agreement to humanize one of these antibodies. Fujisawa paid us a \$1.5 million licensing and signing fee. We have received a milestone payment and are entitled to receive another milestone payment, annual maintenance fees and royalties on any product sales.

**Celltech Chiroscience Limited.** In December 1999, we entered into a patent rights agreement with Celltech covering specified patents relating to humanized monoclonal antibodies. Under the agreement, Celltech paid us a \$3.0 million fee for the right to obtain worldwide licenses under our antibody humanization patents for up to three Celltech antibodies. We paid Celltech a fee for the right to obtain worldwide licenses under Celltech's antibody humanization patent for up to three of our antibodies. When a license is taken by either company, the other will be entitled to an additional license fee. Each company will pay royalties to the other on any sales of licensed antibodies.

**Tanox, Inc.** In March 2000, we entered into a patent rights agreement with Tanox under our humanization patents. Tanox paid us a \$2.5 million fee, which reflected a \$1.5 million credit for a fee Tanox previously paid to us for a patent license for an antibody which was incorporated into this agreement. Tanox can obtain up to four patent licenses for humanized antibodies upon payment of an additional fee of at least \$1.0 million per antibody, as well as royalties on any product sales.

**Eli Lilly and Company.** In August and September 2000, we entered into two agreements to humanize antibodies for Lilly. Lilly paid us signing and licensing fees of \$1.7 million and \$1.36 million, has made milestone payments and has agreed to pay royalties on any sales of the humanized antibodies.

**InterMune Pharmaceuticals, Inc.** In November 2000, we entered into an agreement to humanize an antibody targeted to the bacteria *Pseudomonas aeruginosa* for InterMune. InterMune agreed to pay us a signing and licensing fee and to make additional payments upon the achievement of specified milestones and to pay royalties on any sales of the humanized antibody.

**Millennium Pharmaceuticals, Inc.** In March 2001, we entered into a patent rights agreement with Millennium under our humanization patents for which they paid us an upfront fee. Millennium can obtain up to three patent licenses for humanized antibodies upon payment of additional fees, as well as royalties on any product sales. The term of the agreement may be extended upon payment of additional fees.

**Other Patent License Agreements.** We have entered into patent license agreements with a number of other companies that are independently developing humanized antibodies. In each license agreement, we granted a worldwide, exclusive or nonexclusive license under our patents to the other company for an antibody to a specific target antigen. In general, we received a licensing and signing fee and the right to receive annual maintenance fees and royalties on any product sales. Under some of these agreements, we also may receive milestone payments. In addition to Herceptin, we receive royalties on sales of Synagis, an antibody developed by MedImmune which is currently marketed in the U.S. and Europe, and on Mylotarg, an antibody developed by American Home Products which is currently marketed in the U.S. In addition to Genentech, MedImmune and American Home Products, we have patent license agreements with Sankyo, Biogen, IDEC Pharmaceuticals, Elan Pharmaceuticals, Medarex, GlaxoSmithKline, Merck KGaA and Chugai.

## MANUFACTURING AND FACILITIES

We own two buildings comprising approximately 92,000 square feet of research and development and general office space in Fremont, California. We relocated our California headquarters and research and development facilities to this space beginning in September 1998.

We lease approximately 47,000 square feet of manufacturing, laboratory and office space in Plymouth, Minnesota. Our lease will terminate on February 29, 2004, subject to our options to extend the lease for two additional five year terms. Although these facilities are sufficient for our present manufacturing operations, in order to obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to expand and improve our manufacturing capabilities. We intend to acquire additional space and construct a commercial manufacturing facility.

Of the products that we currently have in clinical development, Roche is responsible for manufacturing Zenapax, GlaxoSmithKline is responsible for manufacturing the humanized anti-IL-4 antibody and Scil is responsible for manufacturing the SMART Anti-L-Selectin Antibody. We are responsible for manufacturing our other products for our own development. We intend to continue to manufacture potential products for use in preclinical and clinical trials in accordance with standard procedures that comply with appropriate regulatory standards.

## PATENTS AND PROPRIETARY TECHNOLOGY



Our success depends significantly on our ability to obtain and maintain patent protection for our products and technologies, to preserve our trade secrets and to operate without infringing on the proprietary rights of third parties. While we file and prosecute patent applications to protect our inventions, our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology.

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 our programs. Some of these applications or patents may be competitive with our applications or contain material which could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents.

The scope, enforceability and effective term of patents issued to companies, universities and research institutions can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or 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 we are unable to predict the extent of patent protection in any country.

We have been issued patents in the U.S., Europe and Japan which we believe cover many or most humanized antibodies. Some of these patents also cover other aspects of our SMART antibody technology. We have filed similar patent applications in other countries.

Our two humanization patents issued by the European Patent Office apply in the United Kingdom, Germany, France, Italy and eight other European countries. The European Patent Office procedures provide for an opposition period in which other parties may submit arguments as to why a patent was incorrectly granted and should be withdrawn or limited. Eighteen notices of opposition to our first European patent were filed during the opposition period for the patent, including oppositions by major pharmaceutical and biotechnology companies. At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims in our first European patent. We plan to appeal the Opposition Division's decision to the Technical Board of Appeal at the European Patent Office. The Technical Board of Appeal will consider all issues anew. The appeal suspends the decision of the Opposition Division during the appeals process, which is likely to take several years.

The nine month opposition period for our second European antibody humanization patent ended in May 2000. Eight notices of opposition have been filed with respect to this patent. Also, three opposition statements have been filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings; however, we may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If our appeal with respect to our first European patent is unsuccessful or if the outcome of the other European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

## **GOVERNMENT REGULATION**

The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the U.S. and other countries. In the U.S., pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and nonclinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires a number of years and the expenditure of substantial resources. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

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 rigorous guidelines 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 these FDA approved guidelines. These foreign manufacturing establishments are subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, pharmaceutical product manufacturing facilities may also be regulated by state, local and other authorities.

For the marketing of pharmaceutical products outside the U.S., we and our collaborative partners are subject to foreign regulatory requirements and, if the particular product is manufactured in the U.S., FDA and other U.S. export provisions. 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 us or our licensees or marketing

partners in our respective efforts to secure necessary governmental approvals. This could delay or prevent us, our licensees or our marketing partners from marketing potential pharmaceutical products.

Both before and after approval is obtained, a biological pharmaceutical product, its manufacturer and the holder of the Biologics License Application (BLA) for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny a BLA if applicable regulatory criteria are not satisfied. 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, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. 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, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holder.

## **COMPETITION**

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our SMART antibody technology. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

Any product that we or our collaborative partners succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources, and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, has received approval to market Simulect, a product competitive with Zenapax, in the U.S. and Europe.

Other competitive factors include:

- the capabilities of our 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 our products relative to their cost
- method of and frequency of administration of our products
- price of our products, and
- patent protection of our products.

## **HUMAN RESOURCES**

As of December 31, 2000, we had 307 full-time employees. Of the total, 110 employees were engaged in research and development, 52 in quality assurance and compliance, 57 in clinical and regulatory, 39 in manufacturing and 49 in general and administrative functions. Our scientific staff members have diversified experience and expertise in molecular and cell biology, biochemistry, immunology, protein chemistry, computational chemistry and computer modeling. Our success will depend in large part on our ability to attract and retain skilled and experienced employees. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

## **ENVIRONMENT**

We seek to comply with environmental statutes and the regulations of federal, state and local governmental agencies. We have put into place processes and procedures and maintain records in order to monitor environmental compliance. We 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, in addition to historical information, forward-looking statements which involve risks and uncertainties. Our actual results may differ significantly from the results discussed in forward-looking statements. Factors that may cause such a difference include those discussed in the material set forth below and elsewhere in this document. Additional risks and uncertainties not presently known to us or that we currently see as immaterial may also impair our business. If any of these risks actually occurs, it could materially harm our business, financial condition or operating results.*

### **We have a history of operating losses and may not achieve sustained profitability.**

Our expenses have generally exceeded revenues. As of December 31, 2000, we had an accumulated deficit of approximately \$ 78.6 million. Our losses may increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in new research areas and improve and expand our manufacturing, marketing and sales capabilities. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We may be unable to achieve sustained profitability.

Our commitment of resources to the continued development of our products will require significant additional funds for development. Our operating expenses may also increase as:

- additional potential products are selected as clinical candidates for further development
- we invest in additional manufacturing capacity
- we defend or prosecute our patents and patent applications, and
- we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

### **Our revenues, expenses and operating results will likely fluctuate in future periods.**

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon:

- the seasonality of sales of licensed products
- the existence of competing products
- the marketing efforts of our licensees
- potential reductions in royalties payable to us due to credits for prior payments to us
- the timing of royalty reports, some of which are required quarterly and others semi-annually
- our method of accounting for royalty revenues from our licensees, and
- our ability to successfully defend and enforce our patents.

Other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees, payments for manufacturing and clinical development services, and payments for the achievement of milestones under new and existing collaborative, humanization, and patent licensing agreements. Revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

In addition, our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include payments owed by us and to us under collaborative agreements for reimbursement of expenses and which are reported under our policy during the quarter in which such expenses are reported to us or to our collaborative partners and agreed to by us or our partners.

We receive royalty revenues on sales of the product Synagis. This product has higher sales in the fall and winter, which to date have resulted in much higher royalties paid to us in our first and second quarters than in other quarters. The seasonality of Synagis sales could contribute to fluctuation of our revenues from quarter to quarter.

### **Our humanization patents are being opposed and a successful challenge could limit our future revenues.**

Most of our current revenues are related to our humanization patents. At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European humanization patent. We plan to appeal this decision and until our appeal is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if our appeal is unsuccessful, our ability to collect royalties on European sales of antibodies humanized by others would depend on the scope and validity of our second European patent, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, the Opposition Division's decision could encourage challenges of our related patents in other jurisdictions, including the U.S. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the appeals process with respect to our first European patent, if we were to commence an infringement action to enforce that patent, such an action would likely be stayed until the appeal is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents. Eight notices of opposition have been filed with respect to our second European antibody humanization patent. Also, three opposition statements have been filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings; however, we may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If our appeal with respect to our first European patent is unsuccessful or if the outcome of the other European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

**If we are unable to protect our patents and proprietary technology, we may not be able to compete successfully.**

Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology.

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 our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or 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 we are unable to predict the extent of patent protection in any country.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

**We may require additional patent licenses in order to manufacture or sell our potential products.**

Other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or may not be able to market our products at all.

Celltech has been granted a European patent covering humanized antibodies, which we have opposed. At an oral hearing in September 2000, the Opposition Division of the European Patent Office decided to revoke this patent. Celltech may elect to appeal that decision. Also, Celltech has a pending divisional patent application in Europe, which is currently drafted with broad claims directed towards humanized antibodies. We cannot predict whether Celltech will be able to successfully appeal the decision of the Opposition Division with respect to their first European patent or whether they will be able to obtain the grant of a patent from the pending application with claims broad enough to generally cover humanized antibodies. Celltech has also been issued a corresponding U.S. patent that contains claims that may be considered broader in scope than their first European patent. We have entered into an agreement with Celltech providing each company with the right to obtain nonexclusive licenses for up to three antibody targets under the other company's humanization patents. Nevertheless, if our SMART antibodies were covered by Celltech's European or U.S. patents and if we were to need more than the three licenses under those patents currently available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

In addition, if the Celltech U.S. patent or any related patent applications conflict with our U.S. patents or patent applications, we may become involved in proceedings to determine which company was the first to invent the products or processes contained in the conflicting patents. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation would reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

Lonza Biologics, Inc. has a patent issued in Europe to which we do not have a license that may cover a process that we use to produce our potential products. In addition, we do not have a license to an issued U.S. patent assigned to Stanford University and Columbia University, which may cover a process we use to produce our potential products. We have been advised that an exclusive license has been previously granted to a third party under this patent. If our processes were covered by either of these patents, we might be required to obtain licenses or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflicts with these patents or to obtain licenses on acceptable terms.

**If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products.**

To obtain regulatory approval for the commercial sale of any of our potential products or to promote these products for expanded indications, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in indications for which approval is requested. We have conducted only a limited number of clinical trials to date. Moreover, we have a relatively large number of potential products in clinical development. We may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise. Our potential inability to commence or continue clinical trials, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of our potential products, further adds to the uncertainty of regulatory approval for our potential products.

Larger and later stage clinical trials may not produce the same results as early stage trials. Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials.

Even when a drug candidate shows indications of efficacy in a clinical trial, it may be impossible to further develop or receive regulatory approval for the drug if it causes an unacceptable incidence or severity of side effects, or further development may be slowed down by the need to find dosing regimens that do not cause such side effects. For example, while Nuvion has shown biological activity in some patients in the Phase I/II trial for psoriasis, it has also at some dose levels caused a level of side effects that would be unacceptable in this patient population. Hence, we plan to conduct a Phase II trial of Nuvion in psoriasis in an attempt to find a dosing regimen that is both well tolerated and effective. However, we may not be able to find such a regimen, and inability to do so would prevent further development of Nuvion for the psoriasis indication. As a second example, the SMART 1D10 Antibody produced partial clinical responses in some B-cell lymphoma patients but at some dose levels there were significant side effects. Hence, we are conducting a Phase II trial of SMART 1D10 to determine a useful dosing regimen.

**Our clinical trial strategy may increase the risk of clinical trial difficulties.**

Research, preclinical testing and clinical trials may take many years to complete and the time required can vary depending on the indication being addressed and the nature of the product. We may at times elect to use aggressive clinical strategies in order to advance potential products through clinical development as rapidly as possible. For example, we may commence clinical trials without conducting preclinical animal efficacy testing where an appropriate animal efficacy testing model does not exist, or we may conduct later stage trials based on limited early stage data. As a result, we anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

For example, we have entered the SMART M195 Antibody into a Phase III clinical trial in acute myelogenous leukemia with a clinical regimen that has not been tested previously with this antibody in combination with chemotherapy. Results from our prior Phase II and Phase II/III studies showed only a limited number of complete and partial remissions using the antibody without concomitant chemotherapy. In addition, based in part on the nature and severity of the disease, we initiated the Phase III study without a meeting with the FDA or European regulatory authorities to discuss the protocol and its adequacy to support approval of the SMART M195 Antibody. This study may not be successful, or the FDA or European regulatory authorities may not agree that the study will be adequate to obtain regulatory approval, even if the study is successful.

**We may be unable to enroll sufficient patients to complete our clinical trials.**

The rate of completion of our clinical trials, and those of our collaborators, is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population
- perceived risks and benefits of the drug under study
- availability of competing therapies
- availability of clinical drug supply

- availability of clinical trial sites
- design of the protocol
- proximity of and access by patients to clinical sites
- patient referral practices of physicians
- eligibility criteria for the study in question, and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

**Our revenues from licensed technologies depend on the efforts and successes of our licensees.**

In those instances where we have licensed rights to our technologies, the product development and marketing efforts and successes of our licensees will determine the amount and timing of royalties we may receive, if any. We have no assurance that any licensee will successfully complete the product development, regulatory and marketing efforts required to sell products. The success of products sold by licensees will be affected by competitive products, including potential competing therapies that are marketed by the licensee or others.

**If our collaborations are not successful, we may not be able to effectively develop and market some of our products.**

We have collaborative agreements with several pharmaceutical and other companies to develop, manufacture and market Zenapax and some of our potential products. In some cases, we are relying on our collaborative partners to manufacture such products, to conduct clinical trials, to compile and analyze the data received from these trials, to obtain regulatory approvals and, if approved, to market these licensed products. As a result, we may have little or no control over the manufacturing, development and marketing of these potential products and little or no opportunity to review clinical data prior to or following public announcement.

Our collaborative agreements can generally be terminated by our partners on short notice. A collaborator may terminate its agreement with us or separately pursue alternative products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by us or our collaborative effort. Even if a collaborator continues its contributions to the arrangement, it may nevertheless determine not to actively pursue the development or commercialization of any resulting products. In these circumstances, our ability to pursue potential products could be severely limited.

Continued funding and participation by collaborative partners will depend on the timely achievement of our research and development objectives, the retention of key personnel performing work under those agreements and on each collaborative partner's own financial, competitive, marketing and strategic considerations. Such considerations include:

- the commitment of management of the collaborative partners to the continued development of the licensed products or technology
- the relationships among the individuals responsible for the implementation and maintenance of the collaborative efforts, and
- the relative advantages of alternative products or technology 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.

Our ability to enter into new collaborations and the willingness of our existing collaborators to continue development of our potential products depends upon, among other things, our patent position with respect to such products. If we are unable to successfully maintain our patents we may be unable to collect royalties on existing licensed products or enter into additional collaborations and agreements.

**Our lack of experience in sales, marketing and distribution may hamper market introduction and acceptance of our products.**

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with collaborative partners. To market products directly, we must either establish a marketing group and direct sales force or obtain the assistance of another company. We may not be able to establish marketing, sales and distribution capabilities or succeed in gaining market acceptance for our products. If we were to enter into co-promotion or other marketing arrangements with pharmaceutical or biotechnology companies, our revenues would be subject to the payment provisions of these arrangements and dependent on the efforts of third parties.

**Manufacturing difficulties could delay commercialization of our products.**

Of the products that we currently have in clinical development, Roche is responsible for manufacturing Zenapax, GlaxoSmithKline is responsible for manufacturing the humanized anti-IL-4 antibody and Scil Biomedicals is responsible for manufacturing the SMART Anti-L-Selectin Antibody. We are responsible for manufacturing our other products for our own development. We intend to continue to manufacture potential products for use in preclinical and clinical trials using our manufacturing facility in accordance with standard procedures that comply with appropriate regulatory standards. The manufacture of sufficient quantities of antibody products that comply with these standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays. We and our collaborative partners have experienced some manufacturing difficulties. Product supply interruptions could significantly delay clinical development of our potential products, reduce third party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization and sales of these products. Manufacturing difficulties can even interrupt the supply of marketed products, thereby reducing revenues and risking loss of market share. For example, in December 1999, Roche received a warning letter from the FDA regarding deficiencies in the manufacture of various products. Although the letter primarily related to products other than Zenapax, Roche has also experienced difficulties in the manufacture of Zenapax leading to interruptions in supply. If future manufacturing difficulties arise and are not corrected in a timely manner, Zenapax supplies could be interrupted, which could cause a delay or termination of our clinical trials of Zenapax in autoimmune disease and could force Roche to withdraw Zenapax from the market temporarily or permanently, resulting in loss of revenue to us. These occurrences could impair our competitive position.

We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture our potential products on a commercial scale. To obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to improve and expand our existing manufacturing capabilities. We are reviewing plans to improve our current manufacturing plant in order to manufacture initial commercial supplies of certain products, including at least the SMART M195 Antibody in the event that the Phase III trial of that antibody is successful. Our ability to file for, and to obtain, marketing approval for the SMART M195 Antibody, as well as the timing of such filing, will depend on our ability to successfully improve our current manufacturing plant. We may be unable to do so, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis. Failure to do so could delay commercialization of this product.

In addition, we plan to construct a new commercial manufacturing plant, including possible acquisition and conversion of an existing building into a manufacturing plant or construction of an entirely new building. When we implement these plans we will incur substantial costs. Any construction or other delays could impair our ability to obtain necessary regulatory approvals and to produce adequate commercial supplies of our potential products on a timely basis. Failure to do so could delay commercialization of some of our products and could impair our competitive position.

#### **Our revenue may be adversely affected by competition and rapid technological change.**

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our SMART antibody technology. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

Any product that we or our collaborative partners succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, has received approval to market Simulect, a product competitive with Zenapax, in the U.S. and Europe.

#### **We may be unable to obtain or maintain regulatory approval for our products.**

The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the U.S. and other countries. In the U.S., pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and nonclinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires a number of years and the expenditure of substantial resources. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

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 rigorous guidelines 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 these FDA approved guidelines. These foreign manufacturing establishments are subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, pharmaceutical product manufacturing facilities may also be regulated by state, local and other authorities.

For the marketing of pharmaceutical products outside the U.S., we and our collaborative partners are subject to foreign regulatory requirements and, if the particular product is manufactured in the U.S., FDA and other U.S. export provisions. 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 us or our licensees or marketing partners in our respective efforts to secure necessary governmental approvals. This could delay or prevent us, our licensees or our marketing partners from marketing potential pharmaceutical products.

Both before and after approval is obtained, a biologic 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. 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, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. 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, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holder.

### **Manufacturing changes may result in delays in obtaining regulatory approval or marketing for our products.**

Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. If we make changes in the manufacturing process, we may be required to demonstrate to the FDA and corresponding foreign authorities that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. This is particularly important if we want to rely on results of prior preclinical studies and clinical trials performed using the previously produced drug material. Depending upon the type and degree of differences between the newer and older drug material, we may be required to conduct additional animal studies or human clinical trials to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material. We have made manufacturing changes and are likely to make additional manufacturing changes for the production of our products currently in clinical development. These manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

### **Our business may be harmed if we cannot obtain sufficient quantities of raw materials.**

We depend on outside vendors for the supply of raw materials used to produce our product candidates. Once a supplier's materials have been selected for use in our manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

### **If we do not attract and retain key employees, our business could be impaired.**

To be successful we must retain our qualified clinical, manufacturing, scientific and management personnel. Because we are located in a high technology area, we face competition for personnel from other companies, academic institutions, government entities and other organizations. We are currently conducting a search for several senior management personnel. If we are unsuccessful in filling these positions or retaining qualified personnel, our business could be impaired.

### **We may be subject to product liability claims, and our insurance coverage may not be adequate to cover these claims.**

We face 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. This risk will exist even with respect to any products that receive regulatory approval for commercial sale. While we have obtained liability insurance for our products, it may not be sufficient to satisfy any liability that may arise. Also, adequate insurance coverage may not be available in the future at acceptable cost, if at all.

### **We may incur significant costs in order to comply with environmental regulations or to defend claims arising from accidents involving the use of hazardous materials.**

We are subject to federal, state and local laws and regulations governing the use, discharge, handling and disposal of materials and wastes used in our operations. As a result, we may be required to incur significant costs to comply with these laws and regulations. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities which exceed our resources. In addition, we cannot predict the extent of the adverse effect on our business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

### **Changes in the U.S. and international health care industry could adversely affect our revenues.**

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. Cost containment measures, whether instituted by



health care providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payors may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the U.S., pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

We may not be able to obtain or maintain our desired price for our products. Our products may not be considered cost effective relative to alternative therapies. As a result, adequate third-party reimbursement may not be available to enable us to maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed health care in the U.S. and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborative partners.

**Our common stock price is volatile and an investment in our company could decline in value.**

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile so that investment in our securities involves substantial risk. Additionally, 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. The following are some of the factors that may have a significant effect on the market price of our common stock:

- developments or disputes as to patent or other proprietary rights
- disappointing sales of approved products
- approval or introduction of competing products and technologies
- results of clinical trials
- failures or unexpected delays in obtaining regulatory approvals or FDA advisory panel recommendations
- delays in manufacturing or clinical trial plans
- fluctuations in our 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 us or our competitors
- initiation, termination or modification of agreements with our collaborative partners
- loss of key personnel
- litigation or the threat of litigation
- public concern as to the safety of drugs developed by us
- sales of our common stock held by collaborative partners or insiders
- comments and expectations of results made by securities analysts, and
- general market conditions.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the common stock would likely drop significantly. A significant drop in the price of a company's common stock often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

**ITEM 2. PROPERTIES**

PDL owns two buildings comprising approximately 92,000 square feet of research and development and general office space in Fremont, California. We relocated our California headquarters and research and development facilities to this space beginning in September 1998.

PDL also leases approximately 47,000 square feet of manufacturing, laboratory and office space in Plymouth, Minnesota. Our lease will terminate on February 29, 2004, subject to our options to extend the lease for two additional five year terms. We plan to obtain additional manufacturing space in the future and may lease or acquire additional space as required.

PDL also leases approximately 6,000 square feet of general office space in Somerville, New Jersey. Our lease will terminate on October 31, 2005.

We own substantially all of the equipment used in our facilities. See Note 4 to the financial statements.

### ITEM 3. LEGAL PROCEEDINGS

PDL is involved in administrative opposition proceedings being conducted by the European Patent Office with respect to our first European patent relating to humanized antibodies. At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European patent. We plan to appeal the Opposition Division's decision to the Technical Board of Appeals at the European Patent Office. The Technical Board of Appeals will consider all issues anew. The appeal suspends the decision of the Opposition Division during the appeals process, which is likely to take several years.

Until our appeal is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if our appeal is unsuccessful, our ability to collect royalties on European sales of antibodies humanized by others would depend on the scope and validity of our second European patent, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, the Opposition Division's decision could encourage challenges of our related patents in other jurisdictions, including the U.S. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the appeals process with respect to our first European patent, if we were to commence an infringement action to enforce that patent, such an action would likely be stayed until the appeal is decided by the European Patent Office. We may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents. Eight notices of opposition have been filed with respect to our second European antibody humanization patent. Also, three opposition statements have been filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings; however, we may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If our appeal with respect to our first European patent is unsuccessful or if the outcome of the other European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

### 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 (\$)

1999	High	Low
First Quarter	13.25	6.63
Second Quarter	11.00	7.19
Third Quarter	18.07	11.07
Fourth Quarter	36.32	16.13
2000	High	Low
First Quarter	163.63	29.72
Second Quarter	92.00	29.66
Third Quarter	125.69	60.59
Fourth Quarter	142.81	70.88

Our Common Stock trades on the Nasdaq National Market under the symbol "PDLI." Prices indicated above are the high and low closing bid prices as reported by the Nasdaq National Market System for the periods indicated, and adjusted for the stock split described below. We have never paid any cash dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future. On August 22, 2000, we effected a two-for-one stock split of our Common Stock in the form of a dividend of one share of Protein Design Labs, Inc. Common Stock for each share held at the close of business on August 1, 2000. Our stock began trading on a split-adjusted basis on August 23, 2000.

As of December 31, 2000, we had approximately 189 common stockholders of record. Because many of these shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by

these record holders. The market for our securities is volatile. See "Risk Factors."

## ITEM 6. SELECTED FINANCIAL DATA

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

	YEARS ENDED DECEMBER 31,				
	2000	1999	1998	1997	1996
CONSOLIDATED STATEMENTS OF OPERATIONS DATA:					
Revenues:					
Revenue under agreements with third parties - related	\$ --	\$ --	\$ --	\$ --	\$11,000
Revenue under agreements with third parties - other	39,907	26,811	21,325	11,137	5,500
Interest and other income	23,149	8,943	9,503	9,118	6,100
<b>Total revenues</b>	<b>63,056</b>	<b>35,754</b>	<b>30,828</b>	<b>20,255</b>	<b>22,600</b>
Costs and expenses:					
Research and development	42,334	36,090	31,645	25,614	28,795
General and administrative	12,110	9,842	8,685	6,629	5,601
Special charge (1)	--	--	--	11,887	--
Interest expense	7965	155	--	--	--
<b>Total costs and expenses</b>	<b>62,409</b>	<b>46,087</b>	<b>40,330</b>	<b>44,130</b>	<b>34,396</b>
<b>Net income/(loss)</b>	<b>\$647</b>	<b>(\$10,333)</b>	<b>(\$9,502)</b>	<b>(\$23,875)</b>	<b>(\$11,796)</b>
Net income/(loss) per share (2):					
Basic	\$0.02	(\$0.28)	(\$0.26)	(\$0.68)	(\$0.38)
Diluted	\$0.01	(\$0.28)	(\$0.26)	(\$0.68)	(\$0.38)
Shares used in computation of net income/(loss) per share:					
Basic	40,452	37,396	37,050	35,298	31,208
Diluted	44,281	37,396	37,050	35,298	31,208

	DECEMBER 31,				
	2000	1999	1998	1997	1996
BALANCE SHEET DATA:					
Cash, cash equivalents and investments	\$661,173	\$137,237	\$143,439	\$163,655	\$99,667
Working capital	651,641	22,669	82,394	66,490	74,221
Total assets	704,980	182,551	171,850	175,026	110,331
Long-term debt obligations, less current portion	159,324	9,724	--	--	--
Accumulated deficit	(78,570)	(79,217)	(68,884)	(59,382)	(35,507)
Total stockholders' equity	534,144	164,743	162,496	168,468	105,112

(1)Represents a non-cash special charge of approximately \$11.9 million related to the extension of the term of all outstanding stock options held by employees, officers, directors and consultants to the Company that were granted prior to February 1995, with the single exception of stock options granted to one non-employee director. The extension conforms the term of previously granted stock options, which was six years, to those granted since February 1995, ten years.

(2)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

### OVERVIEW

In general, we have a history of operating losses and may not achieve sustained profitability. Our expenses have generally exceeded revenues. As of December 31, 2000, we had an accumulated deficit of approximately \$78.6 million. Our losses may increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual

product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in new research areas and improve and expand our manufacturing, marketing and sales capabilities. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. Although we have had some profitable reporting periods, we may be unable to achieve sustained profitability.

Our commitment of resources to the continued development of our products will require significant additional funds for development. Our operating expenses may also increase as some of our earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as we invest in additional manufacturing capacity, as we defend or prosecute our patents and patent applications, and as we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

Our revenues, expenses and operating results will likely fluctuate in future periods. Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of our licensees, potential reductions in royalties payable to us due to credits for prior payments to us, the timing of royalty reports, some of which are required quarterly and others semi-annually, our method of accounting for royalty revenues from our licensees, and our ability to successfully defend and enforce our patents.

Other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees, payments for manufacturing and clinical development services and payments for the achievement of milestones under new and existing collaborative, humanization, and patent licensing agreements. Revenue historically recognized under our prior agreements may not be an indicator of revenue from any future collaborations.

In addition, our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include payments owed by us and to us under collaborative agreements for reimbursement of expenses and which are reported under our policy during the quarter in which such expenses are reported to us or to our collaborative partners and agreed to by us or our partners.

We receive royalty revenues on sales of the product Synagis. This product has higher sales in the fall and winter, which to date have resulted in much higher royalties paid to us in our first and second quarters than in other quarters. The seasonality of Synagis sales could contribute to fluctuation of our revenues from quarter to quarter.

## **RESULTS OF OPERATIONS**

*Years ended December 31, 2000, 1999 and 1998*

Our total revenues were \$63.1 million in 2000 as compared to \$35.8 million in 1999 and \$30.8 million in 1998.

Total revenue under agreements with third parties represented \$39.9 million, \$26.8 million and \$21.3 million of total revenues in 2000, 1999 and 1998, respectively. Revenue under agreements with third parties include royalties, licensing and signing fees, payments recognized under humanization agreements, milestone payments, research and development reimbursement funding, payments for manufacturing services and license maintenance fees. The increase in total revenue under agreements with third parties in 2000 from the prior years was primarily attributable to an increase in royalties during the period. Of the amounts we expended for research and development, \$2.3 million in 2000, \$2.4 million in 1999 and \$1.8 million in 1998 represented third-party funded research and development activities (not including licensing and signing fees, milestone payments and product sales).

Interest and other income increased to \$23.1 million in 2000 from \$8.9 and \$9.5 million in 1999 and 1998, respectively. The increase in 2000 is primarily attributable to the interest earned on our cash, cash equivalents, and marketable debt securities balances as a result of our public offering of common stock in the second half of 2000 which raised approximately \$343.6 in net proceeds and the sale of \$150 million convertible subordinated notes in February 2000.

Total costs and expenses increased to \$62.4 million in 2000 from \$46.1 million in 1999 and \$40.3 million in 1998.

Research and development expenses in 2000 increased to \$42.3 million from \$36.1 million in 1999 and \$31.6 million in 1998. The increase in 2000 costs and expenses as compared to 1999 and 1998 was primarily a result of the addition of staff, the expansion of clinical development programs and research and pharmaceutical development capabilities, including support for both clinical development and manufacturing process development, and payments related to manufacturing of the humanized anti-IL-4 antibody.

General and administrative expenses for 2000 increased to \$12.1 million from \$9.8 million in 1999 and \$8.7 million in 1998. These increases were primarily the result of increased staffing and associated expenses necessary to manage and support our expanding operations including pre-marketing expenses associated with our clinical development program.

Interest expense increased in 2000 to \$8.0 million from \$0.2 million in 1999 and zero in 1998. The increase is primarily due to the interest expense associated with our convertible subordinated notes issued in February 2000.

## LIQUIDITY AND CAPITAL RESOURCES

To date, we have financed our operations primarily through public and private placements of equity and debt securities, revenue under agreements with third parties and interest income on invested capital. At December 31, 2000, we had cash, cash equivalents and marketable securities in the aggregate of \$661.2 million, compared to \$137.2 million at December 31, 1999 and \$143.4 million at December 31, 1998.

As set forth in the Statements of Cash Flows, net cash provided by our operating activities was approximately \$6.8 million for the year ended December 31, 2000 compared to net cash used of approximately \$10.7 million in 1999 and \$6.7 million in 1998. The change was primarily due to our net income in 2000, changes in working capital and other assets as compared to our net losses and changes in working capital in 1999 and 1998.

As set forth in the Statements of Cash Flows, net cash used in our investing activities for the year ended December 31, 2000 was \$118.2 million and \$24.9 million in 1999 as compared to net cash provided by our investing activities of \$21.4 million in 1998. The change in 2000 was primarily the result of our reinvestment activities associated with the purchases of short- and long-term investments.

As set forth in the Statements of Cash Flows, net cash provided by our financing activities for the year ended December 31, 2000 was \$515.8 million compared to \$24.9 million in 1999 and \$3.9 million in 1998. The change in 2000 was primarily the result our public offering of common stock in the second half of 2000 which raised approximately \$343.6 million in net proceeds and the sale of \$150 million convertible subordinated notes in February 2000.

Our future capital requirements will depend on numerous factors, including, among others, royalties from sales of products of third party licensees, including Synagis, Herceptin, Zenapax and Mylotarg; our ability to enter into additional collaborative, humanization and patent licensing arrangements; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; investment in existing and new research and development programs; time required to gain regulatory approvals; resources we devote to self-funded products, manufacturing facilities and methods and advanced technologies; our ability to obtain and retain funding from third parties under collaborative arrangements; our continued development of internal marketing and sales capabilities; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. In order to develop and commercialize our potential products we 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.

## ITEM 7a. MARKET RISKS

We do not use derivative financial instruments for speculative or trading purposes. We maintain a non-trading investment portfolio of investment grade, highly liquid, debt securities which limits the amount of credit exposure to any one issue, issuer, or type of instrument. The securities in our investment portfolio are not leveraged and are classified as available for sale and therefore are subject to interest rate risk. We do not currently hedge interest rate exposure. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes ending fair values include principal plus accrued interest. If market interest rates were to increase by 100 basis points from December 31, 2000 levels, the fair value of the portfolio would decline by approximately \$3.5 million.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**(In thousands, except par value per share)**

	December 31,	
	2000	1999
ASSETS	-----	-----

Current assets:		
Cash and cash equivalents	\$421,541	\$17,138
Marketable securities	239,632	120,098
Other current assets	1,980	6,719
	-----	-----
Total current assets	663,153	143,955
Property, plant and equipment, net	37,673	38,047
Other assets	4,154	549
	-----	-----
	\$704,980	\$182,551
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$1,062	\$877
Accrued compensation	1,729	1,090
Accrued clinical trials	1,103	712
Accrued interest	3,071	--
Other accrued liabilities	2,692	2,762
Deferred revenue	1,455	2,275
Current portion of long-term debt	400	368
	-----	-----
Total current liabilities	11,512	8,084
Convertible subordinated notes	150,000	--
Long-term debt	9,324	9,724
	-----	-----
Total liabilities	170,836	17,808
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 10,000 shares authorized; no shares issued and outstanding	--	--
Common stock, par value \$0.01 per share, 90,000 shares authorized; 43,576 and 38,564 issued and outstanding at December 31, 2000 and December 31, 1999, respectively	436	386
Additional paid-in capital	611,690	245,619
Accumulated deficit	(78,570)	(79,217)
Accumulated other comprehensive income (loss)	588	(2,045)
	-----	-----
Total stockholders' equity	534,144	164,743
	-----	-----
	\$704,980	\$182,551
	=====	=====

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
	-----	-----	-----
Revenues:			
Revenue under agreements with third parties - other	\$39,907	\$26,811	\$21,325
Interest and other income	23,149	8,943	9,503
	-----	-----	-----
Total revenues	63,056	35,754	30,828
Costs and expenses:			
Research and development	42,334	36,090	31,645
General and administrative	12,110	9,842	8,685
Special charge	--	--	--

Interest expense	7,965	155	--
Total costs and expenses	62,409	46,087	40,330
Net loss	\$647	(\$10,333)	(\$9,502)
Net income / (loss) per share:			
Basic	\$0.02	(\$0.28)	(\$0.26)
Diluted	\$0.01	(\$0.28)	(\$0.26)
Shares used in computation of net income / (loss) per share:			
Basic	40,452	37,396	37,050
Diluted	44,281	37,396	37,050

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands, except per share and shares of common stock data)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	Other	Stock-
			Capital		Compre-	holders'
					hensive	Equity
					Income	
Balance at December 31, 1997	36,695,954	\$367	\$226,909	(\$59,382)	\$574	\$168,468
Issuance of common stock	494,544	5	3,940			\$3,945
Comprehensive Income (Loss)						
Net loss				(9,502)		(9,502)
Other comprehensive income (loss)						
Unrealized loss on securities					(415)	(415)
Total comprehensive income (loss)						(9,917)
Balance at December 31, 1998	37,190,498	372	230,849	(68,884)	159	162,496
Issuance of common stock	1,373,020	14	14,770			14,784
Comprehensive Income (Loss)						
Net loss				(10,333)		(10,333)
Other comprehensive income (loss)						
Unrealized loss on securities					(2,204)	(2,204)
Total comprehensive income (loss)						(12,537)
Balance at December 31, 1999	38,563,518	386	245,619	(79,217)	(2,045)	164,743
Follow-on public offering of common stock at \$118.4375 per share (net of underwriters discount of \$18,103 and offering expenses of approximately \$500)	3,058,000	31	343,548			343,579
Issuance of common stock	1,955,132	19	22,523			22,542
Comprehensive Income (Loss)						
Net income				647		647
Other comprehensive income (loss)						
Unrealized loss on securities					2,633	2,633
Total comprehensive income (loss)						3,280
Balance at December 31, 2000	43,576,650	436	611,690	(78,570)	588	\$534,144

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	YEARS ENDED DECEMBER 31		
	2000	1999	1998
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$647	(\$10,333)	(\$9,502)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	3,570	3,538	3,690
Amortization of convertible notes offering cost	628	--	--
Other	(1,920)	(413)	303
Changes in assets and liabilities:			
Other current assets	4,739	(2,111)	(3,829)
Other assets	(4,233)	238	(191)
Accounts payable	185	(433)	835
Accrued liabilities	4,031	(1,245)	1,330
Deferred revenue	(820)	40	631
<b>Total adjustments</b>	<b>6,180</b>	<b>(386)</b>	<b>2,769</b>
<b>Net cash provided by (used in) operating activities</b>	<b>6,827</b>	<b>(10,719)</b>	<b>(6,733)</b>
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(129,821)	(81,336)	(166,120)
Maturities of marketable securities	15,000	74,900	204,300
Purchase of property, plant and equipment	(3,355)	(18,815)	(16,751)
Proceeds from sale of equipment	--	325	--
<b>Net cash provided by (used in) investing activities</b>	<b>(118,176)</b>	<b>(24,926)</b>	<b>21,429</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of capital stock, net	366,121	14,784	3,945
Proceeds from issuance of convertible notes	150,000	--	--
Proceeds from issuance of long-term debt	--	10,150	--
Payments on long-term debt	(369)	(58)	--
<b>Net cash provided by financing activities</b>	<b>515,752</b>	<b>24,876</b>	<b>3,945</b>
<b>Net increase (decrease) in cash and cash equivalent</b>	<b>404,403</b>	<b>(10,769)</b>	<b>18,641</b>
Cash and cash equivalents at beginning of year	17,138	27,907	9,266
<b>Cash and cash equivalents at end of year</b>	<b>\$421,541</b>	<b>\$17,138</b>	<b>\$27,907</b>

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
December 31, 2000

**1. Summary of Significant Accounting Policies**

Organization and Business

Protein Design Labs, Inc. is a biotechnology company engaged in the development of humanized antibodies to prevent or treat various disease conditions. PDL currently has antibodies under development for autoimmune and inflammatory conditions, asthma and cancer. PDL holds fundamental patents in the U.S., Europe and Japan for its antibody humanization technology.

Principles of Consolidation

The consolidated financial statements include the accounts of Protein Design Labs, Inc. and its wholly-owned subsidiaries, Fremont Holding L.L.C. and Fremont Management, Inc., after elimination of inter-company accounts and transactions.



## Cash Equivalents, Marketable Securities and Concentration of Credit Risk

We consider all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. The "Other" adjustments line item in the Statements of Cash Flows represents the accretion of the book value of certain debt securities. We place our cash and marketable debt securities with high-credit-quality financial institutions and in securities of the U.S. government, U.S. government agencies and U.S. corporations and, by policy, limit the amount of credit exposure in any one financial instrument. To date, we have not experienced credit losses on investments in these instruments.

## Revenue Recognition

Contract revenues from research and development arrangements are recognized based on the performance requirements of the contracts. Revenues from achievement of milestones are 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.

Our collaborative, humanization and patent licensing agreements with third parties provide for the payment of royalties to us based on net sales of the licensed product under the agreement. The agreements generally provide for royalty payments to us following completion of each calendar quarter or semi-annual period and royalty revenue is recognized when royalty reports are received from the third party. Non-refundable signing and licensing fees under collaborative and humanization agreements are recognized over the period in which performance obligations are achieved. Non-refundable signing and licensing fees under patent licensing agreements are recognized as revenue when there are no future performance obligations remaining with respect to such fees.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). The adoption of SAB 101 did not have a material effect on our results of operations or our financial position.

## Net Income (Loss) Per Share

In accordance with Financial Accounting Standards Board Statement No. 128, "Earnings Per Share" (FAS 128), basic and diluted net income (loss) per share amounts have been computed using the weighted average number of shares of common stock outstanding during the periods presented. Calculation of diluted net income per share also includes the dilutive effect of outstanding stock options in 2000, but does not include the dilutive effect of outstanding convertible notes because the assumed conversion of these notes would be anti-dilutive. We incurred a net loss for the years ended December 31, 1999 and 1998, and as such, we did not include the effect of outstanding stock options in the diluted net loss per share calculation as their effect is anti-dilutive.

The following is a reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share computations for the periods presented below:

(In thousands, except basic and diluted net income (loss) per share)

	YEARS ENDED DECEMBER 31		
	2000	1999	1998
Numerator:			
Net income (loss)	\$647	(\$10,333)	(\$9,502)
Denominator:			
Basic net income (loss) per share - Weighted-average shares	40,452	37,396	37,050
Dilutive potential common shares - Stock Options	3,829	--	--
Denominator for diluted net income (loss) per share	44,281	37,396	37,050
Basic net income (loss) per share	\$0.02	\$(0.28)	\$(0.26)
Diluted net income (loss) per share	\$0.01	\$(0.28)	\$(0.26)

## Comprehensive Income (Loss)

In accordance with Financial Accounting Standards Board Statement No. 130, "Reporting Comprehensive Income" (FAS 130), we are required to display comprehensive income (loss) and its components as part of our complete set of financial statements. The measurement and presentation of net income (loss) did not change. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in equity that are excluded from our net income (loss), specifically, the unrealized gains and losses on our holdings of available-for-sale securities. Comprehensive income (loss) for the years ended December 31, 2000, 1999 and 1998 is reflected in the Statements of Stockholders' Equity.

## Accounting for Certain Transactions Involving Stock Compensation

In April 2000, the Financial Accounting Standards Board Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB Opinion No. 25" (FIN 44) was issued. FIN 44 clarifies the application of APB No. 25 for certain issues. Among other issues, FIN 44 clarifies the definition of employee for purposes of applying APB No. 25, the criteria for determining whether a plan qualifies as a non-compensatory plan, the accounting consequences of various modifications to the term of a previously fixed stock option or award, and the accounting for an exchange of stock compensation awards in a business combination. FIN 44 became effective July 1, 2000, but certain conclusions in this interpretation cover specific events that occur after either December 15, 1998 or January 12, 2000. The adoption of FIN 44 did not have a significant effect on our financial position or results of operations.

## Segment Disclosure

In accordance with Financial Accounting Standards Board Statement No. 131, "Disclosure about Segments of an Enterprise and Related Information" (FAS 131), we are required to report operating segments and related disclosures about our products, services, geographic areas and major customers. We have no significant product revenue and have only one segment with facilities solely within the U.S. As a result, the adoption of FAS 131 had no impact on our reporting.

## Derivative Instruments and Hedging Activities

In June 1998, the Financial Accounting Standards Board issued Statement No. 133 "Accounting for Derivative Instruments and Hedging Activities" (FAS 133). FAS 133 is not required to be adopted until 2001. However, the Company has reviewed FAS 133 and because it does not use derivatives, the adoption of FAS 133 is not expected to effect the results of operations or the financial position of the Company.

## Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, we have a policy of recording 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 related to each patient are recognized ratably beginning upon entry into the trial and over the course of 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. Our estimates and assumptions could differ significantly from the amounts which may actually be incurred.

## Property and Equipment

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

(In thousands)

	December 31,	
	2000	1999
Land	\$6,790	\$6,790
Building and improvements	21,793	21,720
Leasehold improvements	4,349	4,322
Laboratory and manufacturing equipment	20,484	18,057
Computer and office equipment	5,465	4,785
Furniture and fixtures	1,442	1,294
	60,323	56,968
Less accumulated depreciation	(22,650)	(18,921)
	<u>\$37,673</u>	<u>\$38,047</u>

Depreciation is computed using the straight-line method over the following estimated useful lives:

Buildings and improvements	15 to 30 years
Leasehold improvements	Term of lease
Laboratory and manufacturing equipment	7 years
Computer and office equipment	3 years
Furniture and fixtures	7 years

## **2. Collaborative, Humanization and Patent Licensing Arrangements**

Hoffmann-La Roche Inc. and its affiliates (Roche)

In 1989, we entered into agreements with Roche to collaborate on the research and development of antibodies which bind to the IL-2 receptor, including Zenapax. Under these agreements, Roche has exclusive, worldwide rights to manufacture, market and sell Zenapax. We began receiving royalties on sales of Zenapax in 1998. Our royalties are subject to offsets for milestones, third party license fees and royalties, and patent expenses paid by Roche.

In October 1999, we agreed with Roche to replace the 1989 agreements with new agreements under which we assumed worldwide responsibility for the clinical development of Zenapax for the potential treatment of autoimmune diseases. Roche retained exclusive worldwide rights to Zenapax for non-autoimmune diseases and is continuing to market Zenapax for the prevention of kidney transplant rejection. In return for undertaking clinical development in autoimmune indications, we will receive a significant share of Zenapax revenues from sales for autoimmune indications, either from our own marketing efforts or from revenue sharing with Roche.

In the U.S. and Canada, we will have the right to market Zenapax in autoimmune indications and will pay for these activities from our share of revenues. Outside the U.S. and Canada, Roche may choose to market Zenapax in autoimmune indications. In this case, we will receive a substantial portion of Zenapax revenue from these indications. For countries and indications for which Roche elects not to market, we will receive an exclusive license to market Zenapax and pay Roche a small royalty.

#### Scil Biomedicals GmbH

In March 1999, we entered into an agreement with Scil for rights to develop and market SMART Anti-L-Selectin in Europe. Scil paid us a \$3.0 million signing and licensing fee for these rights, and we will be entitled to royalties on any product sales. We agreed to make milestone payments to Scil, at our election, upon the achievement of specified clinical and regulatory goals.

#### GlaxoSmithKline plc

In September 1999, we signed agreements with SmithKline Beecham, now GlaxoSmithKline, involving two humanized antibodies for the possible treatment of asthma. We obtained a license to GlaxoSmithKline's humanized anti-IL-4 antibody and granted an exclusive license under our antibody humanization patents to GlaxoSmithKline for its humanized anti-IL-5 antibody. We have completed the Phase I clinical program for the humanized anti-IL-4 antibody, are conducting a Phase I/II trial and plan to conduct a Phase II trial in asthma patients. We will be entitled to exclusive, worldwide development, marketing and sales rights to the anti-IL-4 antibody unless GlaxoSmithKline pays a fee to acquire marketing rights at the end of a specified Phase II trial. If GlaxoSmithKline decides to participate in the further development of the antibody, we will share future development costs and profits at a pre-agreed ratio. We also may receive co-promotion rights in the U.S.

#### Toagosei Co., Ltd.

In July 1999, we signed a licensing and joint development agreement with Toagosei for an antibody developed by Toagosei and humanized by us. The antibody, SMART Anti-VEGF, binds to vascular endothelial growth factor, a protein that regulates new blood vessel formation in certain tissues and in tumors. Due to competitive factors and the need to devote greater resources to more advanced programs, we have recently notified Toagosei that we are withdrawing from this joint development agreement. Toagosei has also announced that it is terminating development of SMART Anti-VEGF.

#### Eli Lilly and Company

In December 1997, we signed a collaborative agreement with Lilly to discover and develop new small molecule drugs for the treatment of some types of infections, including those caused by organisms that are resistant to available antibiotics. The agreement involved a program to identify microbial genes that are differentially expressed when an infectious agent, such as a bacteria, infects a host. Lilly terminated the research program under this agreement on November 30, 2000. We received an initial \$3.0 million payment under the agreement and have received research funding totaling \$4.8 million over the three-year term. PDL retains all rights to discoveries made by PDL in this program.

#### Humanization Agreements

We have entered into a number of antibody humanization agreements pursuant to which we have performed antibody humanization services and granted patent licenses to specified antibody targets. Generally, under these agreements, we received a licensing and signing fee and the right to receive milestone payments for achievement of certain specified milestones, as well as royalties on product sales, if any. Under some of these agreements, we received certain rights to co-promote the product.

#### Patent Licensing and Rights Arrangements

We have entered into patent license and rights agreements with a number of other companies that are independently developing humanized antibodies. In each license agreement, we granted a worldwide, exclusive or nonexclusive license under our patents to the other company for an antibody to a specific target antigen. In general, we received a licensing and signing fee and the right to receive annual maintenance fees and royalties on any product sales. Under some of these agreements, we also may receive milestone payments. We receive royalties on sales of Synagis, an antibody developed by MedImmune which is currently marketed in the U.S. and Europe, on Herceptin, an antibody developed by Genentech which is currently marketed in the U.S. and Europe, and on Mylotarg, an antibody developed by American Home Products which is currently marketed in the U.S. In addition to Genentech, MedImmune and American Home Products, we have patent license or rights agreements with Sankyo, Biogen, IDEC Pharmaceuticals, Elan Pharmaceuticals, Medarex, GlaxoSmithKline, Celltech, Tanox, Merck KGaA and Chugai.

### 3. Other Accrued Liabilities

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

(In thousands)

	December 31,	
	2000	1999
Employee stock purchase plan	\$698	\$477
Contract payable	--	660
Other accrued liabilities	1,994	1,625
	<u>\$2,692</u>	<u>\$2,762</u>

We have a policy of recording 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 related to each patient are recognized ratably beginning upon entry into the trial and over the course of the trial. In the event of early termination of a clinical trial, management accrues an amount based on our estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial.

### 4. Commitments

We occupy leased facilities under agreements that expire in 2004 and 2005. We also have leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately \$1.6 million, \$2.7 million, and \$2.5 million for the years ended December 31, 2000, 1999 and 1998, respectively. In December 2000, the Company's sublease of its Mountain View, California facility to two third parties expired. Under these subleases, the Company recognized rental income of approximately \$0.2 million, \$1.2 million and \$0.1 million for the years ended December 31, 2000, 1999 and 1998, respectively.

At December 31, 2000 the total future minimum non-cancelable payments under these operating lease agreements are approximately as follows (in thousands):

2001	\$620
2002	610
2003	588
2004	253
2005	72
	<u>\$2,143</u>

### 5. Short- and Long-Term Investments

We invest our excess cash balances primarily in short-term and long-term marketable debt securities. 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 accumulated other comprehensive loss 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.

(In thousands)

	Available-for-Sale Securities			Estimated Fair Value
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	
December 31, 2000				
Securities of the U.S.				
Government and its agencies maturing:				
within 1 year	\$64,568	\$64	(\$191)	\$64,441
between 1-3 years	136,473	568	(250)	136,791
U.S. corporate debt securities maturing:				
between 1-3 years	38,003	397	--	38,400

Total marketable debt securities	\$239,044	\$1,029	(\$441)	\$239,632
	=====	=====	=====	=====
December 31, 1999				
Securities of the U.S.				
Government and its agencies maturing:				
between 1-3 years	\$117,147	\$--	(\$2,183)	\$114,964
U.S. corporate debt securities maturing:				
within 1 year	4,996	138	--	\$5,134
	-----	-----	-----	-----
Total marketable debt securities	\$122,143	\$138	(\$2,183)	\$120,098
	=====	=====	=====	=====

During 2000 and 1999, there were no realized gains or losses on the sale of available-for-sale securities, as all securities liquidated in each of these years were held to maturity.

## 6. Stockholders' Equity

### Stock Split

In July 2000, we announced that our Board of Directors approved a two- for-one stock split of the outstanding shares of our common stock.

The stock split was effected in the form of a stock dividend. Each stockholder of record at the close of business on August 1, 2000 was entitled to receive one additional share of common stock for every share of common stock held on that date. The stock dividend resulting from the stock split was distributed by our transfer agent on August 22, 2000. The share and per share amounts in the accompanying financial statements and notes reflect the effect of this stock split.

### 2000 Public Offering

In the second half of 2000, we completed a public offering of 3,058,000 shares of common stock at a price of \$118.4375 per share. Net proceeds from the offering were approximately \$343.6 million.

### 1991 Stock Option Plan

In December 1991, the Board of Directors adopted the 1991 Stock Option Plan (Option Plan). We reserved 8,000,000 shares of common stock for the grant of options under the Option Plan. At December 31, 2000, 651,495 shares were available for grant.

At December 31, 2000, options to purchase 1,105,368 shares were exercisable at prices ranging from \$3.62 to \$42.03. 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 two or five years in the case of advisors and consultants.

### Outside Directors' Stock Option Plan

In February 1992 the Board of Directors adopted the Outside Directors' Stock Option Plan (Directors' Plan). We reserved 400,000 shares of common stock for the grant of options under the Directors' Plan. Through December 31, 2000, the Company granted options to purchase 330,000 shares at exercise prices ranging from \$3.62 to \$19.38 per share, of which 50,000 were canceled. At December 31, 2000, 44,000 were exercisable. Options granted pursuant to the Directors' Plan vest ratably over five years. A total of 72,000 options were exercised through December 31, 2000.

### 1993 Employee Stock Purchase Plan

In February 1993, the Board of Directors adopted the 1993 Employee Stock Purchase Plan (Employee Purchase Plan). We reserved 1,200,000 shares of common stock for the purchase of shares by employees under the Employee Purchase Plan. At December 31, 2000, 709,878 shares remain available for purchase. Eligibility to participate in the Employee Purchase Plan is essentially limited to full time employees who own less than 5% of the outstanding shares. Under the Employee Purchase Plan, eligible employees can purchase shares of our 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 2000, an aggregate of 71,770 shares were purchased by employees under the Employee Purchase Plan at prices of \$9.56 or \$29.43 per share.

### 1999 Nonstatutory Stock Option Plan

In August 1999, the Board of Directors adopted the 1999 Nonstatutory Stock Option Plan (the Nonstatutory Option Plan). We reserved 2,000,000 shares of common stock for the grant of options under the Nonstatutory Option Plan. As of December 31, 2000, 534,358 shares were available for grant. Certain options granted in August 1999 vest over a two year period beginning in September 1999.

At December 31, 2000, options to purchase 111,271 shares were exercisable at a prices ranging from \$13.28 to \$113.69. Options granted under the Nonstatutory Option Plan, pursuant to the standard form of option agreement for employees, 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.

### 1999 Stock Option Plan

In April 1999, the Board of Directors adopted the 1999 Stock Option Plan (the 1999 Option Plan) subject to approval by our stockholders, which approval occurred in June 1999. We reserved 1,850,000 shares of common stock for the grant of options under the 1999 Option Plan. As of December 31, 2000, 984,416 shares were available for grant.

At December 31, 2000, options to purchase 67,579 shares were exercisable at a prices ranging from \$13.28 to \$42.03. Options granted under the 1999 Option Plan, pursuant to the standard form of option agreement for employees, 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. Certain options granted in August 1999 vest over a two year period beginning in September 1999.

### Accounting for Stock-Based Compensation

We have elected to follow Accounting Principles Board Opinion No. 25, "Accounting of Stock Issued to Employees" (APB 25) and related interpretations, in accounting for stock-based awards to employees, consultants and directors under the Option Plan, Directors' Plan, the 1999 Nonstatutory Option Plan and the 1999 Option Plan because, as discussed below, the alternative fair value accounting provided for under Financial Accounting Standard 123, "Accounting for Stock-Based Compensation" (FAS 123) requires use of option valuation models that were not developed for use in valuing employee stock-based awards. Under APB 25, because the exercise price of our 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 2000, 1999 and 1998 has been determined as if we had accounted for our stock-based awards 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 2000, 1999 and 1998 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 subsequent years will include additional years of vesting.

(In thousands, except per share data)

	Year Ended December 31,		
	2000	1999	1998
Net income (loss):			
As reported	\$647	(\$10,333)	(\$9,502)
Pro forma	(\$23,866)	(\$17,435)	(\$17,626)
Net income (loss) per share:			
As reported - basic	\$0.02	(\$0.28)	(\$0.26)
As reported - diluted	\$0.01	(\$0.28)	(\$0.26)
Pro forma - basic	(\$0.58)	(\$0.47)	(\$0.48)
Pro forma - diluted	(\$0.58)	(\$0.47)	(\$0.48)

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 each of 2000, 1999 and 1998, respectively: (a) no dividends; (b) expected volatility of 142% for 2000, 72% for 1999 and 75% for prior years; (c) weighted-average risk-free interest rates of 6.14%, 5.39% and 5.45%; and (d) expected lives of 5 years.

A summary of the status of our stock option plans at December 31, 2000, 1999 and 1998, and changes during the years ending those dates is presented below.

(In thousands, except price data)

	2000		1999		1998	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	5,356	\$11.78	4,974	\$12.06	4,200	\$11.13
Granted	1,706	56.28	2,190	11.03	1,604	16.35
Exercised	(1,884)	11.38	(1,278)	10.82	(430)	7.53
Forfeited	(391)	23.73	(530)	12.39	(400)	13.24
Outstanding at end of year	4,787	27.81	5,356	11.78	4,974	12.06
Weighted average fair value of options granted during the year		\$97.71		\$6.96		\$10.62

The following information applies to all stock options outstanding under our stock option plans at December 31, 2000:

(In thousands, except exercise prices and remaining contractual life data)

		Options Outstanding			Options Exercisable		
Range of Exercise Prices		Number Outstanding	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price	
\$3.13	to \$4.44	22	1.73	\$3.66	22	\$3.66	
\$5.19	to \$7.88	3	5.47	\$7.70	3	\$7.70	
\$7.94	to \$11.69	1,473	7.12	\$8.95	683	\$8.61	
\$12.06	to \$17.88	829	7.38	\$14.18	405	\$13.57	
\$19.31	to \$24.00	869	7.38	\$20.13	184	\$19.61	
\$42.03	to \$71.63	1,216	9.34	\$45.56	9	\$42.03	
\$83.38	to \$113.64	375	9.63	\$94.02	0	\$0.00	
		4,787		\$27.81	1,306	\$11.83	

## 7. Income Taxes

As of December 31, 2000, we have federal and California state net operating loss carryforwards of approximately \$205,000,000 and \$58,400,000, respectively. We also have federal and California state research and other tax credit carryforwards of approximately \$6,800,000 and \$5,000,000, respectively. The federal net operating loss and credit carryforwards will expire at various dates beginning in the year 2002 through 2020, if not utilized. The California state net operating losses will expire at various dates beginning in 2001 through 2005, if not utilized.

Utilization of the federal and California state net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating losses and credits before utilization.

Significant components of our deferred tax assets for federal and state income taxes as of December 31 are as follows:

(In thousands)

	2000	1999
Deferred tax assets:		
Net operating loss carryforwards	\$73,000	\$24,000
Research and other credits	11,800	6,300
Deferred revenue	600	900
Capitalized research and development	4,800	2,100
Other	1,800	1,900
Total deferred tax assets	92,000	35,200
Valuation allowance for deferred tax asset	(92,000)	(35,200)
Net deferred tax assets	\$ --	\$ --

Because of our lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$6,200,000 and \$900,000 during 1999 and 1998, respectively.

Approximately \$52,600,000 of the valuation allowance for deferred tax assets at December 31, 2000 relates to benefits of stock option deductions which, when recognized, will be allocated directly to contributed capital.

## 8. Legal Proceedings

PDL is involved in administrative opposition proceedings being conducted by the European Patent Office with respect to our first European patent relating to humanized antibodies. At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European patent. We plan to appeal the Opposition Division's decision to the Technical Board of Appeals at the European Patent Office. The Technical Board of Appeals will consider all issues anew. The appeal suspends the decision of the Opposition Division during the appeals process, which is likely to take several years.

Until our appeal is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if our appeal is unsuccessful, our ability to collect royalties on European sales of antibodies humanized by others would depend on the scope and validity of our second European patent, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, the Opposition Division's decision could encourage challenges of our related patents in other jurisdictions, including the U.S. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the appeals process with respect to our first European patent, if we were to commence an infringement action to enforce that patent, such an action would likely be stayed until the appeal is decided by the European Patent Office. We may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents. Eight notices of opposition have been filed with respect to our second European antibody humanization patent. Also, three opposition statements have been filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings; however, we may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If our appeal with respect to our first European patent is unsuccessful or if the outcome of the other European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

## 9. Long-Term Debt

In September 1999, Fremont Holding L.L.C. (a wholly owned subsidiary of Protein Design Labs, Inc.) obtained a \$10.2 million term loan to purchase our Fremont, California facilities. The loan bears interest at the rate of 7.64% per year amortized over 15 years with principal and interest payable monthly. The loan is secured by our Fremont, California facilities and is subject to the terms and covenants of the loan agreement.

At December 31, 2000 the maturities of principal payments under this term loan are approximately as follows (in thousands):

2001	\$400
2002	432
2003	466
2004	502
2005	543
Thereafter	7,381
	-----
	\$9,742
	=====

## 10. Convertible Notes

In February 2000, we issued 5.50% Convertible Subordinated Notes due February 15, 2007 with a principal amount of \$150 million (the Convertible Notes). The Convertible Notes are convertible into our common stock at a conversion price of \$75.50 per share, subject to adjustment as a result of certain events and at the holders' option. Interest on the Convertible Notes is payable semiannually in arrears on February 15 and August 15 of each year. The Convertible Notes are unsecured and are subordinated to all our existing and future Senior Indebtedness (as defined in the indenture relating to the Convertible Notes). The Convertible Notes may be redeemed at our option, in whole or in part, beginning on February 15, 2003 at the redemption prices set forth in the Convertible Notes indenture. In June 2000, a shelf registration statement was declared effective covering resales of the Convertible Notes and the common stock issuable upon conversion of the Convertible Notes. Issuance costs associated with the Convertible Notes aggregating \$5.1 million are included in other assets and are amortized to interest expense over the term of the debt. The accumulated amortization at December 31, 2000 was \$0.6 million.

## QUARTERLY FINANCIAL DATA (UNAUDITED)

(In thousands, except price per share data)

	2000 Quarter Ended			
	December 31	September 30	June 30	March 31
Revenues:				
Revenue under agreements with third parties	\$ 6,682	\$4,702	\$15,893	\$12,450
Interest and other income	10,735	4,892	4,472	3,050
	-----	-----	-----	-----
Total revenues	17,597	9,594	20,365	15,500
Costs and expenses:				
Research and development	11,607	9,442	10,216	11,069



General and administrative	3,791	2,991	2,870	2,458
Interest expense	2,250	2,255	2,257	1,203
	-----	-----	-----	-----
Total costs and expenses	17,648	14,688	15,343	14,730
	-----	-----	-----	-----
Net income/(loss)	\$(51)	\$(5,094)	\$5,022	\$770
	=====	=====	=====	=====
Net income/(loss) per share:				
Basic	\$(0.00)	\$(0.13)	\$0.13	\$0.02
	=====	=====	=====	=====
Diluted	\$(0.00)	\$(0.13)	\$0.12	\$0.02
	=====	=====	=====	=====
Shares used in computation of net income/(loss) per share:				
Basic	43,323	40,050	39,514	38,920
	=====	=====	=====	=====
Diluted	43,323	40,050	43,262	43,052
	=====	=====	=====	=====

	1999 Quarter Ended			
	December 31	September 30	June 30	March 31
	-----	-----	-----	-----
Revenues:				
Revenue under agreements with third parties	\$ 5,906	\$8,401	\$6,039	\$6,462
Interest and other income	2,152	2,172	2,249	2,373
	-----	-----	-----	-----
Total revenues	8,058	10,573	8,288	8,835
Costs and expenses:				
Research and development	11,352	7,944	8,513	8,280
General and administrative	2,523	2,448	2,450	2,445
Interest expense	131	--	--	--
	-----	-----	-----	-----
Total costs and expenses	14,006	10,392	10,963	10,725
	-----	-----	-----	-----
Net income/(loss)	\$(5,948)	\$181	\$(2,675)	\$(1,890)
	=====	=====	=====	=====
Net income/(loss) per share:				
Basic	\$(0.16)	\$0.00	\$(0.07)	\$(0.05)
	=====	=====	=====	=====
Diluted	\$(0.16)	\$0.00	\$(0.07)	\$(0.05)
	=====	=====	=====	=====
Shares used in computation of net income/(loss) per share:				
Basic	37,760	37,336	37,250	37,236
	=====	=====	=====	=====
Diluted	37,760	38,710	37,250	37,236
	=====	=====	=====	=====

## Report of Ernst & Young LLP, Independent Auditors

Board of Directors and Stockholders Protein Design Labs, Inc.

We have audited the accompanying consolidated balance sheets of Protein Design Labs, Inc. as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Protein Design Labs, Inc. as of December 31, 2000 and 1999, and the consolidated results of its operations and its cash flows for

each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 5, 2001

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## **PART II (con't)**

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

Not Applicable.

## **PART III**

Certain information required by Part III is omitted from this Report in that the Registrant will file in a definitive proxy statement pursuant to Regulation 14A for the 2001 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Report, and certain information included therein is incorporated by reference.

### **ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS**

The information concerning our directors as required by this Item is incorporated by reference to the Section entitled "Nomination of Directors" of the Proxy Statement.

The information concerning our executive officers as required by this Item is incorporated by reference to the Section entitled "Executive Officers of the Registrant" of the Proxy Statement.

The information concerning compliance with requirements regarding reporting of timely filing of statements regarding changes in beneficial ownership of our securities as required by this Item is incorporated by reference to the Section entitled "Section 16(a) Reporting" of the Proxy Statement.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is incorporated by reference to the Section entitled "Executive Compensation and Other Matters" of the Proxy Statement.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The information required by this Item is incorporated by reference to the Section entitled "Security Ownership of Certain Beneficial Owners and Management" of the Proxy Statement.

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

The information required by this Item is incorporated by reference to the Section entitled "Executive Compensation and Other Matters - Compensation Committee Interlocks and Insider Participation" of the Proxy Statement.

## **PART IV**

### **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

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

[Consolidated Balance Sheets](#)

[Consolidated Statements of Operations](#)

[Consolidated Statements of Stockholders' Equity](#)

(2) All 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 \_\_\_ are incorporated herein by reference.

(b) Reports on Form 8-K.

We filed a Current Report on Form 8-K on October 6, 2000 (SEC File No. 000-19756 announcing:

On September 2, 2000 that the Company has agreed to adapt for human use a murine antibody from Eli Lilly and Company.

On September 18, 2000 that Company has entered into a second antibody agreement with Eli Lilly and Company.

On September 25, 2000, the Company's public offering of 3,000,000 shares of its common stock at a price of \$118.4365.

On September 29, 2000, the completion of the Company's public offering of 3,000,000 shares of its common stock at a price of \$118.4365.

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

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

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### SIGNATURES

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

PROTEIN DESIGN LABS, INC.

By: /s/ LAURENCE JAY KORN

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

March 26, 2001

*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 26, 2001
/s/ ROBERT L. KIRKMAN ----- (Robert L. Kirkman)	Vice President, Business Development ----- and Corporate Communications (Principal Accounting Officer)	March 26, 2001
/s/ JON S. SAXE ----- (Jon S. Saxe)	Director	March 26, 2001
/s/ CARY L. QUEEN	Director	March 26, 2001

-----  
(Cary L. Queen)

/s/ GEORGE M. GOULD            Director

March 26, 2001

-----  
(George M. Gould)

/s/ MAX LINK                    Director

March 26, 2001

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(Max Link)

/s/ JURGEN DREWS            Director

March 26, 2001

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(Jurgen Drews)

## INDEX TO EXHIBITS

<b><u>Exhibit Number</u></b>	<b><u>Exhibit Title</u></b>
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.)
*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	1993 Employee Stock Purchase Plan. (Incorporated by reference to Exhibit 10.32 to Annual Report on Form 10-K filed March 31, 1993.)
10.3	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, as amended.)
10.4	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.)
10.5	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.)
10.6	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.)
10.7	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, as amended.)
10.8	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.)
10.9	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, as amended.)
10.10	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, as amended.)
*10.11	Form of Director and Officer Indemnification Agreement. (Incorporated by reference to Exhibit 10.1 to Registration Statement No. 33-44562 effective January 28, 1992, as amended.)
10.12	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.)

- 10.13 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.)
- 10.14 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.)
- 10.15 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.)
- 10.16 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.)
- 10.17 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.)
- 10.18 Development and License Agreement between the Company and Mochida Pharmaceutical Co., Ltd. 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.)
- 10.19 Amendment No. 3 to Lease Agreement between the Company and St. Paul Properties, effective as of November 27, 1996. (Incorporated by Reference to Exhibit 10.39 to Annual Report on Form 10-K filed February 13, 1997.)
- 10.20 Amendment No. 2 to Amended and Restated Agreement between the Company and Sloan-Kettering Institute for Cancer Research dated January 2, 1997. (Incorporated by Reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 14, 1997.)
- \*10.21 Outside Directors Stock Option Plan together with form of nonqualified stock option agreement as amended effective February 6, 1997. (Incorporated by Reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 14, 1997.)
- 10.22 Patent Licensing Master Agreement between the Company and Genentech, Inc., dated as of September 25, 1998 (with certain confidential information deleted and marked by a box surrounding the deleted information). (Incorporated by reference to Exhibit 10.10 to Quarterly Report on Form 10-Q filed November 16, 1998.)
- 10.23 Agreement of Purchase and Sale between Fremont Holding L.L.C., a Delaware limited liability company, as assignee effective September 13, 1999, and Ardenstone LLC, a Delaware limited liability company, effective June 21, 1999. (Incorporated by reference to Exhibit 10.46 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.24 Promissory Note between Fremont Holding L.L.C., a Delaware limited liability company and Wells Fargo Bank, National Association, dated September 9, 1999. (Incorporated by reference to Exhibit 10.47 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.25 Deed of Trust and Absolute Assignment of Rents and Security Agreement (Fixture Filings) between Fremont Holding L.L.C., a Delaware limited liability company and Wells Fargo Bank, National Association, dated September 9, 1999. (Incorporated by reference to Exhibit 10.48 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.26 Patent Rights Agreement between the Company and Smithkline Beecham Corporation, effective as of September 28, 1999 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.49 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.27 IL-5 Patent License Agreement between the Company and Smithkline Beecham Corporation, effective as of September 28, 1999 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.50 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.28 Development and License Agreement between the Company and Smithkline Beecham Corporation, effective as of September 28, 1999 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.51 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.29 Amended and Restated Agreement between the Company and Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd, dated as of October 20, 1999 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.52 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- 10.30 Amended and Restated Agreement between the Company and F. Hoffmann- La Roche Ltd, dated as of October 20, 1999 (with certain confidential portions deleted and marked by notation indicating such

- deletion). (Incorporated by reference to Exhibit 10.53 to Quarterly Report on Form 10-Q filed November 15, 1999.)
- \*10.31 1999 Stock Option Plan, together with forms of Incentive Stock Option Agreement and Nonstatutory Stock Option Agreement. (Incorporated by reference to Exhibit 10.31 to Registration Statement No. 333-87957 effective September 29, 1999.)
  - 10.32 1999 Nonstatutory Stock Option Plan, together with form Nonstatutory Stock Option Agreement. (Incorporated by reference to Exhibit 10.32 to Registration Statement No. 333-87957 effective September 29, 1999.)
  - 10.33 Indenture Agreement between the Company and Chase Manhattan Bank And Trust Company, National Association, a national banking association, dated February 15, 2000. 1999.)
  - 10.34 Registration Rights Agreement for the Company's 5.50% Convertible Subordinated Notes due February 15, 2007, dated February 15, 2000.
  - 10.35 Amendment to Amended and Restated Agreement dated as of June 2, 2000 by and among the Company, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd.(with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 14, 2000)
  - \*10.36 Outside Directors Stock Option Plan as amended on June 29, 2000 together with the form of nonqualified stock option agreement.
  - 10.37 1999 Nonstatutory Stock Option Plan as amended on December 14, 2000.
  - 10.38 Amendment No. 2 to Amended Restated Agreement dated February 23, 2001 by and among the Company, Hoffmann La-Roche Inc. and F. Hoffmann-La Roche Ltd.
  - 10.39 Amendment No. 1 to Amended Restated Agreement dated February 23, 2001 by and among the Company and F. Hoffmann-La Roche Ltd.
  - 21.1 Fremont Holding L.L.C., a Delaware limited liability company. Fremont Management, Inc., a Delaware corporation, doing business in California as Delaware Fremont Management. (Incorporated by reference to Exhibit 21.1 to Quarterly Report on Form 10-Q filed November 15, 1999.)
  - 23.1 Consent of Ernst & Young LLP, Independent Auditors.

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\* Management contract or compensatory plan or arrangement

**PROTEIN DESIGN LABS, INC. OUTSIDE DIRECTORS STOCK OPTION PLAN**

(As amended June 29, 2000)

1. Purpose. The Protein Design Labs, Inc. Outside Directors Stock Option Plan (the "Plan") is established to create additional incentive for the non-employee directors of Protein Design Labs, Inc. and any successor corporation thereto (collectively referred to as the "Company"), to promote the financial success and progress of the Company and any present or future parent and/or subsidiary corporations of the Company (all of whom along with the Company being individually referred to as a "Participating Company" and collectively referred to as the "Participating Company Group"). The Plan shall be effective as of the date it is approved by the stockholders of the Company (the "Effective Date"). For purposes of the Plan, a parent corporation and a subsidiary corporation shall be as defined in sections 424(e) and 424(f) of the Internal Revenue Code of 1986, as amended (the "Code").
2. Administration. The Plan shall be administered by the Board of Directors of the Company (the "Board") and/or by a duly appointed committee of the Board having such powers as shall be specified by the Board. Any subsequent references herein to the Board shall also mean the committee if such committee has been appointed and, unless the powers of the committee have been specifically limited, the committee shall have all of the powers of the Board granted herein, including, without limitation, the power to terminate or amend the Plan at any time, subject to the terms of the Plan and any applicable limitations imposed by law. The Board shall have no authority, discretion, or power to select which non-employee directors of the Company will receive options under the Plan, to set the exercise price of the options granted under the Plan, to determine the number of shares of common stock to be granted under an option or the time at which any options are to be granted, to establish the duration of option grants, or alter any other terms or conditions specified in the Plan, except in the sense of administering or amending the Plan subject to the provisions of the Plan. All questions of interpretation of the Plan or of any options granted under the Plan (an "Option") shall be determined by the Board, and such determinations shall be final and binding upon all persons having an interest in the Plan and/or any Option. The Chief Executive Officer, President or General Counsel of the Company shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, or election which is the responsibility of or which is allocated to the Company herein.
3. Eligibility and Type of Option. Options may be granted only to directors of the Company who are not employees of the Company or any present parent and/or subsidiary corporations of the Company ("Outside Directors"). Options granted to Outside Directors shall be nonqualified stock options; that is, options which are not treated as having been granted under section 422(b) of the Code.
4. Shares Subject to Option. Options shall be for the purchase of shares of the authorized but unissued common stock or treasury shares of common stock of the Company (the "Stock"), subject to adjustment as provided in paragraph 8 below. The maximum number of shares of Stock which may be issued under the Plan shall be two hundred thousand (200,000) shares. In the event that any outstanding Option for any reason expires or is terminated and/or shares of Stock subject to repurchase are repurchased by the Company, the shares allocable to the unexercised portion of such Option, or such repurchased shares, may again be subject to an Option grant.
5. Time for Granting Options. All Options shall be granted, if at all, within ten (10) years from the Effective Date.
6. Terms, Conditions and Form of Options. Options granted pursuant to the Plan shall be evidenced by written agreements specifying the number of shares of Stock covered thereby, in substantially the form attached hereto as Exhibit A (the "Option Agreement"), which written agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:
  - (a) Automatic Grant of Options. Subject to execution by each Outside Director of an Option Agreement, options shall be granted automatically and without further action of the Board, as follows:
    - (i) Each person who is newly appointed or elected as an Outside Director after February 6, 1997 or who becomes an Outside Director as a result of ceasing to be an employee of the Company or any parent or subsidiary corporation of the Company after June 29, 2000 (a "Future Outside Director") shall be granted an Option for thirty thousand (30,000) shares of Stock upon the date such person becomes an Outside Director.
    - (ii) Each Outside Director shall be granted an Option for thirty thousand (30,000) shares of Stock upon the fifth Anniversary Date (as defined below) and each subsequent five year Anniversary Date thereafter (e.g., 10th, 15th, etc.) of such Outside Director.
    - (iii) The Anniversary Date of each Outside Director shall be the date the Outside Director became an Outside Director except that if he or she elected not to receive an option at that time under paragraph 6(a)(iv) then his or her Anniversary Date shall be the date upon which he or she was first granted an Option under the Plan. If an Outside Director subsequently elects not to receive an Option and later revokes that election, his or her Anniversary Date may be adjusted as provided in paragraph 6(a)(iv).
    - (iv) Notwithstanding the foregoing, any Outside Director may elect not to receive an Option granted pursuant to this paragraph 6(a) by delivering written notice of such election to the Board no later than the day prior to the date such Option would otherwise be granted. A person so declining an Option shall receive no payment or other consideration in lieu of such declined Option. An Outside Director who has declined an Option may revoke such election by delivering written notice of such revocation to the

Board, in which event such Outside Director shall be automatically granted an Option on the later of the date the Option would otherwise have been granted to such Outside Director or the date of such notice (and in such latter event the Outside Director's Anniversary Date shall then become the date of such notice).

(v) Notwithstanding any other provision of the Plan, no Option shall be granted to any individual on his or her Anniversary Date when he or she is no longer serving as an Outside Director of the Company on such Anniversary Date.

(b) Option Exercise Price. The Option exercise price per share of Stock for an Option shall be the fair market value of a share of the common stock of the Company on the date of the granting of the Option. Where there is a public market for the common stock of the Company, the fair market value per share of Stock shall be the mean of the bid and asked prices of the common stock of the Company on the date of the granting of the Option, as reported in the Wall Street Journal (or, if not so reported, as otherwise reported by the National Association of Securities Dealers Automated Quotation ("NASDAQ") System) or, in the event the common stock of the Company is listed on the NASDAQ National Market System or a national or regional securities exchange, the fair market value per share of Stock shall be the closing price on such National Market System or exchange on the date of the granting of the Option, as reported in the Wall Street Journal. If the date of the granting of an Option does not fall on a day on which the common stock of the Company is trading on the NASDAQ National Market System or other national or regional securities exchange, the date on which the Option exercise price per share shall be established shall be the last day on which the common stock of the Company was so traded prior to the date of the granting of the Option.

(c) Exercise Period and Exercisability of Options. An Option granted pursuant to the Plan shall be exercisable for a term of ten (10) years. Options granted pursuant to the Plan shall become exercisable over a sixty (60) month period commencing one (1) month after the date of grant as provided in the form of Option Agreement.

(d) Payment of Option Exercise Price. Payment of the Option exercise price for the number of shares of Stock being purchased pursuant to any Option shall be made (i) in cash, by check, or in cash equivalent, (ii) by the assignment of the proceeds of a sale of some or all of the shares being acquired upon the exercise of an Option (including, without limitation, through an exercise complying with the provisions of Regulation T as promulgated from time to time by the Board of Governors of the Federal Reserve System), or (iii) by any combination thereof. The Company reserves, at any and all times, the right, in the Company's sole and absolute discretion, to establish, decline to approve and/or terminate any program and/or procedure for the exercise of Options by means of an assignment of the proceeds of a sale of some or all of the shares of Stock to be acquired upon such exercise.

(e) Transfer of Control. A "Transfer of Control" shall be deemed to have occurred in the event any of the following occurs with respect to the Company:

(i) any acquisition of the Company's stock or any reorganization as defined in section 368(a)(1) of the Code to which the Company is a party as defined in section 368(b) of the Code and in which the Company is not the surviving corporation or is not immediately after the reorganization engaged in the active conduct of a trade or business or in which the stockholders of the Company will own less than fifty percent (50%) of the voting securities of the surviving corporation; or

(ii) any sale or conveyance of substantially all of the net assets of the Company, unless immediately after such sale the Company is engaged in the active conduct of a trade or business.

In the event of a Transfer of Control, the surviving, continuing, successor, or purchasing corporation, as the case may be (the "Acquiring Corporation"), shall either assume the Company's rights and obligations under outstanding stock option agreements or substitute options for the Acquiring Corporation's stock for such outstanding Options unless the Company's Board otherwise agrees. In the event that, with the Board's consent, the Acquiring Corporation elects not to assume or substitute for such outstanding Options in connection with a merger in which the Company is not the surviving corporation or a reverse triangular merger in which the Company is the surviving corporation where the stockholders of the Company before such merger do not retain, directly or indirectly, at least a majority of the beneficial interest in the voting stock of the Company after such merger, the Board may, but shall not be obligated to, provide that any unexercisable and/or unvested portion of the outstanding Options shall be immediately exercisable and vested as of a date prior to the Transfer of Control, as the Board so determines. The exercise and/or vesting of any Option that was permissible solely by reason of this paragraph 6(e) shall be conditioned upon the consummation of the Transfer of Control. Any Options which are neither assumed or 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.

7. Authority to Vary Terms. The Board shall have the authority from time to time to vary the terms of the Option Agreement either in connection with the grant of an individual Option or in connection with the authorization of a new standard form or forms; provided, however, that the terms and conditions of such revised or amended standard form or forms of Option Agreement shall be in accordance with the terms of the Plan. Such authority shall include, but not by way of limitation, the authority to grant Options which are immediately exercisable subject to the Company's right to repurchase any unvested shares of Stock acquired by the Optionee on exercise of an Option in the event such Optionee's service as a director of the Company is terminated for any reason.

8. Effect of Change in Stock Subject to Plan. Appropriate adjustments shall be made in the number and class of shares of Stock subject to the Plan and to any outstanding Options and in the Option exercise price of any outstanding Options in the event of a stock dividend, stock split, reverse stock split, combination, reclassification, or like change in the capital structure of the Company.

9. Options Non-Transferable. Except as may be permitted by the Board and expressly provided in an Option agreement granted by the Board, Options may not be assigned or transferred by an Optionee except by will or by the laws of descent and distribution.



10. Termination or Amendment of Plan. The Board, including any duly appointed committee of the Board, may terminate or amend the Plan at any time; provided, however, that without the approval of the stockholders of the Company, there shall be (a) no increase in the total number of shares of Stock covered by the Plan (except by operation of the provisions of paragraph 8 above), and (b) no expansion in the class of persons eligible to receive Options. In any event, no amendment may adversely affect any then outstanding Option, or any unexercised portion thereof, without the consent of the Optionee.

IN WITNESS WHEREOF, the undersigned Secretary of the Company certifies that the foregoing Protein Design Labs, Inc. Outside Directors Stock Option Plan was approved by the stockholders of the Company at the Annual Meeting of Stockholders on the twentieth day of October, 1992, and subsequently amended by the Board on October 17, 1996, February 6, 1997 and June 29, 2000, in accordance with applicable laws and the terms of the Plan.

Date:

By:

Douglas O. Ebersole

Secretary

## EXHIBIT A

### PROTEIN DESIGN LABS, INC. NONQUALIFIED STOCK OPTION AGREEMENT FOR OUTSIDE DIRECTORS

Protein Design Labs, Inc., a Delaware corporation (the "Company"), hereby grants to (the "Optionee") an option to purchase a total of thirty thousand (30,000) shares of the common stock of the Company (the "Number of Option Shares") under the Protein Design Labs, Inc. Outside Directors Stock Option Plan (the "Plan"), at an exercise price of \$ per share and in the manner and subject to the provisions of this Option Agreement (the "Option"). The grant, in all respects, is subject to the terms and conditions of this Option Agreement and the Plan, the provisions of which are incorporated by reference herein. Unless otherwise provided in this Option Agreement, defined terms shall have the meaning given to such terms in the Plan.

1. Grant of the Option. The Option is granted effective as of (the "Date of Option Grant"). The Number of Option Shares and the exercise price per share of the Option are subject to adjustment from time to time as provided in the Plan.

2. Status of the Option. The Option is intended to be a nonqualified stock option and shall not be treated as an incentive stock option as described in section 422 of the Internal Revenue Code of 1986, as amended.

3. Term of the Option. The Option shall terminate and may no longer be exercised on the first to occur of (i) the date ten (10) years after the Date of Option Grant (the "Option Term Date"), (ii) the last date for exercising the Option following termination of the Optionee's service as a director of the Company as described in paragraph 6 below, or (iii) upon a Transfer of Control of the Company as described in the Plan.

4. Exercise of the Option.

(a) Right to Exercise. The Option shall first become exercisable on the date occurring one (1) month after the Date of Option Grant (the "Initial Exercise Date"). The Option shall be exercisable on and after the Initial Exercise Date and prior to the termination of the Option in the amount equal to the Number of Option Shares multiplied by the Vested Ratio as set forth below less the number of shares previously acquired upon exercise of the Option:

	Vested Ratio
Prior to Initial Exercise Date	0
On Initial Exercise Date, provided the Optionee has continuously served as a director of Company from the Date of Option Grant until the Initial Exercise Date	1/60
Plus	
For each full month of the Optionee's continuous service as a director of the Company from the Initial Exercise Date	1/60

In no event shall the Vested Ratio exceed 1/1.

In no event shall the Option be exercisable for more shares than the Number of Option Shares. Notwithstanding the foregoing, the Option may not be exercised more frequently than twice in any continuous twelve (12) month period; provided, however, that the foregoing restriction shall not apply so as to prevent an exercise (i) following termination of the Optionee's service as a director of the Company as described in paragraph 6 below or (ii) during the thirty (30) day period immediately preceding a Transfer of Control of the Company as described in the Plan.

(b) Method of Exercise. The Option may be exercised by written notice to the Company which must state the election to exercise the Option, the number of shares of stock for which the Option is being exercised and such other representations and agreements as to the Optionee's investment intent with respect to such shares as may be required pursuant to the provisions of this Option Agreement and the Plan. The written notice must be signed by the Optionee and must be delivered in person, by facsimile or by certified or registered mail, return receipt requested, to the President of the Company, or other authorized representative of the Participating Company Group, prior to the termination of the Option as set forth in paragraph 3 above, accompanied by full payment of the exercise price for the number of shares of stock being purchased in a form permitted under the terms of the Plan.

(c) Withholding. At the time the Option is exercised, in whole or in part, or at any time thereafter as requested by the Company, the Optionee shall make adequate provision for the foreign, federal and state tax withholding obligations of the Company, if any, which arise in connection with the Option including, without limitation, obligations arising upon (i) the exercise, in whole or in part, of the Option, (ii) the transfer, in whole or in part, of any shares of stock acquired on exercise of the Option, or (iii) the lapsing of any restriction with respect to any shares acquired on exercise of the Option.

(d) Certificate Registration. The certificate or certificates for the shares of stock as to which the Option shall be exercised shall be registered in the name of the Optionee, or, if applicable, the heirs of the Optionee.

(e) Restriction on Grant of the Option and Issuance of Shares. The grant of the Option and the issuance of shares of stock on exercise of the Option shall be subject to compliance with all of the applicable requirements of federal or state law with respect to such securities. The Option may not be exercised if the issuance of shares of stock upon such exercise would constitute a violation of any applicable federal or state securities laws or other law or regulation. In addition, no Option may be exercised unless (i) a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), shall at the time of exercise of the Option be in effect with respect to the shares of stock issuable upon exercise of the Option, or (ii) in the opinion of legal counsel to the Company, the shares issuable upon exercise of the Option may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. As a condition to the exercise of the Option, the Company may require the Optionee to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company.

(f) Fractional Shares. The Company shall not be required to issue fractional shares of stock upon the exercise of the Option.

5. Non-Transferability of the Option. The Option may be exercised during the lifetime of the Optionee only by the Optionee and may not be assigned or transferred in any manner except by will or by the laws of descent and distribution.

6. Termination of Service as a Director.

(a) Termination of Director Status. If the Optionee ceases to be a director of the Company for any reason except death or disability within the meaning of section 22(e)(3) of the Code, the Option, to the extent unexercised and exercisable by the Optionee on the date on which the Optionee ceased to be a director, may be exercised by the Optionee at any time prior to the expiration of three (3) months from the date on which the Optionee's service as a director of the Company terminated, but in any event no later than the Option Term Date. If the Optionee ceases to be a director of the Company because of the death or disability of the Optionee within the meaning of section 22(e)(3) of the Code, the Option, to the extent unexercised and exercisable by the Optionee on the date on which the Optionee ceased to be a director, may be exercised by the Optionee (or the Optionee's legal representative) at any time prior to the expiration of twelve (12) months from the date on which the Optionee's service as a director of the Company terminated, but in any event no later than the Option Term Date. The Optionee's service as a director of the Company shall be deemed to have terminated on account of death if the Optionee dies within three (3) months after the Optionee's termination of service as a director of the Company. Except as provided in this paragraph 6, an Option shall terminate and may not be exercised after the Optionee ceases to be a director of the Company.

(b) Extension of Exercise Prevented by Law. Notwithstanding the foregoing, if the exercise of the Option within the applicable time periods set forth above is prevented because the issuance of shares of stock upon such exercise would constitute a violation of any applicable federal or state securities law or other law or regulation, the Option shall remain exercisable until three (3) months after the date the Optionee is notified by the Company that the Option is exercisable, but in any event no later than the Option Term Date.

(c) Extension if Optionee Subject to Section 16(b). Notwithstanding the foregoing, if the exercise of the Option within the applicable time periods set forth above would subject the Optionee to suit under Section 16(b) of the Exchange Act, the Option shall remain exercisable until the earliest to occur of (i) the tenth (10th) day following the date on which the Optionee would no longer be subject to such suit, (ii) the one hundred and ninetieth (190th) day after the Optionee's termination of service as a director of the Company and (iii) the Option Term Date.

7. Rights as a Stockholder. The Optionee shall have no rights as a stockholder with respect to any shares of stock covered by the Option until the date of the issuance of a certificate or certificates for the shares for which the Option has been exercised. No

adjustment shall be made for dividends or distributions or other rights for which the record date is prior to the date such stock certificate or certificates are issued, except as provided in the Plan.

8. Legends. The Company may at any time place legends referencing any applicable federal or state securities law restrictions on all certificates representing shares of stock subject to the provisions of this Option Agreement. The Optionee shall, at the request of the Company, promptly present to the Company any and all certificates representing shares of stock acquired pursuant to the Option in the possession of the Optionee in order to effectuate the provisions of this paragraph.

9. Binding Effect. This Option Agreement shall inure to the benefit of the successors and assigns of the Company and be binding upon the Company and the Optionee and the Optionee's heirs, executors, administrators, successors and assigns.

10. Termination or Amendment. The Board, including any duly appointed committee of the Board, may terminate or amend the Plan and/or the Option at any time subject to any limitations described in the Plan; provided, however, that no such termination or amendment may adversely affect the Option or any unexercised portion hereof without the consent of the Optionee.

11. Integrated Agreement. This Option Agreement and the Plan constitute the entire understanding and agreement of the Optionee and the Company with respect to the subject matter contained herein and therein, and there are no agreements, understandings, restrictions, representations, or warranties among the Optionee and the Company other than those as set forth or provided for herein or therein. To the extent contemplated herein and therein, the provisions of this Option Agreement and the Plan shall survive any exercise of the Option and shall remain in full force and effect.

12. Applicable Law. This Option Agreement shall be governed by the laws of the State of California as such laws are applied to agreements between California residents entered into and to be performed entirely within the State of California.

13. Arbitration. In the event a dispute between the parties to this Option Agreement arises out of, in connection with, or with respect to this Option Agreement, or any breach of this Option Agreement, such dispute will, on the written request of one (1) party delivered to the other party, be submitted and settled by arbitration in Palo Alto, California in accordance with the rules of the American Arbitration Association then in effect and will comply with the California Arbitration Act, except as otherwise specifically stated in this paragraph 13. Judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction. The parties submit to the in personam jurisdiction of the Supreme Court of the State of California for the purpose of confirming any such award and entering judgment upon the award. Notwithstanding anything to the contrary that may now or in the future be contained in the rules of the American Arbitration Association, the parties agree as follows:

(a) Each party will appoint one person approved by the American Arbitration Association to hear and determine the dispute within twenty (20) days after receipt of notice of arbitration from the noticing party. The two (2) persons so chosen will select a third impartial arbitrator. The majority decision of the arbitrators will be final and conclusive upon the parties to the arbitration. If either party fails to designate its arbitrator within twenty (20) days after delivery of the notice provided for in this paragraph 13(a), then the arbitrator designated by the one (1) party will act as the sole arbitrator and will be considered the single, mutually approved arbitrator to resolve the controversy. In the event the parties are unable to agree upon a rate of compensation for the arbitrators, they will be compensated for their services at a rate to be determined by the American Arbitration Association.

(b) The parties will enjoy, but are not limited to, the same rights to discovery as they would have in the United States District Court for the Northern District of California.

(c) The arbitrators will, upon the request of either party, issue a written opinion of their findings of fact and conclusions of law.

(d) Upon receipt by the requesting party of said written opinion, said party will have the right within ten (10) days to file with the arbitrators a motion to reconsider, and upon receipt of a timely request the arbitrators will reconsider the issues raised by said motion and either confirm or change their majority decision which will then be final and conclusive upon the parties to the arbitration.

(e) The arbitrators will award to the prevailing party in any such arbitration reasonable expenses, including attorneys' fees and costs, incurred in connection with the dispute.

PROTEIN DESIGN LABS, INC.

By:

Title:

The Optionee represents that the Optionee is familiar with the terms and provisions of this Option Agreement and the Plan and hereby accepts the Option subject to all of the terms and provisions thereof.

The undersigned acknowledges receipt of a copy of the Plan.

Date:

Signature:



**PROTEIN DESIGN LABS, INC. 1999 NONSTATUTORY STOCK OPTION PLAN****1. ESTABLISHMENT, PURPOSE AND TERM OF PLAN.**

1.1 Establishment. The Protein Design Labs, Inc. 1999 Nonstatutory Stock Option Plan (the "Plan") is hereby established effective as of August 19, 1999.

1.2 Purpose. The purpose of the Plan is to advance the interests of the Participating Company Group and its stockholders by providing an incentive to attract, retain and reward Persons performing services for the Participating Company Group and by motivating such Persons to contribute to the goals of the Participating Company Group.

1.3 Term of Plan. The Plan shall continue in effect until the earlier of its termination by the Board or the date on which all of the shares of Stock available for issuance under the Plan have been issued and all restrictions on such shares under the terms of the Plan and the agreements evidencing Options granted under the Plan have lapsed.

**2. DEFINITIONS AND CONSTRUCTION.**

2.1 Definitions. Whenever used herein, the following terms shall have their respective meanings set forth below:

(a) "Board" means the Board of Directors of the Company. If one or more Committees have been appointed by the Board to administer the Plan, "Board" also means such Committee(s).

(b) "Code" means the Internal Revenue Code of 1986, as amended, and any applicable regulations promulgated thereunder.

(c) "Committee" means the committee(s) of the Board, if any, duly appointed to administer the Plan and having such powers as shall be specified by the Board. Unless the powers of a Committee have been specifically limited, the Committee shall have all of the powers of the Board granted herein, including, without limitation, the power to amend or terminate the Plan at any time, subject to the terms of the Plan and any applicable limitations imposed by law.

(d) "Company" means Protein Design Labs, Inc., a Delaware corporation, or any successor corporation thereto.

(e) "Consultant" means any Person, including an advisor, engaged by a Participating Company to render services other than as an Employee or a member of the Board.

(f) "Disability" means the permanent and total disability of the Optionee within the meaning of Section 22(e)(3) of the Code.

(g) "Employee" means any Person treated as an employee in the records of a Participating Company.

(h) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(i) "Fair Market Value" means, as of any date, the value of a share of Stock or other property as determined by the Board, in its discretion, subject to the following:

(i) If, on such date, the Stock is listed on a national or regional securities exchange or market system, the Fair Market Value of a share of Stock shall be the closing sale price of a share of Stock (or the mean of the closing bid and asked prices of a share of Stock if the Stock is so quoted instead) as quoted on the Nasdaq National Market, The Nasdaq SmallCap Market or such other national or regional securities exchange or market system constituting the primary market for the Stock, as reported in the Wall Street Journal or such other source as the Board deems reliable. If the relevant date does not fall on a day on which the Stock has traded on such securities exchange or market system, the date on which the Fair Market Value shall be established shall be the last day on which the Stock was so traded prior to the relevant date, or such other appropriate day as shall be determined by the Board, in its discretion.

(ii) If, on such date, the Stock is not listed on a national or regional securities exchange or market system, the Fair Market Value of a share of Stock shall be as determined by the Board without regard to any restriction other than a restriction which, by its terms, will never lapse.

(j) "Nonstatutory Stock Option" means an Option not intended to be an incentive stock option within the meaning of Section 422(b) of the Code.

(k) "Option" means a right to purchase Stock (subject to adjustment as provided in Section 4.2) pursuant to the terms and conditions of the Plan. All Options shall be Nonstatutory Stock Options.

(l) "Option Agreement" means a written agreement between the Company and an Optionee setting forth the terms, conditions and restrictions of the Option granted to the Optionee and any shares of Stock acquired upon the exercise thereof.

(m) "Optionee" means a Person who has been granted one or more Options.

(n) "Parent Corporation" means any present or future "parent corporation" of the Company, as defined in Section 424(e) of the Code.

(o) "Participating Company" means the Company or any Parent Corporation or Subsidiary Corporation.

(p) "Participating Company Group" means, at any point in time, all corporations collectively which are then Participating Companies.

(q) "Person" means a natural person.

(r) "Securities Act" means the Securities Act of 1933, as amended.

(s) "Service" means an Optionee's employment or service with the Participating Company Group, whether in the capacity of an Employee or a Consultant. Unless otherwise provided by the Board, an Optionee's Service shall not be deemed to have terminated merely because of a change in the capacity in which the Optionee renders Service to the Participating Company Group or a change in the Participating Company for which the Optionee renders such Service, provided that there is no interruption or termination of the Optionee's Service. Furthermore, an Optionee's Service with the Participating Company Group shall not be deemed to have terminated if the Optionee takes any bona fide leave of absence approved by the Company. Notwithstanding the foregoing, unless otherwise required by law, the Company may provide that an approved leave of absence shall not be treated as Service for purposes of determining vesting under the Optionee's Option Agreement. An Optionee's Service shall be deemed to have terminated either upon an actual termination of Service or upon the corporation for which the Optionee performs Service ceasing to be a Participating Company. Subject to the foregoing, the Company, in its discretion, shall determine whether an Optionee's Service has terminated and the effective date of such termination.

(t) "Stock" means the common stock of the Company, as adjusted from time to time in accordance with Section 4.2.

(u) "Subsidiary Corporation" means any present or future "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

2.2 Construction. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

### 3. ADMINISTRATION.

3.1 Administration by the Board. The Plan shall be administered by the Board. All questions of interpretation of the Plan or of any Option shall be determined by the Board, and such determinations shall be final and binding upon all Persons having an interest in the Plan or such Option.

3.2 Authority of Officers. The Chief Executive Officer shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election which is the responsibility of or which is allocated to the Company herein.

3.3 Powers of the Board. In addition to any other powers set forth in the Plan and subject to the provisions of the Plan, the Board shall have the full power and authority, in its discretion:

(a) to determine the Persons to whom, and the time or times at which, Options shall be granted and the number of shares of Stock to be subject to each Option;

(b) to determine the Fair Market Value of shares of Stock or other property in the event such property is proposed as consideration for payment for the exercise of an Option;

(c) to determine the terms, conditions and restrictions applicable to each Option (which need not be identical) and any shares of Stock acquired upon the exercise thereof, including, without limitation, (i) the exercise price of the Option, (ii) the method of payment for shares of Stock purchased upon the exercise of the Option, (iii) the method for satisfaction of any tax withholding obligation arising in connection with the Option or such shares of Stock, including by the withholding or delivery of shares of Stock, (iv) the timing, terms and conditions of the exercisability of the Option or the vesting of any shares of Stock acquired upon the exercise thereof, (v) the time of the expiration of the Option, (vi) the effect of the Optionee's termination of Service with the Participating Company Group on any of the foregoing, and (vii) all other terms, conditions and restrictions applicable to the Option or such shares of Stock not inconsistent with the terms of the Plan;

(d) to approve one or more forms of Option Agreement;

(e) to amend, modify, extend, cancel, renew, or grant a new Option in substitution for, any Option or to waive any restrictions or conditions applicable to any Option or any shares acquired upon the exercise thereof;

(f) to accelerate, continue, extend or defer the exercisability of any Option or the vesting of any shares acquired upon the exercise thereof, including with respect to the period following an Optionee's termination of Service with the Participating Company Group;

(g) to prescribe, amend or rescind rules, guidelines and policies relating to the Plan, or to adopt supplements to, or alternative versions of, the Plan, including, without limitation, as the Board deems necessary or desirable to comply with the laws of, or to

accommodate the tax policy or custom of, foreign jurisdictions whose citizens may be granted Options; and

(h) to correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Option Agreement and to make all other determinations and take such other actions with respect to the Plan or any Option as the Board may deem advisable to the extent consistent with the Plan and applicable law.

#### 4. SHARES SUBJECT TO PLAN.

4.1 Maximum Number of Shares Issuable. Subject to adjustment as provided in Section 4.2, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be 1,000,000 and shall consist of authorized but unissued or reacquired shares of Stock or any combination thereof. If an outstanding Option for any reason expires or is terminated or canceled or if unvested shares of Stock are acquired upon the exercise of an Option subject to a Company repurchase option and are repurchased by the Company, the shares of Stock allocable to the unexercised portion of such Option or such unvested repurchased shares of Stock shall again be available for issuance under the Plan.

4.2 Adjustments for Changes in Capital Structure. In the event of any stock dividend, stock split, reverse stock split, recapitalization, combination, reclassification or similar change in the capital structure of the Company, appropriate adjustments shall be made in the number and class of shares subject to the Plan and to any outstanding Options and in the exercise price per share of any outstanding Options. If a majority of the shares which are of the same class as the shares that are subject to outstanding Options are exchanged for, converted into, or otherwise become (whether or not pursuant to an Ownership Change Event, as defined in Section 8.1) shares of another corporation (the "New Shares"), the Board may unilaterally amend the outstanding Options to provide that such Options are exercisable for New Shares. In the event of any such amendment, the number of shares subject to, and the exercise price per share of, the outstanding Options shall be adjusted in a fair and equitable manner as determined by the Board, in its discretion. Notwithstanding the foregoing, any fractional share resulting from an adjustment pursuant to this Section 4.2 shall be rounded down to the nearest whole number, and in no event may the exercise price of any Option be decreased to an amount less than the par value, if any, of the stock subject to the Option. The adjustments determined by the Board pursuant to this Section 4.2 shall be final and binding.

#### 5. ELIGIBILITY AND OPTION LIMITATIONS.

5.1 Persons Eligible for Options. Options may be granted only to Employees and Consultants. For purposes of the foregoing sentence, "Employees" and "Consultants" shall include prospective Employees and prospective Consultants to whom Options are granted in connection with written offers of employment or other service relationship with the Participating Company Group. However, notwithstanding any other provision herein to the contrary, no Person shall be eligible to be granted an Option under the Plan whose eligibility would require approval of the Plan by the Stockholders of the Company under any law or regulation or the rules of any stock exchange or market system upon which the Stock may then be listed. If not inconsistent with any such law, regulation or rule, an Option may be granted to a Person, not previously employed by the Company, as an inducement essential to entering into an employment contract with the Company. Eligible Persons may be granted more than one (1) Option.

5.2 Options Authorized. Options granted under the Plan may only be Nonstatutory Stock Options.

#### 6. TERMS AND CONDITIONS OF OPTIONS.

Options shall be evidenced by Option Agreements specifying the number of shares of Stock covered thereby, in such form as the Board shall from time to time establish. No Option or purported Option shall be a valid and binding obligation of the Company unless evidenced by a fully executed Option Agreement. Option Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

6.1 Exercise Price. The exercise price for each Option shall be established in the discretion of the Board.

6.2 Exercise Period. Options shall be exercisable at such time or times, or upon such event or events, and subject to such terms, conditions, performance criteria, and restrictions as shall be determined by the Board and set forth in the Option Agreement evidencing such Option; provided, however, that no Option granted to a prospective Employee or prospective Consultant may become exercisable prior to the date on which such Person commences Service with a Participating Company. Subject to the foregoing, unless otherwise specified by the Board in the grant of an Option, any Option granted hereunder shall have a term of ten (10) years from the effective date of grant of the Option.

6.3 Payment of Exercise Price.

(a) Forms of Consideration Authorized. Except as otherwise provided below, payment of the exercise price for the number of shares of Stock being purchased pursuant to any Option shall be made (i) in cash, by check or cash equivalent, (ii) by tender to the Company, or attestation to the ownership, of shares of Stock owned by the Optionee having a Fair Market Value not less than the exercise price, (iii) by the assignment of the proceeds of a sale or loan with respect to some or all of the shares being acquired upon the exercise of the Option (including, without limitation, through an exercise complying with the provisions of Regulation T as promulgated from time to time by the Board of Governors of the Federal Reserve System) (a "Cashless Exercise"), (iv) by such other consideration as may be approved by the Board from time to time to the extent permitted by applicable law, or (v) by any combination thereof. The Board may at any time or from time to time, by approval of or by amendment to the standard form of Option Agreement described in Section 7, or by other means, grant Options which do not permit all of the foregoing forms of consideration to be used in payment of the exercise price or which otherwise restrict one or more forms of consideration.

(b) Limitations on Forms of Consideration.

(i) Tender of Stock. Notwithstanding the foregoing, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock to the extent such tender or attestation would constitute a violation of the provisions of any law, regulation or agreement restricting the redemption of the shares of Stock. Unless otherwise provided by the Board, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock unless such shares either have been owned by the Optionee for more than six (6) months or were not acquired, directly or indirectly, from the Company.

(ii) Cashless Exercise. The Company reserves, at any and all times, the right, in the Company's sole and absolute discretion, to establish, decline to approve or terminate any program or procedures for the exercise of Options by means of a Cashless Exercise.

6.4 Tax Withholding. The Company shall have the right, but not the obligation, to deduct from the shares of Stock issuable upon the exercise of an Option, or to accept from the Optionee the tender of, a number of whole shares of Stock having a Fair Market Value equal to all or any part of the federal, state, local and foreign taxes, if any, required by law to be withheld by the Participating Company Group with respect to such Option or the shares of Stock acquired upon the exercise thereof. Alternatively or in addition, in its discretion, the Company shall have the right to require the Optionee, through payroll withholding, cash payment or otherwise, including by means of a Cashless Exercise, to make adequate provision for any such tax withholding obligations of the Participating Company Group arising in connection with the Option or the shares of Stock acquired upon the exercise thereof. The Company shall have no obligation to deliver shares of Stock until the Participating Company Group's tax withholding obligations have been satisfied by the Optionee.

6.5 Effect of Termination of Service.

(a) Option Exercisability. Subject to earlier termination of the Option as otherwise provided herein and unless otherwise provided by the Board in the grant of an Option and set forth in the Option Agreement, an Option shall be exercisable after an Optionee's termination of Service as follows:

(i) Disability. If the Optionee's Service with the Participating Company Group is terminated because of the Disability of the Optionee, the Option, to the extent unexercised and exercisable on the date on which the Optionee's Service terminated, may be exercised by the Optionee (or the Optionee's guardian or legal representative) at any time prior to the expiration of twelve (12) months after the date on which the Optionee's Service terminated, but in any event no later than the date of expiration of the Option's term as set forth in the Option Agreement evidencing such Option (the "Option Expiration Date").

(ii) Death. If the Optionee's Service with the Participating Company Group is terminated because of the death of the Optionee, the Option, to the extent unexercised and exercisable on the date on which the Optionee's Service terminated, may be exercised by the Optionee's legal representative or other Person who acquired the right to exercise the Option by reason of the Optionee's death at any time prior to the expiration of twelve (12) months after the date on which the Optionee's Service terminated, but in any event no later than the Option Expiration Date. The Optionee's Service shall be deemed to have terminated on account of death if the Optionee dies within three (3) months after the Optionee's termination of Service.

(iii) Termination After Change in Control. If the Optionee's Service with the Participating Company Group ceases as a result of Termination After Change in Control (as defined below), then (1) the Option, to the extent unexercised on the date on which the Optionee's Service terminated, may be exercised by the Optionee (or the Optionee's guardian or legal representative) at any time prior to the expiration of six (6) months after the date on which the Optionee's Service terminated, but in any event no later than the Option Expiration Date, and (2) the exercisability and vesting of the Option shall be accelerated effective as of the date on which the Optionee's Service terminated to such extent, if any, as shall have been determined by the Board, in its discretion, and set forth in the Option Agreement. Notwithstanding the foregoing, if it is determined that the provisions or operation of this Section 6.5(a)(iii) would preclude treatment of a Change in Control as a "pooling-of-interests" for accounting purposes and provided further that in the absence of the preceding sentence such Change in Control would be treated as a "pooling-of-interests" for accounting purposes, then this Section 6.5(a)(iii) shall be void ab initio, and the vesting and exercisability of the Option shall be determined under any other applicable provision of the Plan or the Option Agreement evidencing such Option.

(iv) Other Termination of Service. If the Optionee's Service with the Participating Company Group terminates for any reason, except Disability, death, or Termination After Change in Control, the Option, to the extent unexercised and exercisable by the Optionee on the date on which the Optionee's Service terminated, may be exercised by the Optionee within three (3) months (or such longer period of time as determined by the Board, in its discretion) after the date on which the Optionee's Service terminated, but in any event no later than the Option Expiration Date.

(b) Extension if Exercise Prevented by Law. Notwithstanding the foregoing, if the exercise of an Option within the applicable time periods set forth in Section 6.5(a) is prevented by the provisions of Section 11 below, the Option shall remain exercisable until ninety (90) days after the date the Optionee is notified by the Company that the Option is exercisable, but in any event no later than the Option Expiration Date.

(c) Extension if Optionee Subject to Section 16(b). Notwithstanding the foregoing, if a sale within the applicable time periods set forth in Section 6.5(a) of shares acquired upon the exercise of the Option would subject the Optionee to suit under Section 16(b) of the Exchange Act, the Option shall remain exercisable until the earliest to occur of (i) the thirtieth (30th) day following the date on which a sale of such shares by the Optionee would no longer be subject to such suit, (ii) the two hundred tenth (210th) day after the Optionee's termination of Service, or (iii) the Option Expiration Date.



(d) Certain Definitions. The following terms shall have their respective meanings set forth below:

(i) "Termination After Change in Control" shall mean either of the following events occurring within twelve (12) months after a Change in Control:

(1) termination by the Participating Company Group of the Optionee's Service with the Participating Company Group for any reason other than for Cause (as defined below); or

(2) the Optionee's resignation from all capacities in which the Optionee is then rendering Service to the Participating Company Group within a reasonable period of time following an event constituting a Constructive Termination (as defined below).

Notwithstanding any provision herein to the contrary, Termination After Change in Control shall not include any termination of the Optionee's Service with the Participating Company Group which (1) is for Cause (as defined below); (2) is a result of the Optionee's death or disability; (3) is a result of the Optionee's voluntary termination of Service other than upon a Constructive Termination; or (4) occurs prior to the effectiveness of a Change in Control.

(ii) "Cause" shall mean any of the following: (1) the Optionee's theft, dishonesty, or falsification of any Participating Company documents or records; (2) the Optionee's improper use or disclosure of a Participating Company's confidential or proprietary information; (3) any action by the Optionee which has a detrimental effect on a Participating Company's reputation or business; (4) the Optionee's failure or inability to perform any reasonable assigned duties after written notice from the Participating Company Group of, and a reasonable opportunity to cure, such failure or inability; (5) any material breach by the Optionee of any employment agreement between the Optionee and the Participating Company Group, which breach is not cured pursuant to the terms of such agreement; or (6) the Optionee's conviction (including any plea of guilty or nolo contendere) of any criminal act which impairs the Optionee's ability to perform his or her duties with the Participating Company Group.

(iii) "Constructive Termination" shall mean any one or more of the following:

(1) without the Optionee's express written consent, any assignment to the Optionee of any duties, or any limitation of the Optionee's responsibilities, substantially inconsistent with the Optionee's positions, duties, responsibilities and status with a Participating Company immediately prior to the date of the Change in Control;

(2) without the Optionee's express written consent, the relocation of the principal place of the Optionee's Service to a location that is more than fifty (50) miles from the Optionee's principal place of Service immediately prior to the date of the Change in Control, or the imposition of travel requirements substantially more demanding of the Optionee than such travel requirements existing immediately prior to the date of the Change in Control;

(3) any failure by a Participating Company to pay, or any material reduction by a Participating Company of, (A) the Optionee's base salary in effect immediately prior to the date of the Change in Control, or (B) the Optionee's bonus compensation, if any, in effect immediately prior to the date of the Change in Control (subject to applicable performance requirements with respect to the actual amount of bonus compensation earned by the Optionee); or

(4) any failure by a Participating Company to (A) continue to provide the Optionee with the opportunity to participate, on terms not materially less favorable than those in effect for the benefit of any employee group which customarily includes a Person holding the employment position or a comparable position with the Participating Company then held by the Optionee, in any benefit or compensation plans and programs, including, but not limited to, the Participating Company's life, disability, health, dental, medical, savings, profit sharing, stock purchase and retirement plans, if any, in which the Optionee was participating immediately prior to the date of the Change in Control, or their equivalent, or (B) provide the Optionee with all other fringe benefits (or their equivalent) from time to time in effect for the benefit of any employee group which customarily includes a Person holding the employment position or a comparable position with the Participating Company then held by the Optionee.

## 7. STANDARD FORM OF OPTION AGREEMENT.

7.1 Nonstatutory Stock Option Agreement. Unless otherwise provided by the Board at the time the Option is granted, each Option shall comply with and be subject to the terms and conditions set forth in the appropriate form of Nonstatutory Stock Option Agreement adopted by the Board concurrently with its adoption of the Plan and as amended from time to time.

7.2 Authority to Vary Terms. The Board shall have the authority from time to time to vary the terms of the standard form of Option Agreement described in this Section 7 either in connection with the grant or amendment of an individual Option or in connection with the authorization of a new standard form or forms; provided, however, that the terms and conditions of any such new, revised or amended standard form or forms of Option Agreement are not inconsistent with the terms of the Plan.

## 8. CHANGE IN CONTROL. 8.1 Definitions. The following terms shall have their respective meanings set forth below:

(a) An "Ownership Change Event" shall be deemed to have occurred if any of the following occurs with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the stockholders of the Company of more than fifty percent (50%) of the voting stock of the Company; (ii) a merger or consolidation in which the Company is a party; (iii) the sale, exchange, or transfer of all or substantially all of the assets of the Company; or (iv) a liquidation or dissolution of the Company.

(b) A "Change in Control" shall mean an Ownership Change Event or a series of related Ownership Change Events (collectively, the "Transaction") wherein the stockholders of the Company immediately before the Transaction do not retain immediately after the Transaction, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately before the Transaction, direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding voting stock of the Company or the corporation or corporations to which the assets of the Company were transferred (the "Transferee Corporation(s)"), as the case may be. For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting stock of one or more corporations which, as a result of the Transaction, own the Company or the Transferee Corporation(s), as the case may be, either directly or through one or more subsidiary corporations. The Board shall have the right to determine whether multiple sales or exchanges of the voting stock of the Company or multiple Ownership Change Events are related, and its determination shall be final, binding and conclusive.

8.2 Effect of Change in Control on Options. In the event of a Change in Control, the surviving, continuing, successor, or purchasing corporation or parent corporation thereof, as the case may be (the "Acquiring Corporation"), may either assume the Company's rights and obligations under outstanding Options or substitute for outstanding Options substantially equivalent options for the Acquiring Corporation's stock. In the event the Acquiring Corporation elects not to assume or substitute for outstanding Options in connection with a Change in Control, the exercisability and vesting of each such outstanding Option held by an Optionee whose Service has not terminated prior to such date shall be accelerated effective as of the date ten (10) days prior to the date of the Change in Control to such extent, if any, as shall have been determined by the Board, in its discretion, and set forth in the Option Agreement evidencing such Option. The exercise or vesting of any Option that was permissible solely by reason of this Section 8.2 and the provisions of such Option Agreement shall be conditioned upon the consummation of the Change in Control. Any Options which are neither assumed or substituted for by the Acquiring Corporation in connection with the Change in Control nor exercised as of the date of the Change in Control shall terminate and cease to be outstanding effective as of the date of the Change in Control. Notwithstanding the foregoing, if the corporation the stock of which is subject to the outstanding Options immediately prior to an Ownership Change Event described in Section 8.1(a)(i) constituting a Change in Control is the surviving or continuing corporation and immediately after such Ownership Change Event less than fifty percent (50%) of the total combined voting power of its voting stock is held by another corporation or by other corporations that are members of an affiliated group within the meaning of Section 1504(a) of the Code without regard to the provisions of Section 1504(b) of the Code, the outstanding Options shall not terminate unless the Board otherwise provides in its discretion.

## 9. PROVISION OF INFORMATION.

Each Optionee shall be given access to information concerning the Company equivalent to that information generally made available to the Company's common stockholders.

## 10. TRANSFERABILITY OF OPTIONS.

During the lifetime of the Optionee, an Option shall be exercisable only by the Optionee or the Optionee's guardian or legal representative. No Option shall be assignable or transferable by the Optionee, except by will or by the laws of descent and distribution. Notwithstanding the foregoing, an Option shall be assignable or transferable to the extent permitted by the Board and set forth in the Option Agreement evidencing such Option.

## 11. COMPLIANCE WITH SECURITIES LAW.

The grant of Options and the issuance of shares of Stock upon exercise of Options shall be subject to compliance with all applicable requirements of federal, state or foreign law with respect to such securities. Options may not be exercised if the issuance of shares of Stock upon exercise would constitute a violation of any applicable federal, state or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Stock may then be listed. In addition, no Option may be exercised unless (a) a registration statement under the Securities Act shall at the time of exercise of the Option be in effect with respect to the shares of Stock issuable upon exercise of the Option or (b) in the opinion of legal counsel to the Company, the shares of Stock issuable upon exercise of the Option may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance and sale of any shares of Stock hereunder shall relieve the Company of any liability in respect of the failure to issue or sell such shares of Stock as to which such requisite authority shall not have been obtained. As a condition to the exercise of any Option, the Company may require the Optionee to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company.

## 12. TERMINATION OR AMENDMENT OF PLAN.

The Board may terminate or amend the Plan at any time. However, no termination or amendment of the Plan shall affect any then outstanding Option unless expressly provided by the Board. In any event, no termination or amendment of the Plan may adversely affect any then outstanding Option without the consent of the Optionee, unless such termination or amendment is necessary to comply with any applicable law, regulation or rule.

IN WITNESS WHEREOF, the undersigned Secretary of the Company certifies that the foregoing sets forth the Protein Design Labs, Inc. 1999 Nonstatutory Stock Option Plan as adopted by the Board on August 19, 1999.

Douglas O. Ebersole

Secretary

## PLAN HISTORY

August 19, 1999 Board adopts Plan, with an initial share reserve of 1,000,000 shares. No stockholder approval is required.

August 23, 2000 Plan adjusted for 2:1 stock split. (Note: Section 4.1 is not restated to reflect split.)

December 14, 2000 Board adopts amendments to Section 2.1 of the Plan as to the definitions of the terms "Board" and "Committee".

No stockholder approval is required.

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**AMENDMENT NO. 2 TO AMENDED AND RESTATED AGREEMENT (U.S. and Canada)**

This AMENDMENT NO. 2 TO AMENDED AND RESTATED AGREEMENT (the "Amendment"), is entered into as of February 23, 2001 by and among, on the one hand, HOFFMANN-LA ROCHE INC., a New Jersey corporation having offices at 340 Kingsland Street, Nutley, New Jersey 07110 ("Roche- Nutley") and F. HOFFMANN-LA ROCHE LTD of Basel, Switzerland ("F. Roche") (Roche-Nutley and F.Roche are hereinafter individually and collectively referred to as "Roche") and, on the other hand, PROTEIN DESIGN LABS, INC., a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555, U.S.A. ("PDL") and amends that certain Amended and Restated Agreement dated October 20, 1999, as amended (the "Agreement"). Except as expressly provided herein, capitalized terms shall have the meaning set forth in the Agreement.

## RECITALS

A. WHEREAS, Roche and PDL are parties to the Agreement; and

B. WHEREAS, Roche and PDL have previously amended the Agreement by letter amendment dated June 2, 2000 with respect to certain manufacturing matters.

C. WHEREAS, Roche and PDL desire to amend the Agreement to clarify that asthma is included in the definition of Autoimmune Indications under Section 1.16 of the Agreement.

## AGREEMENT

NOW THEREFORE, the parties agree as follows:

Except as expressly set forth herein, capitalized terms and references to Sections, Exhibits and Articles shall be deemed references to the Agreement.

## 1. AMENDMENT OF AGREEMENT.

Section 1.16 is amended to add "asthma," where indicated by underlining below and to read in full as follows:

1.16 "Autoimmune Indications" means (1) asthma and (2) all indications that involve pathogenic consequences, including tissue injury, produced by autoantibodies or autoreactive T lymphocytes interacting with self epitopes, i.e., autoantigens. Autoimmune Indications shall include, without limitation, psoriasis, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, juvenile rheumatoid arthritis, polymyositis, Type I diabetes, sarcoidosis, Sjogrens syndrome, chronic active non-pathogenic hepatitis, non-infectious uveitis (Behcets), aplastic anemia, regional non-pathogenic enteritis (including ulcerative colitis, Crohn's Disease and inflammatory bowel disease), Kawasaki's disease, post-infectious encephalitis, multiple sclerosis, and tropic spastic paraparesis.

2. NO OTHER CHANGES. On and after the date hereof, each reference in the Agreement to "this Amended and Restated Agreement," "hereunder," "hereof," or words of like import referring to the Agreement, shall mean and be a reference to the Agreement as amended hereby. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment through their duly authorized representatives as of the date first set forth above.

Protein Design Labs, Inc.

F. Hoffmann-La Roche Ltd

By

By

Title

Title

Hoffmann-La Roche Inc.

By

Title



**AMENDMENT NO. 1 TO AMENDED AND RESTATED AGREEMENT (ROW)**

This AMENDMENT NO. 1 TO AMENDED AND RESTATED AGREEMENT (the "Amendment"), is entered into as of February 23, 2001 by and between F. HOFFMANN-LA ROCHE LTD of Basel, Switzerland ("F. Roche") and PROTEIN DESIGN LABS, INC., a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555, U.S.A. ("PDL") and amends that certain Amended and Restated Agreement dated October 20, 1999 (the "Agreement"). Except as expressly provided herein, capitalized terms shall have the meaning set forth in the Agreement.

## RECITALS

A. WHEREAS, F. Roche and PDL are parties to the Agreement; and

B. WHEREAS, F. Roche and PDL desire to amend the Agreement to clarify that asthma is included in the definition of Autoimmune Indications under Section 1.18 of the Agreement.

## AGREEMENT

NOW THEREFORE, the parties agree as follows:

Except as expressly set forth herein, capitalized terms and references to Sections, Exhibits and Articles shall be deemed references to the Agreement.

## 1. AMENDMENT OF AGREEMENT.

Section 1.18 is amended to add "asthma," where indicated by underlining below and to read in full as follows:

1.18 "Autoimmune Indications" means (1) asthma and (2) all indications that involve pathogenic consequences, including tissue injury, produced by autoantibodies or autoreactive T lymphocytes interacting with self epitopes, i.e., autoantigens. Autoimmune Indications shall include, without limitation, psoriasis, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, juvenile rheumatoid arthritis, polymyositis, Type I diabetes, sarcoidosis, Sjogrens syndrome, chronic active non-pathogenic hepatitis, non-infectious uveitis (Behcets), aplastic anemia, regional non-pathogenic enteritis (including ulcerative colitis, Crohn's Disease and inflammatory bowel disease), Kawasaki's disease, post-infectious encephalitis, multiple sclerosis, and tropic spastic paraparesis.

2. NO OTHER CHANGES. On and after the date hereof, each reference in the Agreement to "this Amended and Restated Agreement," "hereunder," "hereof," or words of like import referring to the Agreement, shall mean and be a reference to the Agreement as amended hereby. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment through their duly authorized representatives as of the date first set forth above.

Protein Design Labs, Inc.

F. Hoffmann-La Roche Ltd

By

By

Title

Title

By

Title

**CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

We consent to the incorporation by reference in the Registration Statements Form S-3 Nos. 333-44754 and 333-36708 pertaining to the issuance of shares of Protein Design Labs, Inc.'s common stock and to the issuance of 5.50% Convertible Subordinated Notes and related shares of common stock issuable upon conversion of the notes, respectively, and Form S-8 Nos. 333-44762, 333-87957, 33-65224, 33-50116, 33-50114, and 33-96318 pertaining to the 1993 Employee Stock Purchase Plan, Outside Directors Stock Option Plan, 1991 Stock Option Plan, 1999 Nonstatutory Stock Option Plan and 1999 Stock Option Plan of Protein Design Labs, Inc. of our report dated February 5, 2001, with respect to the consolidated financial statements of Protein Design Labs, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2000.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 29, 2001

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