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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, 2002 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 No.)

34801 Campus Drive  
Fremont, CA 94555  
(Address of principal executive offices)  
Telephone Number (510) 574-1400

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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of Act). Yes ☒ No ☐

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the average bid and ask price of the common stock on June 28, 2002, as reported on the NASDAQ National Market System, was approximately \$930,000,000.

As of January 31, 2003, registrant had outstanding 89,180,845 shares of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive Proxy Statement for the registrant's 2003 Annual Meeting of Stockholders, to be filed with the Commission on or prior to April 30, 2003, are incorporated by reference into Part III of this report.

**This Annual Report (including all of its Parts) for Protein Design Labs, Inc. includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are “forward looking statements” for purposes 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, Nuvion and SMART are registered U.S. trademarks and the PDL logo, HuZAF and ZamyI are trademarks 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 recognized leader in the discovery and development of humanized monoclonal antibodies for the treatment of disease. Our key areas of disease focus include oncology and inflammatory and autoimmune diseases. We have several humanized antibodies in clinical development for inflammatory bowel disease, psoriasis and asthma. We are fully integrated from research through clinical development. We conduct multiple activities in support of the clinical development program, including pre-clinical studies, process development, and antibody manufacturing. We have significant research activities aimed at the discovery of new antibodies that may be useful for the treatment of certain cancers and autoimmune and inflammatory diseases.

Based on the strength of our proprietary platform, the number of antibody programs in development and the flexibility provided by our financial position, our goal is to launch our first proprietary product into the North American market by the end of calendar year 2007. We currently derive revenue primarily from an active out-licensing effort aimed at licensing rights under our fundamental antibody humanization patents to developers of antibody-based therapeutics. To date, we have entered into numerous patent agreements, and the resulting fees and royalty revenues from these licenses have led to a reduced cash burn. We receive royalties on four antibody products launched during the past five years.

## 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 with the aim of marketing our own proprietary drug in North America by 2007. Currently, we derive revenues from three major sources:

- ***Sales of products that we have developed.*** We receive royalties on sales of Zenapax (daclizumab) by our licensee, Hoffmann La-Roche and affiliates (Roche). In addition, we have currently prioritized and are actively managing four humanized antibodies in clinical development, three for indications including inflammatory bowel disease, and the fourth for the potential treatment of asthma. Our partner for the asthma program, GlaxoSmithKline plc (GSK), retains potential rights to further develop and market this antibody on a global basis, providing downstream return to us through a cost- and profit-sharing mechanism. We plan to market or co-promote our three remaining products, if approved, in North America, principally aiming at specialty markets that we believe can be effectively serviced with a relatively small sales force. In addition, we are seeking to out-license marketing rights for some antibodies in some geographical areas to other biotechnology or pharmaceutical companies, and may receive upfront fees and milestone payments and/or research funding, in addition to royalties on any product sales by our licensees.
- ***Patent licensing arrangements with other companies.*** We license our patents covering humanized antibodies in return for license fees, annual maintenance payments and royalties on product sales. Three of the four humanized antibodies currently approved by the FDA in addition to Zenapax are licensed under our patents, Genentech's Herceptin, MedImmune's Synagis and Wyeth's Mylotarg. Combined sales of these products exceeded \$1 billion in 2002. We have patent license or patent rights agreements with numerous other companies for humanized antibodies they are developing, and we will seek to enter into additional agreements on an ongoing basis.
- ***Humanization 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. For 2003, we are re-emphasizing and seeking to expand our humanization services to third parties, and may perform additional services in conjunction with humanization, such as cell-line development necessary for scale-up and future manufacturing of antibodies on a larger scale.

With new management leadership and direction in effect from late 2002, we have undertaken to further improve our capabilities in three areas, in support of our longer range objective of marketing a proprietary drug by 2007. First, in research, we have efforts underway to increase productivity from ongoing discovery efforts, and to identify additional antibody targets, to derive a steady flow of preclinical and clinical antibody candidates. Second, in clinical development, we are defining a clear set of product requirements for each step of the development process, with larger and more experienced teams managing these efforts. Third, we are actively exploring near term commercial opportunities, principally in the antibody area, which might be synergistic with our ongoing development efforts.

## PDL PRODUCTS IN CLINICAL STAGE DEVELOPMENT

The following table summarizes the potential therapeutic applications and development status for our priority clinical product candidates. Not all clinical trials being conducted are listed.

The development and commercialization of our product candidates are subject to numerous risks and uncertainties.

| <b><u>Antibody Product</u></b> | <b><u>Indication(s)</u></b> | <b><u>Status</u></b> |
|--------------------------------|-----------------------------|----------------------|
| Zenapax (daclizumab)           | Kidney transplant rejection | Marketed/Roche       |
|                                | Asthma                      | Phase II             |
|                                | Uveitis                     | Phase II             |
|                                | Multiple sclerosis          | Phase I/II           |
|                                | Ulcerative colitis          | Phase I/II           |
| Nuvion                         | Graft-versus-host disease   | Phase II             |
|                                | Ulcerative colitis          | Phase I              |
| Anti-IL-4                      | Asthma                      | Phase II             |
| HuZAF (Anti-Gamma Interferon)  | Crohn's disease             | Phase II             |
|                                | Psoriasis                   | Phase I/II           |

***Daclizumab.*** The FDA approved daclizumab (Zenapax) in December 1997 for the prevention of kidney transplant rejection. It has since been approved in Europe and a number of 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 renal transplant indication and we receive royalties on Zenapax sales.

Daclizumab 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 certain autoimmune diseases and often following organ transplants. IL-2 stimulates T cells to divide and participate in an immune response. Daclizumab blocks the binding of IL-2 to its receptor on T cells, suppressing an immune response by inhibiting the proliferation of activated T cells.

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

Daclizumab is currently being investigated in a PDL-sponsored Phase II trial in asthma. A Phase II trial of daclizumab to maintain remission following cyclosporine induction in psoriasis was completed in 2002, but did not meet the primary endpoint of the trial. Daclizumab is also under investigation in investigator-sponsored trials for ulcerative colitis, uveitis, multiple sclerosis, type I diabetes, aplastic anemia and the ocular manifestations of Behcet's disease. In the early stage clinical trial for uveitis, an autoimmune disease of the eye, daclizumab was safely administered to patients for one year and was active in controlling the disease in most patients, some of whom have continued to receive the drug for over four years. During 2003, we hope to initiate two Phase II company-sponsored trials, the first in ulcerative colitis and the second in multiple sclerosis. The trials are targeted to begin in the second and fourth quarter respectively.

***Nuvion (visilizumab).*** We are developing this humanized antibody for the treatment of graft-versus-host disease and ulcerative colitis. It binds to the CD3 antigen, a key receptor for

stimulating T cells. Nuvion has completed a Phase I trial for steroid-refractory graft-versus-host disease, in which the response rate was 100%. We are conducting a Phase II trial in steroid-refractory graft-versus-host disease and a Phase I trial in primary graft-versus-host disease. The latter trial has experienced slow enrollment, and primary graft-versus-host disease will not be pursued as a registration strategy. In late 2002, we initiated a Phase I trial investigating Nuvion in severe refractory ulcerative colitis, and hope to complete this trial during 2003.

We conducted a Phase I/II trial of Nuvion in psoriasis. Many patients in this trial experienced adverse events consistent with the cytokine release syndrome, causing flu-like symptoms often associated with certain cytokine-related drugs, that prevented escalation of the dose to a level likely to be consistently effective. Based on these results, we have discontinued development of Nuvion in psoriasis at this time. We have retained worldwide rights to Nuvion, and we plan to seek a partner for development and commercialization outside the U.S. and Canada.

***HuZAF (Anti-Gamma Interferon Antibody).*** This humanized antibody targets gamma interferon, a protein that stimulates several types of white blood cells and that has been shown by academic researchers to play a role in certain autoimmune diseases. We have completed two Phase I trials of anti-gamma interferon in normal volunteers, which indicated that the antibody is well tolerated and has biological activity. We have also completed a Phase I/II trial in patients with Crohn's disease, a form of inflammatory bowel disease. Data from the single dose portion of this trial showed a trend toward a higher rate of response and a greater number of remissions as the dose was increased, although there was a high rate of response in the placebo group. Based on results from this study, we are currently conducting a U.S.-based 175 patient Phase II trial of anti-gamma interferon in Crohn's disease patients examining the same doses as were used in the Phase I/II trial. In addition, we expect to initiate a second Phase II trial in Crohn's disease patients in 2003, which will examine a higher dose as well as a slightly modified treatment protocol, and be conducted in Europe. We currently expect to complete and analyze results from both trials by the end of the first quarter of 2004.

We are also conducting a Phase I/II trial in psoriasis, which will be concluded prior to the end of 2003. In the future, we may initiate clinical trials in other autoimmune diseases, as gamma interferon is implicated in a range of autoimmune diseases including systemic lupus and rheumatoid arthritis. We have retained worldwide rights to HuZAF, although we are now actively seeking a partner for development and commercialization for rights outside the U.S. and Canada.

***Anti-IL-4 Antibody.*** We licensed this humanized antibody, for the potential treatment of asthma and allergy, from SmithKline Beecham, now GlaxoSmithKline plc (GSK), in 1999. The 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. GSK began a Phase I trial of the antibody, which we completed. We have also completed a Phase I/II multiple dose study. We completed patient accrual in a Phase II trial in moderate to severe asthma patients in late 2002 and plan to report data from this trial in May 2003.

Under the agreement with GSK, we conducted and paid for initial clinical trials of the anti-IL-4 antibody. GSK made a milestone payment to us upon the initiation of the ongoing U.S. Phase II trial. At the completion of a specified, larger confirmatory Phase II trial to be conducted by PDL, GSK may choose to pay us an "opt-in" fee to re-acquire marketing rights to this antibody. In that case, we and GSK will share future development costs and profits from any product sales. If GSK elects not to pay this fee, we will have the right to develop and market the antibody in exchange for paying certain milestones and royalties on net sales to GSK.

***Other Programs.*** During 2002 we reported data from a Phase III trial of Zamy1 in patients with relapsed or refractory acute myeloid leukemia. The data showed that the antibody was well tolerated but did not meet the primary efficacy endpoint of the trial. Also in 2002, we increased the

dose of Remitogen in our ongoing Phase II trial in patients with non-Hodgkin's lymphoma. No responses were observed at the higher dosing level. Based on these data, we have discontinued further development of these antibodies and are seeking out-license partners. We have also decided to conduct additional preclinical studies with our anti-IL-12 antibody before considering further clinical development. Recent scientific investigations have suggested that the putative role of IL-12 in autoimmune disease may actually be mediated by a structurally related cytokine, IL-23.

## **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 particular, we are aware of approximately 50 humanized antibodies in clinical trials, including several antibodies addressing large markets. Ten human, humanized or chimeric antibodies have already been approved for marketing by the FDA.

### *Our SMART Antibody Platform*

Our patented SMART antibody platform technology has positioned us as a leader in the development of therapeutic antibodies that overcome many of the problems associated with murine antibodies. Our SMART antibodies are "humanized", 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 humanized antibodies generally have the desired antibody characteristics, including low immunogenicity and a usefully long half-life.

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 typically is about 90% human.

## **OUR RESEARCH**

We are engaged in research activities intended to provide antibody product candidates that we may enter into preclinical and clinical development. These research activities include efforts to discover new targets for antibodies in our core areas of therapeutic focus, namely oncology and autoimmune and inflammatory diseases. We use a variety of sophisticated methods to discover these targets. In May 2001, we entered into an agreement with Exelixis to discover and develop humanized antibodies for the diagnosis, prevention, and treatment of cancer. As a result of this agreement, Exelixis has provided a number of potential antibody targets in oncology that we and Exelixis are currently evaluating further. In addition, we have in-licensed rights to targets or antibodies from academic institutions or other biotechnology or pharmaceutical companies, and we may in-license rights to additional targets or antibodies in the future.

We also are engaged in efforts to validate targets that result from our own discovery efforts, our collaborations and in-licensing, which include evaluating antibodies against these targets in a number of different *in vitro* and *in vivo* assays. The purpose of these validation activities is to determine which antibodies have sufficiently potent biological activities for us to humanize them using our proprietary technology and subsequently enter them into pre-clinical testing and clinical development.

We conduct additional research activities intended to improve the general characteristics of antibodies that are used as human therapeutics. As examples, we are examining factors which influence the interaction of antibodies with other components of the human immune system and factors which influence the duration of circulation of antibodies in man, with the aim of engineering antibodies with even more favorable biological characteristics.

## **OUR ANTIBODY MANUFACTURING**

Antibodies for use as human therapeutics are generally manufactured through the culture of mammalian cell lines, which produce the antibodies. We maintain facilities and personnel for the

production and characterization of such cell lines. We also engage in process development activities intended to improve the productivity and other characteristics of such cell lines.

We manufacture antibodies for use as clinical trial material in a 74,000 square foot manufacturing facility in Plymouth, Minnesota, which we have leased since 1992. We have manufactured Nuvion, our anti-gamma interferon antibody, Remitogen, and other antibodies in that facility. We have recently renovated this facility to make it potentially able to be licensed as a commercial manufacturing facility. We expect to complete validation of the renovated facility and to resume manufacturing of antibodies in the first half of 2003. Daclizumab is currently manufactured by Roche and the anti-IL-4 antibody by GlaxoSmithKline. Under certain circumstances we have the right to manufacture daclizumab and we may acquire rights to manufacture the anti-IL4 antibody.

We have begun construction of a new commercial manufacturing facility in Brooklyn Park, Minnesota. Physical construction is expected to be completed in 2004, followed by validation and start up activities. We currently expect to be able to produce antibodies for commercial sale in this facility in 2007. Antibodies currently in our clinical-stage pipeline which may be made in this facility include Nuvion, anti-gamma interferon, daclizumab, and anti-IL-4. We intend to seek manufacturing rights for additional antibodies from collaborative or humanization partners.

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

### *Collaborative and Product Licensing 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 daclizumab (marketed for prevention of kidney transplant rejection as Zenapax). Under these agreements, Roche had 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 daclizumab for the potential treatment of autoimmune diseases, later amended to include asthma. 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 daclizumab in potential new autoimmune indications and will pay for these activities from our share of revenues. In Europe and certain other countries, Roche may choose to market daclizumab in autoimmune indications. In this case, we will receive a substantial portion of daclizumab revenue from these indications. For countries and indications for which Roche elects not to market, we will receive an exclusive license to market daclizumab and pay Roche a small royalty.

**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 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.

We have completed Phase I and Phase I/II clinical trials for the humanized anti-IL-4 antibody and are conducting 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, larger 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.

***Exelixis, Inc.*** In May 2001, we signed a collaborative agreement with Exelixis to discover and develop humanized antibodies for the diagnosis, prevention and treatment of cancer. We agreed to provide Exelixis with \$4.0 million in annual research funding for two or more years, and we purchased a \$30.0 million five year note convertible at our option anytime after the first year of the collaboration into Exelixis common stock. We received an exclusive, worldwide license to develop antibodies against certain targets identified by Exelixis that are involved in cell growth, cell death and proliferation. Exelixis has the right to co-fund development of antibodies resulting from the collaboration. For antibody products we develop that Exelixis elects not to co-fund, we have agreed to make specified milestone payments and royalty payments on any product sales. We have notified Exelixis that we will not extend the research funding beyond the initial two year term.

***Igeneon AG.*** In July 2002, we signed an agreement with Igeneon AG, a European biotechnology company focused on cancer immunotherapies, for exclusive worldwide rights to develop and market HuABL364, a humanized antibody against the Lewis Y antigen. We received a licensing fee and milestone payments and may receive additional milestone payments and royalties on any product sales generated by the antibody.

#### *Humanization and Patent Licensing Arrangements*

We have entered into patent license agreements with numerous other companies that are independently developing humanized antibodies, including Biogen, Celltech, Chugai, Elan Pharmaceuticals, Genentech, GSK, IDEC Pharmaceuticals, Medarex, MedImmune, Merck KGaA, Sankyo, and Wyeth. In each license agreement, we granted a worldwide, exclusive or nonexclusive license under our patents to the other company for antibodies to a specific target antigen. In general, we received an upfront licensing 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, we have entered into patent rights agreements with Celltech, Genentech, GSK, MedImmune, Millennium Pharmaceuticals and Tanox. Under these agreements, licensees currently purchase a research license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of target antigens. Our patent rights agreements with Celltech and Genentech also give us rights to purchase licenses under certain of their patents. We have also entered into agreements to use our technology to humanize antibodies for other companies, including Ajinomoto, Fujisawa Pharmaceuticals, Eli Lilly, InterMune Pharmaceuticals, Mochida Pharmaceutical, Progenics Pharmaceuticals, Teijin, Wyeth and Yamanouchi Pharmaceutical. In general, we received an upfront licensing and the right to receive additional payments upon the achievement of certain milestones and royalties on any product sales.

#### **ACQUISITION OF EOS BIOTECHNOLOGY, INC.**

In February 2003, we announced the signing of a definitive merger agreement with Eos Biotechnology, Inc., a South San Francisco-based antibody discovery company, for approximately 4.3 million shares of our common stock. The acquisition is expected to close early in the second

quarter of 2003. In conjunction with the merger, we expect to record a charge related to acquired in-process research and development. We will report the purchase accounting effects of the merger in our financial results for the period in which the transaction closes. Upon closing, this acquisition will expand our research personnel and add new capabilities in antibody target identification and validation, particularly in oncology. We will also obtain two pre-clinical antibody product candidates, one of which is expected to initiate clinical investigation for potential treatment of solid tumors in the first half of 2003, and the second, in early 2004.

## **MANUFACTURING AND FACILITIES**

We own two buildings comprising approximately 92,000 square feet of research and development and general office space in Fremont, California. In addition, we lease approximately 22,000 square feet of general office space in Fremont, California, which lease term will expire on February 28, 2006. In October 2002, we leased 1,600 square feet of general office space in Menlo Park, California. The lease term will expire on March 31, 2005. We plan to obtain additional research and development and general office space in the future and may lease or acquire additional space as required.

In Plymouth, Minnesota, we lease approximately 74,000 square feet of manufacturing, laboratory and office space. The lease term will expire on February 29, 2009, subject to our options to extend the lease for an additional five-year term. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and we have begun to build a new commercial manufacturing plant on this property.

In Somerville, New Jersey we lease approximately 6,000 square feet of general office space. The lease term will expire on October 31, 2005.

In Paris, France, we lease approximately 1,000 square feet of general office space. The lease term will expire on March 31, 2004.

Of the products that we currently have in clinical development, Roche is responsible for manufacturing Zenapax and GlaxoSmithKline is responsible for manufacturing the humanized anti-IL-4 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 facilities 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. Additionally, 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.

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 seventeen 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 have appealed 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.

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 and we have filed our response with the European Patent Office. Oral hearings are scheduled to take place in October 2003. 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 received a decision from the Japanese Opposition Board in March 2001, supporting one aspect of the position of the opponents, and we filed a response in September 2001. In April 2002, the examiner issued a further Office Action maintaining the earlier decision of the Opposition Board, to which we filed an additional response in May 2002. We now await a final decision from the examiner.

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.

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, 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 approval to 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 murine, chimeric, 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 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.

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, 2002, we had 397 full-time employees. Of the total, 108 employees were engaged in research and process development, 54 in quality assurance and compliance, 90 in clinical and regulatory, 71 in manufacturing and 74 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.

## **AVAILABLE INFORMATION**

We file electronically with the Securities and Exchange Commission (or SEC) our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is <http://www.sec.gov>.

You may obtain a free copy of our most recent annual report on Form 10-K, quarterly report on Form 10-Q and proxy statement on our website on the World Wide Web at <http://www.pdl.com>. Additionally, you may obtain a free copy of these filings, as well as any other reports or filings we have filed with the SEC, by contacting the Corporate Communications Department at our corporate offices by calling (510) 574-1406 or by sending an e-mail message to [cc@pdl.com](mailto:cc@pdl.com). You can direct requests for literature to our Corporate Communications Department or on our website.

### **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.**

In general, our expenses have exceeded revenues. As of December 31, 2002, we had an accumulated deficit of approximately \$90.5 million. We expect our expenses to 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 research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our 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:

- some of our earlier stage potential products move into later stage clinical development
- 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 agreements with third party business partners, 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 receivable due to credits for prior payments to us
- the timing of royalty reports, some of which are required quarterly and others semi-annually
- our ability to successfully defend and enforce our patents.

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.

License and 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 agreements with third party business partners. Revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

Our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, including clinical trial expenses as well as payments owed by us and to us under collaborative agreements for reimbursement of expenses and which are recorded under our policy during the quarter in which such expenses are reported to us or to our partners and agreed to by us or our partners.

In addition, our expenses or other operating results may fluctuate due to the accounting treatment of securities we own or may purchase or securities we have issued or may issue. In May 2002, we entered into an agreement with our Chairman of the Board under which vesting of his stock options may accelerate in certain events, and such acceleration would trigger an accounting expense. In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately held drug discovery company, in exchange for shares of Signature convertible preferred stock. Since the shares we received are not publicly traded, the value of the shares is difficult to estimate. As of December 31, 2002, we estimated that the fair value of our shares owned and to be received in early 2003 had declined to \$150,000 and that an impairment of our investment had occurred and that such impairment was other than temporary. Accordingly, we recorded an impairment charge of \$1.4 million in December 2002. The amount of the charge was based on the difference between the estimated value as determined by our management and our original cost basis in the shares. If we deem the estimated fair value of the shares of Signature

further impaired at the end of any future period, we may incur an additional impairment charge with respect to these shares.

In addition, we hold a \$30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the value of the Exelixis stock in our financial statements. Such a requirement could cause changes in the Exelixis stock price to contribute to fluctuation of our operating results 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 have appealed this decision. 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 and we have filed our response with the European Patent Office. Oral hearings are scheduled to take place in October 2003. Also, three opposition statements were filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998. We received a decision from the Japanese Opposition Board in March 2001, supporting one aspect of the position of the opponents, and we filed a response in September 2001. In April 2002, the examiner issued a further Office Action maintaining the earlier decision of the Opposition Board, to which we filed an additional response in May 2002. We now await a final decision from the examiner. If the examiner maintains her earlier decision, we will have the opportunity to appeal to the Tokyo High Court. The patent will remain valid and enforceable during this appeal process. If this appeal is unsuccessful, we will then have an opportunity to appeal to the Japanese Supreme Court.

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 has appealed that decision. Also, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. In addition, Celltech has a third divisional application 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 Celltech's second European patent will be modified or revoked in any future opposition proceedings, or whether it will be able to obtain the

grant of a patent from the pending divisional 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 humanized 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, Centocor, Inc., under this patent. If our processes were found to be 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.

We are also aware of issued patents that could apply to one or more of our specific products. For example, a U.S. patent recently issued to Advanced Biotherapy, Inc. has claims to the use of anti-gamma interferon antibodies to treat certain autoimmune diseases. The claims issued to Advanced Biotherapy, Inc., however, do not cover treatment of either Crohn's disease or psoriasis, the two indications currently being investigated in our SMART Anti-Gamma Interferon Antibody clinical trials. However, a European patent issued to Genentech in 1998 does have claims to the use of anti-gamma interferon inhibitors, including antibodies, for treatment of inflammatory bowel disease, including Crohn's disease. Additional examples include an issued U.S. patent to Schering Corporation that may cover our humanized anti-IL-4 antibody, issued U.S. and European patents to Genetics Institute (now a wholly-owned subsidiary of Wyeth) that may cover our SMART Anti-IL-12 Antibody, and a recently issued U.S. patent to Genentech claiming humanized antibodies with certain framework region substitutions that may cover some of our antibodies in development. As a result, we might be required to obtain licenses from others. 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 we may not be able to market our products at all.

**If our research efforts are not successful, we may not be able to effectively develop new products.**

We are engaged in research activities intended to identify antibody product candidates that we may enter into clinical development. These research activities include efforts to discover and validate new targets for antibodies in our areas of therapeutic focus. We obtain new targets through our

own drug discovery efforts and through in-licensing targets from institutions or other biotechnology or pharmaceutical companies. Our success in identifying new antibody product candidates depends upon our ability to discover and validate new targets, either through our own research efforts, or through in-licensing or collaborative arrangements. In order to increase the possibilities of identifying antibodies with a reasonable chance for success in clinical studies, part of our business strategy is to identify a number of potential targets. If we are unsuccessful in our research efforts to identify and obtain rights to new targets, our ability to develop new products could be harmed.

**Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we cannot accurately predict the timing and level of such expenses**

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products, and the majority of our expenses are to support these activities. The completion of clinical trials often depends significantly upon the rate of patient enrollment, and our expense levels will vary depending upon the rate of enrollment. In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and is difficult to predict. The expenses associated with each phase of development depend upon the design of the trial. The design of each phase of trials depends in part upon results of prior phases, and additional trials may be needed at each phase. As a result the expense associated with future phases can not be predicted in advance. Further, we may decide to terminate or suspend ongoing trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to unacceptable risks. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future.

**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 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. Additionally, regulatory review of our clinical trial protocols may cause us in some cases to delay or abandon our planned clinical trials. 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.

Earlier clinical trials such as Phase I and II trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed.

Larger or later stage clinical trials may not produce the same results as earlier 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. As an example, in a Phase I trial, Remitogen produced partial clinical responses in several B-cell lymphoma patients. Partial, preliminary results in a Phase II trial of Remitogen, however, did not show a similar response rate. Consequently, the

dosing regimen was amended in that trial to attempt to determine an effective dosing regimen. However, enrollment with this dosing regimen was progressing slowly. Therefore, in November 2002, we decided to terminate this study and we currently do not intend to conduct further clinical trials in this indication.

Even when a drug candidate shows evidence 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 a Phase I/II trial for psoriasis, it has also caused a level of side effects that would be unacceptable in this patient population. Enrollment in this trial currently is suspended and our current plan is not to continue this trial and not to further develop Nuvion for psoriasis.

**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 pursued 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. 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.

**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 agreements with pharmaceutical and other companies to develop, manufacture and market certain of our potential products. In some cases, we are relying on our 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 agreements can generally be terminated by our partners on short notice. A partner 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 partner continues to contribute 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 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 partner's own financial, competitive, marketing and strategic considerations. Such considerations include:

- the commitment of each partner's management to the continued development of the licensed products or technology
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts, and
- the relative advantages of alternative products or technology being marketed or developed by each partner 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 relationships and the willingness of our existing partners 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 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 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 could largely depend on these partners' marketing and promotion efforts.

**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. We are currently conducting a search for a Chief Financial Officer. If we are unsuccessful in filling this position or retaining qualified personnel, our business could be impaired.

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

Of the products that we currently have in clinical development, Hoffmann-La Roche Inc. and its affiliates (Roche) are responsible for manufacturing Zenapax and GlaxoSmithKline is responsible for manufacturing the humanized anti-IL-4 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 and/or the inability to produce sufficient quantities of such products in a commercially viable manner. 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 currently improving our existing manufacturing plant in order to manufacture initial commercial supplies of certain products. Our ability to file for, and to obtain, regulatory approvals for such products, as well as the timing of such filings, will depend on our ability to successfully improve our existing 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 our products.

In addition, we have begun construction of a new commercial manufacturing plant. As 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. In May 2001, Novartis acquired a significant interest in Roche. We cannot predict the impact, if any, that this relationship may have on Roche's efforts to market Zenapax.

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

All of our products in development are subject to risks associated with applicable government regulations. 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 non-clinical 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.

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process 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 approval to 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, regulatory 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 regulatory 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.

**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 unfavorable 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.

**Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position and results of operations.**

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq Stock Market rules, are creating uncertainty for companies such as ours and insurance costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

**Prior and future acquisitions could be difficult to integrate, disrupt our business, dilute stockholder value and harm our operating results.**

Early in the second quarter of 2003, we expect to complete the acquisition of a privately-owned company, EOS Biotechnology, Inc. We expect to continue to review opportunities to acquire other businesses, products or technologies that would complement our current products, expand the breadth of our markets or enhance our technical capabilities, or that may otherwise offer growth opportunities. In our acquisition of EOS, we will issue stock as all of the consideration, and we may be obligated to release additional shares from escrow. The issuance of stock in these and any future transactions has or would dilute stockholders' percentage ownership.

Other risks associated with acquiring the operations of other companies include:

- problems assimilating the purchased operations, technologies or products;
- unanticipated costs associated with the acquisition;
- diversion of management's attention from our existing business;
- the potential loss of key collaborators of the acquired companies;
- lack of synergy, or the inability to realize expected synergies, resulting from the acquisition;
- adverse effects on existing relationships with other third party business partners;
- risks associated with entering markets in which we have no or limited prior experience; and
- potential loss of key employees of acquired organizations.

We cannot assure that we would be successful in overcoming problems encountered in connection with such acquisitions, and our inability to do so could significantly harm our business. In addition, to the extent that the economic benefits associated with such acquisitions diminish in the future, we may be required to record write downs of goodwill, intangible assets or other assets associated with such acquisitions.

## **ITEM 2. PROPERTIES**

We own two buildings comprising approximately 92,000 square feet of research and development and general office space in Fremont, California. In addition, we lease approximately 22,000 square feet of general office space in Fremont, California. Our lease term will expire on February 28,

2006. In October 2002, we leased approximately 1,600 square feet of general office space in Menlo Park, California. Our lease term will expire on March 31, 2005. We plan to obtain additional research and development and general office space in the future and may lease or acquire additional space as required.

In Plymouth, Minnesota, we lease approximately 74,000 square feet of manufacturing, laboratory and office space. Our lease term will expire on February 29, 2009, subject to our option to extend the leases for an additional five year term. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and we have begun to build a new commercial manufacturing plant on this property.

In Somerville, New Jersey, we lease approximately 6,000 square feet of general office space. Our lease term will expire on October 31, 2005.

In Paris, France, we lease approximately 1,000 square feet of general office space. Our lease term will expire on March 31, 2004.

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 have appealed this decision. 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 and we have filed our response to the European Patent Office. Oral hearings are scheduled to take place in October 2003. 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 received a decision from the Japanese Opposition Board in March 2001, supporting one aspect of the position of the opponents, and we filed a response in September 2001. In April 2002, the examiner issued a further Office Action maintaining the earlier decision of the Opposition Board, to which we filed an additional response in May 2002. We now await a final decision from the examiner. If the examiner maintains her earlier decision, we will have the opportunity to appeal to the Tokyo High Court. The patent will remain valid and enforceable during this appeal process. If this appeal is unsuccessful, we will then have an opportunity to appeal to the Japanese Supreme Court.

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 SECURITY HOLDERS**

**Not applicable.**

## PART II

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

#### MARKET INFORMATION AND DIVIDEND POLICY (\$)

| <u>2001</u>    | <u>High</u> | <u>Low</u> |
|----------------|-------------|------------|
| First Quarter  | \$42.25     | \$17.38    |
| Second Quarter | 45.20       | 17.47      |
| Third Quarter  | 42.09       | 20.48      |
| Fourth Quarter | 40.56       | 23.43      |
| <br>           |             |            |
| <u>2002</u>    |             |            |
| First Quarter  | \$31.48     | \$14.93    |
| Second Quarter | 20.02       | 8.95       |
| Third Quarter  | 13.54       | 8.30       |
| Fourth Quarter | 9.82        | 7.43       |

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, 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 October 9, 2001, 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 September 18, 2001. Our stock began trading on a split-adjusted basis as of October 10, 2001.

As of December 31, 2002, we had approximately 134 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 data)

|  | YEARS ENDED DECEMBER 31, |                 |                |                    |                   |
|--|--------------------------|-----------------|----------------|--------------------|-------------------|
|  | 2002                     | 2001            | 2000           | 1999               | 1998              |
| CONSOLIDATED STATEMENTS OF OPERATIONS DATA:                |                          |                 |                |                    |                   |
| Revenues:  |                          |                 |                |                    |                   |
| Royalties  | \$ 40,421                | \$ 30,604       | \$ 19,189      | \$ 11,378          | \$ 822            |
| License and other  | <u>5,952</u>             | <u>13,796</u>   | <u>21,220</u>  | <u>16,762</u>      | <u>20,748</u>     |
| Total revenues   | 46,373                   | 44,400          | 40,409         | 28,140             | 21,570            |
| Costs and expenses:  |                          |                 |                |                    |                   |
| Research and development                                   | 57,978                   | 52,163          | 42,330         | 36,090             | 31,645            |
| General and administrative                                 | <u>19,093</u>            | <u>15,724</u>   | <u>12,109</u>  | <u>9,842</u>       | <u>8,685</u>      |
| Total costs and expenses                                   | 77,071                   | 67,887          | 54,439         | 45,932             | 40,330            |
| Operating loss   | (30,698)                 | (23,487)        | (14,030)       | (17,792)           | (18,760)          |
| Interest income  | 25,978                   | 35,135          | 22,647         | 7,614              | 9,258             |
| Interest expense   | (8,426)                  | (8,989)         | (7,965)        | (155)              | --                |
| Impairment loss on investment (1)                          | <u>(1,366)</u>           | <u>--</u>       | <u>--</u>      | <u>--</u>          | <u>--</u>         |
| Income (loss) before income taxes                          | (14,512)                 | 2,659           | 652            | (10,333)           | (9,502)           |
| Provision for income taxes                                 | <u>42</u>                | <u>12</u>       | <u>5</u>       | <u>--</u>          | <u>--</u>         |
| Net income (loss)  | <u>\$ (14,554)</u>       | <u>\$ 2,647</u> | <u>\$ 647</u>  | <u>\$ (10,333)</u> | <u>\$ (9,502)</u> |
| Net income (loss) per share:                               |                          |                 |                |                    |                   |
| Basic  | <u>\$ (0.16)</u>         | <u>\$ 0.03</u>  | <u>\$ 0.01</u> | <u>\$ (0.14)</u>   | <u>\$ (0.13)</u>  |
| Diluted  | <u>\$ (0.16)</u>         | <u>\$ 0.03</u>  | <u>\$ 0.01</u> | <u>\$ (0.14)</u>   | <u>\$ (0.13)</u>  |
| Shares used in computation of net income (loss) per share: |                          |                 |                |                    |                   |
| Basic  | <u>88,865</u>            | <u>87,624</u>   | <u>80,904</u>  | <u>74,792</u>      | <u>74,100</u>     |
| Diluted  | <u>88,865</u>            | <u>92,889</u>   | <u>88,562</u>  | <u>74,792</u>      | <u>74,100</u>     |

|  | DECEMBER 31, |           |           |           |           |
|--|--------------|-----------|-----------|-----------|-----------|
|  | 2002         | 2001      | 2000      | 1999      | 1998      |
| CONSOLIDATED BALANCE SHEET DATA:                 |              |           |           |           |           |
| Cash, cash equivalents and investments           | \$606,410    | \$650,315 | \$661,173 | \$137,237 | \$143,439 |
| Working capital                                  | 599,215      | 641,896   | 651,641   | 22,669    | 82,394    |
| Total assets                                     | 717,818      | 729,898   | 704,980   | 182,551   | 171,850   |
| Long-term debt obligations, less current portion | 158,426      | 158,892   | 159,324   | 9,724     | --        |
| Accumulated deficit                              | (90,477)     | (75,923)  | (78,570)  | (79,217)  | (68,884)  |
| Total stockholders' equity                       | 544,766      | 558,443   | 534,144   | 164,743   | 162,496   |

- (1) Represents a non-cash charge related to an investment write down. For a description of this investment write down, see Note 1 to the Financial Statements.

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

*This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes 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 licensing or collaborative arrangements, 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 report. All forward-looking statements and reasons why results may differ included in this 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.*

### OVERVIEW

In general, we have a history of operating losses and may not achieve sustained profitability. As of December 31, 2002, we had an accumulated deficit of approximately \$90.5 million. Our expenses will increase because of the extensive resource commitments required to identify and develop antibody candidates, achieve regulatory approval and market potential products for commercial success for any individual product. Over the next several years, we expect to incur substantial additional expenses as we continue to identify, develop and manufacture our potential products, invest in research and improve and expand our development, manufacturing, marketing and sales capabilities. In February 2003, we announced the signing of a definitive merger agreement with Eos Biotechnology, Inc., a privately held South San Francisco-based antibody discovery company, for 4.3 million shares of our common stock. The acquisition is expected to close early in the second quarter of 2003. The Eos acquisition allows us to expand our research personnel and add new capabilities in antibody target identification and validation, particularly in oncology. We will also have obtained two pre-clinical antibody product candidates, one of which is expected to begin clinical development for potential treatment of solid tumors in the first half of 2003, and the second, in early 2004. In conjunction with the merger, we expect to record a charge related to acquired in-process research and development. We will report the purchase accounting effects of the merger in our financial results for the period in which the transaction closes. 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 do not expect to achieve sustained profitability until we are able to market and sell products.

Our commitment of resources to research and the continued development of our products will require significant additional funds. 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 rights 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 in the period reported to us, and our ability to successfully defend and enforce our patents. 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 recognized by us in our first and second quarters than in other quarters. The seasonality of Synagis sales could contribute to future fluctuation of our royalty revenues from quarter to quarter.

License and other revenue may also be unpredictable and may fluctuate due to the timing of payments of upfront 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 clinical trial expenses as well as 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.

## CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

### **Revenue Recognition**

We currently recognize three types of revenues resulting from the licensing and use of our technology, and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use in drug development and production. Revenues, and their respective treatment for financial reporting purposes, are as follows:

#### *Upfront and License Maintenance Fees*

We generally recognize revenue from upfront fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the

arrangement. Revenues recognized from upfront fees typically relate to patent license and patent rights agreements.

- Under patent license agreements, the licensee typically obtains a non-exclusive license to our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements.
- Under patent rights agreements, licensees currently purchase a research patent license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. All of the research is performed by the licensee, and therefore, upon delivery of the patent rights agreement, the earnings process is complete and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses. Subsequent to execution of the agreement, the licensee has the right to purchase patent licenses to certain designated targets, for which the licensee pays separate consideration at a later date. Such consideration is recognized upon exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.
- Under our humanization agreements, at times referred to in our previous filings as research and development agreements, the licensee typically pays an upfront fee for us to “humanize” an antibody. These upfront fees are recognized on a percent completion basis, as the humanization work is performed, which is typically over three to six months.
- Under patent license agreements and humanization agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

#### *Milestone Payments*

Certain agreements include milestone payments which are recognized as revenue when earned as part of a multi-element arrangement. Each element of the contract represents a separate earnings process and as such we recognize milestone amounts when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement and when payment is reasonably assured. Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones include delivery of a humanized antibody meeting a certain binding affinity and, at the customer’s election, delivery of a cell line meeting certain criteria described in the original agreement. We recognize these milestones when we have no further performance obligations with respect to that milestone and the funding party confirms that the milestone stipulated in the agreement has been met.
- Patent license agreements and humanization agreements sometimes require our customers to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the customer’s product. Because we have no obligations with

respect to any of this activity, we record these milestone payments as revenue when received and we have confirmed that the milestone has been achieved.

- We may also receive certain milestone payments in connection with licensing technology to or from our partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when we or they achieve certain levels of development with respect to the licensed technology. These fees are recognized when we have no further performance obligations with respect to the applicable milestone and it is confirmed that the milestone stipulated in the agreement has been met.

### *Royalties*

Under some of our agreements, we also receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from such licensees' approximately one quarter in arrears; that is, generally at the end of the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we have adopted an accounting policy of recording the royalty revenue in the quarter it is reported to us (i.e., generally revenue is recognized one quarter following the quarter in which sales occurred).

### **Clinical Trial Expenses**

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the patients continued participation in the trial. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable 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.

### **Valuation of Financial Instruments**

We invest our excess cash balances primarily in short-term and long-term marketable debt securities. These securities are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Estimated fair value is based upon quoted market prices for these or similar instruments. All available-for-sale securities in our portfolio have readily determinable market prices.

In determining if and when a decline in market value below amortized cost is other-than-temporary, we evaluate the market conditions, offering prices, trends of earnings, price multiples, and other key measures for our investments in marketable debt securities. If such a decline in value is deemed to be other-than-temporary, we recognize an impairment loss in the current period operating results to the extent of the decline.

Historically, we have not recognized any impairment losses on our available-for-sale securities, nor have we realized gains or losses on the sale of available-for-sale securities, as all securities liquidated have been held to maturity.

### Cost Method Investments

In determining if and when a cost method investment's decline in estimated fair value below cost is other-than-temporary, we evaluate the general market conditions, the operating results and business prospects of our investees, and other key considerations. When such a decline in value is deemed to be other-than-temporary, we recognize an impairment loss on the investment in the current period operating results to the extent of the decline.

## RESULTS OF OPERATIONS

*Years ended December 31, 2002, 2001 and 2000*

| (In thousands) | Years Ended December 31, |             |             | Annual Percent Change |                    |
|----------------|--------------------------|-------------|-------------|-----------------------|--------------------|
|                | <u>2002</u>              | <u>2001</u> | <u>2000</u> | <u>2002 / 2001</u>    | <u>2001 / 2000</u> |
| Total Revenues | \$ 46,373                | \$ 44,400   | \$ 40,409   | 4%                    | 10%                |

### Total Revenues

The Company's total revenues for 2002 were \$46.4 million, a 4% increase from 2001 primarily due to higher royalties, partially offset by lower license and other income. Total revenues for 2001 were \$44.4 million, a 10% increase from 2000 primarily due to higher royalties, partially offset by lower license and other income. These revenue changes are further discussed below.

| (In thousands)    | Years Ended December 31, |             |             | Annual Percent Change |                    |
|-------------------|--------------------------|-------------|-------------|-----------------------|--------------------|
|                   | <u>2002</u>              | <u>2001</u> | <u>2000</u> | <u>2002 / 2001</u>    | <u>2001 / 2000</u> |
| <b>Revenues</b>   |                          |             |             |                       |                    |
| Royalties         | \$ 40,421                | \$ 30,604   | \$ 19,189   | 32%                   | 59%                |
| License and other | 5,952                    | 13,796      | 21,220      | (57%)                 | (35%)              |

### Royalties

Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth were \$40.4 million in 2002, an increase of 32% from 2001. Royalty revenue was \$30.6 million in 2001, an increase of 59% from 2000. The increase in 2002 was primarily due to higher third-party sales of Synagis reported by MedImmune and Herceptin reported by Genentech. Royalty revenues from MedImmune and Genentech accounted for 47% and 43% of our royalty revenues in 2002, respectively. The increase in 2001 was also due to higher third-party sales of Synagis as reported by MedImmune and Herceptin as reported by Genentech. Royalty revenues from MedImmune and Genentech accounted for 48% and 39% of our royalty revenues in 2001, respectively.

We expect that in 2003, the increase in royalty revenues will be at a lower rate than 2002. We expect quarterly fluctuations in royalty revenues due to the seasonality of sales of Synagis.

### License and Other Revenues

License and other revenues were \$6.0 million in 2002, a decrease of 57% from 2001. License and other revenues were \$13.8 million in 2001, a decrease of 35% from 2000. License and other revenues recognized primarily consist of upfront patent licensing and patent rights fees, milestones, amortization of upfront fees associated with humanization agreements and license maintenance fees. The decrease in 2002 was primarily due to the fact that we entered into fewer patent licensing,

patent rights and humanization agreements in 2002 as compared with 2001 and due to greater milestone and humanization revenue in 2001 as compared with 2002. In 2002, we entered into one patent rights and one patent licensing agreement, as compared with three patent rights agreements in 2001. In addition, in 2001, we recognized over \$7.0 million in milestone and humanization revenue, with no such comparable revenue in 2002.

The decrease in 2001 was primarily due to the recognition of less revenue under patent licensing, patent rights and research and development funding from a third party that expired in November 2000.

We expect quarterly fluctuations in license and other revenues depending on the number of new contract arrangements and milestones achieved by our licensees.

| (In thousands)             | Years Ended December 31, |               |               | Annual Percent Change |                    |
|----------------------------|--------------------------|---------------|---------------|-----------------------|--------------------|
|                            | <u>2002</u>              | <u>2001</u>   | <u>2000</u>   | <u>2002 / 2001</u>    | <u>2001 / 2000</u> |
| <b>Costs and Expenses</b>  |                          |               |               |                       |                    |
| Research and development   | \$ 57,978                | \$ 52,163     | \$ 42,330     | 11%                   | 23%                |
| General and administrative | <u>19,093</u>            | <u>15,724</u> | <u>12,109</u> | 21%                   | 30%                |
| Total costs and expenses   | \$ 77,071                | \$ 67,887     | \$ 54,439     | 14%                   | 25%                |

### Research and Development Expenses

Research and development expenses in 2002 were \$58.0 million, an increase of 11% from 2001. Research and development expenses in 2001 were \$52.2 million, an increase of 23% from 2000. Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. The increase in 2002 was primarily due to an increase in research and development personnel headcount of approximately 38 employees and associated costs of approximately \$3.4 million, higher research and development funding provided to Exelixis of \$1.7 million reflecting a full year of funding in 2002 compared to a partial year of funding in 2001 and preclinical studies of \$0.8 million. The increase in 2001 was primarily related to an increase in research and development personnel headcount of approximately 39 employees and associated costs of approximately \$3.8 million, higher research and development funding provided to Exelixis of \$2.3 million compared to no such funding in 2000 and increased clinical trial expenses related to the expansion of clinical development programs of \$2.1 million, offset in part by lower research and development reimbursement funding of \$2.6 million and contract manufacturing costs associated with the humanized anti-IL-4 antibody of \$2.5 million.

We expect our research and development expenses will increase further as we invest in manufacturing, advance our product candidates' progress into later stages of development and add new product candidates. More specifically, the increase is expected to be related primarily to expanded clinical trial activity, including associated direct scale-up and manufacturing expenses, and the additional headcount required to execute our clinical trial programs and to continue to develop our research, preclinical, manufacturing and process development infrastructure. In addition, we anticipate that completion of the Eos acquisition would add research and development expenses of approximately \$9.0 million to \$11.0 million in 2003, primarily related to additional headcount, manufacturing expense, rent and on-going collaborations. Certain of these operating expenses related to manufacturing and clinical development are not expected to continue beyond 2003 since certain Eos programs currently rely on outside manufacturing and other contract organizations. Reliance on these organizations beyond 2003 is expected to be reduced given our internal capabilities and core competencies in these areas.

Below is a summary of products and the related stages of development for each product in clinical development, including the research and development expenses recognized in connection with each product. The information in the column labeled “Estimated Completion of Phase” is only our estimate of the timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates provided in the table. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the “Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we can not accurately predict the timing and level of such expenses,” “If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products,” “Our clinical trial strategy may increase the risk of clinical trial difficulties,” “If our collaborations are not successful, we may not be able to effectively develop and market some of our products,” “If we do not attract and retain key employees, our business could be impaired,” and “We may be unable to obtain or maintain regulatory approval for our products” sections of our Risk Factors above.

| Product                              | Description/Indication                    | Phase of Development | Collaborator    | Estimated Completion of Phase | Research and Development Costs for the Year Ended December 31, |                 |                 |
|--------------------------------------|---|----------------------|-----------------|-------------------------------|--|-----------------|-----------------|
|                                      |   |                      |                 |                               | 2002   | 2001            | 2000            |
|                                      |   |                      |                 |                               | (In thousands)   |                 |                 |
| Humanized Anti-IL-4                  | Asthma                                    | Phase IIa            | GlaxoSmithKline | 2003                          | \$2,791  | \$2,961         | \$4,854         |
| SMART Anti-IL-12                     | Autoimmune Diseases                       | Phase I              | --              | Completed <sup>(1)</sup>      | 2,526  | 5,058           | 538             |
| HuZAF                                |   |                      | --              |                               | 14,047   | 6,934           | 2,839           |
|                                      | Crohn's Disease                           | Phase II             |                 | 2004                          |  |                 |                 |
|                                      | Psoriasis                                 | Phase I/II           |                 | 2003                          |  |                 |                 |
| Nuvion                               |   |                      | --              |                               | 4,001  | 4,658           | 3,189           |
|                                      | Steroid Refractory Graft Vs. Host Disease | Phase II             |                 | 2004                          |  |                 |                 |
|                                      | Ulcerative Colitis                        | Phase I              |                 | 2003                          |  |                 |                 |
| Remitogen                            |   |                      | --              |                               | 2,766  | 3,532           | 5,704           |
|                                      | Non-Hodgkin's B-Cell Lymphoma             | Phase II             |                 | Completed <sup>(2)</sup>      |  |                 |                 |
|                                      | Solid Tumors                              | Phase I              |                 | 2003                          |  |                 |                 |
| Zamyl                                | Acute Myeloid Leukemia                    | Phase III            | --              | Completed <sup>(3)</sup>      | 3,981  | 5,036           | 6,261           |
| Daclizumab                           | Asthma                                    | Phase II             | Roche           | 2004                          | 7,778  | 8,329           | 2,064           |
| HuMV833                              | Solid Tumors                              | Phase I              | Toagosei        | Completed <sup>(4)</sup>      | 22   | 383             | 5,246           |
| Other <sup>(5)</sup>                 |   |                      | --              |                               | <u>20,066</u>  | <u>15,272</u>   | <u>11,635</u>   |
| Total Research and Development Costs |   |                      |                 |                               | <u>\$57,978</u>  | <u>\$52,163</u> | <u>\$42,330</u> |

<sup>(1)</sup> Product returned to a preclinical status while further research is conducted.

<sup>(2)</sup> Further development of this product is not currently expected.

<sup>(3)</sup> Product candidate is available for out-license. No further internal development of this product is currently expected.

<sup>(4)</sup> Product development terminated under agreement with Toagosei.

<sup>(5)</sup> No single potential product included in “other” constitutes more than 5% of the total research and development costs for the specified year.

The overall completion dates or total costs to complete our major research and development programs are estimates based on current information. The clinical development portion of these programs may span as many as seven to ten years and any further estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing biopharmaceutical products, including significant and changing government regulation, the uncertainty of future preclinical and clinical study results and uncertainties associated with process development and manufacturing as well as marketing. These risks and uncertainties make reliably estimating overall completion dates and total costs to complete development highly speculative. For additional discussion of factors affecting overall completion dates and total costs, see the "Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we cannot accurately predict the timing and level of such expenses" section of our Risk Factors above.

### General and Administrative Expenses

General and administrative expenses in 2002 were \$19.1 million, an increase of 21% from 2001. In 2001, general and administrative expenses were \$15.7 million, an increase of 30% from 2000. General and administrative costs include costs of personnel, professional services, consulting and other expenses related to our administrative functions and an allocation of facility costs. The increase in 2002 was primarily related to increased personnel and recruiting costs of \$1.9 million, legal costs related to our intellectual property, licensing and other contractual matters of \$0.7 million and \$0.2 million related to maintenance agreements for our document control software systems. The increase in 2001 was primarily due to increased personnel and recruiting costs, pre-marketing expenses associated with our clinical development program, legal costs related to our intellectual property, licensing and other contractual matters and increased third party royalty expenses associated with higher sales by one of our licensees.

We expect that general and administrative expenses will continue to increase as we build infrastructure and support for expanded research and development capabilities of our organization.

(In thousands)

### Interest Income, Interest Expense and Investment Impairment

|                               | <u>Years Ended December 31</u> |             |             | <u>Annual Percent Change</u> |                    |
|-------------------------------|--------------------------------|-------------|-------------|------------------------------|--------------------|
|                               | <u>2002</u>                    | <u>2001</u> | <u>2000</u> | <u>2002 / 2001</u>           | <u>2001 / 2000</u> |
| Interest income               | \$ 25,978                      | \$ 35,135   | \$ 22,647   | (26%)                        | 55%                |
| Interest expense              | (8,426)                        | (8,989)     | (7,965)     | (6%)                         | 13%                |
| Impairment loss on investment | (1,366)                        | -           | -           | 100%                         | -                  |

### Interest Income and Expense

Interest income in 2002 was \$26.0 million, a decrease of 26% from 2001. In 2001, interest income was \$35.1 million, an increase of 55% from 2000. The decrease in interest earned in 2002 was largely due to the decreased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates and to a lesser extent, lower invested balances. The increase in interest earned in 2001 was primarily attributable to the increase in 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 that raised approximately \$343.6 in net proceeds and the sale of \$150 million of convertible subordinated notes in February 2000.

Interest expense, net of amounts capitalized, was related to our 5.5% convertible subordinated notes and a 7.64% term loan associated with the purchase our Fremont, California facilities. Interest expense in 2002 was \$8.4 million, a decrease of 6% from 2001. Interest expense in 2001 was \$9.0 million, an increase of 13% from 2000. The decrease in 2002 was the result of capitalizing \$0.5 million of our interest cost in connection with the renovation of our existing manufacturing

facilities and the development and construction activities for our future manufacturing facilities. The increase in 2001 was attributable to twelve months of interest expense in 2001 versus ten and one half months of interest expense in 2000 in connection with the issuance of our 5.5% convertible subordinated notes in February 2000.

### **Impairment Loss on Investment**

In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately held drug discovery company, in exchange for 523,952 shares of Signature convertible preferred stock. The stock received was recorded at the net book value of the assets sold plus transaction costs incurred, which approximated \$1.3 million. In conjunction with this transaction, in December 2002, we accrued an additional \$0.2 million payable to Signature in connection with cash retention bonuses to designated key employees still employed by Signature after one year. Pursuant to the terms of the agreement, in exchange for these bonus payments we received in early 2003 an additional 149,701 shares of Signature convertible preferred stock, which was recorded as an increase in the carrying value of the preferred stock. Since the shares we received are not publicly traded, the value of the shares is difficult to estimate. As of December 31, 2002, we estimated that the value of our investment in Signature BioScience, Inc. had declined to \$150,000 and that an impairment of our investment had occurred and that such impairment was other than temporary. Accordingly, we recorded an impairment charge of \$1.4 million in December 2002. The amount of the charge was based on the difference between the estimated fair value as determined by our management and our original cost basis in the shares of approximately \$1.6 million. If we deem the estimated fair value of the shares of Signature further impaired at the end of any future period, we may incur an additional impairment charge with respect to these shares.

### **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, 2002, we had cash, cash equivalents and marketable securities in the aggregate of \$606.4 million, compared to \$650.3 million at December 31, 2001.

Net cash used in our operating activities in 2002 was approximately \$5.1 million compared with net cash provided by operating activities of \$2.6 million in 2001. The change was primarily due to a net loss in 2002, partially offset by a decrease in interest receivable in 2002 versus an increase in interest receivable in 2001 and the non-cash impairment loss on an investment in 2002. The decrease in net cash provided by our operating activities in 2001 as compared to net cash provided by operating activities of \$6.8 million in 2000 was primarily due an increase in interest receivable and other current assets, partially offset by higher net income in 2001.

Net cash provided by our investing activities in 2002 was \$168.8 million compared to net cash used in our investing activities of \$316.3 million in 2001. The change in 2002 was primarily the result of an increase in maturities of marketable securities and a decrease in purchases of marketable securities during the period as compared to our maturities and reinvestment activities associated with the purchases of short- and long-term investments in 2001. Capital expenditures in 2002 were primarily related to the purchase of land, renovation of our Plymouth, Minnesota manufacturing facility and development and construction activities for our future manufacturing facility in Brooklyn Park, Minnesota. Capital expenditures in 2001 primarily consisted of equipment purchases and renovation of our Plymouth, Minnesota manufacturing facility. The increase in net cash used in our investing activities in 2001 as compared to net cash used in our investing activities of \$118.2 million in 2000 was primarily the result of an increase in the maturities and purchases of marketable securities and the purchase of a convertible note from Exelixis offset by an increase in maturities of marketable securities.



Net cash provided by our financing activities in 2002 was \$3.8 million compared to \$12.5 million in the 2001 period. The change in 2002 from 2001 was primarily the result of a decrease in the exercise of outstanding stock options. The decrease in net cash provided by our financing activities in 2001 as compared to net cash provided by our financing activities of \$515.8 million in 2000 was primarily the result of our sale of \$150 million of convertible subordinated notes in February 2000 and our public offering of common stock in the second half of 2000, which raised approximately \$343.6 million in net proceeds.

We estimate that our existing capital resources will be sufficient to fund our current level of operations for at least the next few years. Our future capital requirements will depend on numerous factors, including, among others, interest income, royalties from sales of products by third party licensees, including Synagis, Herceptin, Zenapax and Mylotarg; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; 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; significant resources we will devote to constructing our manufacturing facilities; 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.

In Fremont, California; Menlo Park, California; Somerville, New Jersey; Plymouth, Minnesota and Paris, France, we occupy leased facilities under agreements that expire in 2006, 2005, 2005, 2009 and 2004, respectively. We also have leased certain office equipment under operating leases.

In September 1999, Fremont Holding L.L.C. (our wholly owned subsidiary) 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.

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 at the holders' option into our common stock at a conversion price of \$37.75 per share, subject to adjustment as a result of certain events. 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 May 2001, we signed a collaborative agreement with Exelixis to discover and develop humanized antibodies for the diagnosis, prevention and treatment of cancer. We agreed to provide Exelixis with \$4.0 million in annual research funding through June 1, 2003, and we purchased a \$30.0 million five-year note, convertible at our option after the first year of the collaboration into Exelixis common stock. The research funding period will end in June 2003. During the funding

period, Exelixis performs certain genetic screens and other research activities intended to identify and validate targets for antibody therapeutics in oncology. We received an exclusive, worldwide license to develop antibodies against certain targets identified by Exelixis that are involved in cell growth, cell death and proliferation. Exelixis has the right to co-fund development of antibodies resulting from the collaboration. Therefore, we recognized the expense of research funding ratably over the periods for which it was performed. For antibody products we develop that Exelixis elects not to co-fund, we have agreed to make specified milestone payments and royalty payments on any product sales.

In connection with the construction of our new commercial manufacturing facility in Brooklyn Park, Minnesota, we have entered into, and will continue to enter into, agreements with third parties for the construction and design of the facility. As of July 2002, we have engaged Fluor Daniel (a division of Fluor Enterprises) to handle the engineering and certain procurement services. Under that agreement, we will owe an aggregate of approximately \$13.6 million to be paid in 2003 and 2004. The design and project management work to be completed under this agreement is scheduled for completion in the third quarter of 2003 and the construction support work is scheduled to be completed by the third quarter of 2004. In addition, we have entered into various commitments related to the manufacturing equipment required for the new facility of approximately \$6.8 million, which is to be paid in 2003. Additionally, as of September 2002 and October 2002, respectively, we have entered into an interim construction management agreement and a purchasing agreement, respectively, with McGough Construction and are in final negotiations with McGough on agreements for the construction management and certain construction services for the facility. Under those agreements, we will owe an estimated aggregate of approximately \$93 million to be paid in 2003 and 2004. The facility construction is scheduled to be completed in 2004.

Our material contractual obligations under lease, debt, construction and research funding agreements for the next five years and thereafter as of December 31, 2002 are as follows:

| (In thousands)                     | PAYMENTS DUE BY PERIOD |                  |                  |                 |                  |
|------------------------------------|------------------------|------------------|------------------|-----------------|------------------|
|                                    | Less Than 1 Year       | 1-3 Years        | 4-5 Years        | After 5 Years   | Total            |
| CONTRACTUAL OBLIGATIONS (1)        |                        |                  |                  |                 |                  |
| Operating leases                   | \$ 1,462               | \$ 2,285         | \$ 1,583         | \$ 891          | \$ 6,221         |
| Long-term debt                     | 1,139                  | 2,278            | 2,278            | 7,783           | 13,478           |
| Convertible debentures             | 8,250                  | 16,500           | 162,375          | --              | 187,125          |
| Research funding                   | 1,000                  | --               | --               | --              | 1,000            |
| Construction contracts             | <u>81,293</u>          | <u>31,934</u>    | <u>--</u>        | <u>--</u>       | <u>113,227</u>   |
| Total contractual cash obligations | <u>\$ 93,144</u>       | <u>\$ 52,997</u> | <u>\$166,236</u> | <u>\$ 8,674</u> | <u>\$321,051</u> |

- (1) This table does not include (a) any milestone payments from us to third parties which may become payable under research collaborations or license agreements as the timing and likelihood of such payments are not known, (b) any royalty payments from us to third parties as the amounts of such payments and / or likelihood of such payments are not known and (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

### Recent Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board (FASB) issued Statement No. 143, "Accounting for Asset Retirement Obligations" (FAS 143). FAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated retirement costs. The Company is in the process of assessing the effect of adopting FAS 143, which will be effective for the Company's year ending December 31, 2003.

In June 2002, the FASB issued Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (FAS 146), which provides guidance related to accounting for costs associated with disposal activities covered by FAS 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" or with exit or restructuring activities previously covered by EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." FAS 146 supersedes EITF Issue No. 94-3 in its entirety. FAS 146 requires that costs related to exiting an activity or to a restructuring not be recognized until the liability is incurred. FAS 146 will be applied prospectively to exit or disposal activities that are initiated after December 31, 2002.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. Our adoption of FIN 45 did not have a material impact on our results of operations and financial position.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" (FAS 148). FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options and have made the appropriate disclosures in accordance with FAS 148.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A variable interest entity is a corporation, partnership, trust, or any other legal structures used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in research and development or other activities on behalf of another company. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The adoption of FIN 46 is not expected to have a material impact on our results of operations and financial position, because we do not have any transactions involving variable interest entities.

## **ITEM 7a. MARKET RISKS**

## Interest Rate Risk

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. We do not use derivative financial instruments for speculative or trading purposes. We hold a \$30.0 million five-year convertible note receivable purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or changes or interpretations in accounting principles could require us to report the value of the Exelixis stock in our financial statements. Such a requirement could cause us to include changes in the Exelixis stock price on a quarterly basis and would contribute to fluctuation in our operating results from quarter to quarter.

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. If market interest rates were to increase by 100 basis points from December 31, 2002 levels, the fair value of the portfolio would decline by approximately \$3.4 million. 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.

As of December 31, 2002, the aggregate fair values of our long-term debt and convertible subordinated notes were approximately \$9.7 million and \$123.0 million, respectively. The long-term debt bears interest at a fixed rate of 7.64% and the convertible subordinated notes bear interest at a fixed rate of 5.50%. These obligations are subject to interest rate risk because the fixed interest rates under these obligations may exceed current interest rates.

The following table presents information about the Company's debt obligations that are sensitive to changes in interest rates. The table presents principal amounts and related weighted average interest rates by year of expected maturity for the Company's debt obligations. Our convertible notes may be converted to common stock prior to the maturity date.

| <u>Liabilities (000's)</u>                | <u>2003</u> | <u>2004</u> | <u>2005</u> | <u>2006</u> | <u>2007</u> | <u>Thereafter</u> | <u>Total</u> | <u>Fair Value</u> |
|---|-------------|-------------|-------------|-------------|-------------|-------------------|--------------|-------------------|
| Long-term debt, including current portion |             |             |             |             |             |                   |              |                   |
| Fixed Rate                                | \$466       | \$502       | \$543       | \$587       | \$635       | \$6,159           | \$8,892      | \$9,700*          |
| Avg. Interest Rate                        | 7.64%       | 7.64%       | 7.64%       | 7.64%       | 7.64%       | 7.64%             | 7.64%        |                   |
| Convertible subordinated notes            |             |             |             |             |             |                   |              |                   |
| Fixed Rate                                | \$ --       | \$ --       | \$ --       | \$ --       | \$150,000   | \$ --             | \$150,000    | \$123,000         |
| Avg. Interest Rate                        | 5.50%       | 5.50%       | 5.50%       | 5.50%       | 5.50%       | 5.50%             | 5.50%        |                   |

\*The fair value of the remaining payments under the loan is estimated using discounted cash flow analyses, based on the Company's current incremental borrowing rate for similar types of borrowing arrangements.

**Foreign Currency Risk**

As we have operations outside of the United States, our financial results could be affected by changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we operate. To date, our foreign operations have not been significant to our results of operations and financial condition; therefore, our current foreign currency risk is minimal.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**PROTEIN DESIGN LABS, INC.  
CONSOLIDATED BALANCE SHEETS**

(In thousands, except par value per share)

|   | <b>DECEMBER 31,</b> |                   |
|---|---------------------|-------------------|
|   | <b>2002</b>         | <b>2001</b>       |
| <b>ASSETS</b>   |                     |                   |
| Current assets:   |                     |                   |
| Cash and cash equivalents   | \$ 287,730          | \$ 120,268        |
| Marketable securities   | 318,680             | 530,047           |
| Other current assets  | <u>7,432</u>        | <u>4,144</u>      |
| Total current assets  | 613,842             | 654,459           |
| Land, property and equipment, net   | 70,802              | 42,111            |
| Other assets  | 3,174               | 3,328             |
| Convertible note receivable   | <u>30,000</u>       | <u>30,000</u>     |
| Total assets  | <u>\$ 717,818</u>   | <u>\$ 729,898</u> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                     |                   |
| Current liabilities:  |                     |                   |
| Accounts payable  | \$ 1,628            | \$ 1,249          |
| Accrued compensation  | 2,520               | 2,000             |
| Accrued clinical trial costs  | 2,327               | 2,588             |
| Accrued interest  | 3,071               | 3,071             |
| Other accrued liabilities   | 4,576               | 3,123             |
| Deferred revenue  | 38                  | 100               |
| Current portion of long-term debt   | <u>466</u>          | <u>432</u>        |
| Total current liabilities   | 14,626              | 12,563            |
| Convertible subordinated notes  | 150,000             | 150,000           |
| Long-term debt  | <u>8,426</u>        | <u>8,892</u>      |
| Total liabilities   | 173,053             | 171,455           |
| Commitments and Contingencies   |                     |                   |
| Stockholders' equity:   |                     |                   |
| Preferred stock, par value \$0.01 per share,<br>10,000 shares authorized; no shares issued and<br>outstanding   | --                  | --                |
| Common stock, par value \$0.01 per share,<br>250,000 shares authorized; 89,179 and 88,499<br>issued and outstanding at December 31, 2002<br>and December 31, 2001, respectively | 892                 | 885               |
| Additional paid-in capital  | 628,292             | 624,094           |
| Accumulated deficit   | (90,477)            | (75,923)          |
| Accumulated other comprehensive income  | <u>6,059</u>        | <u>9,387</u>      |
| Total stockholders' equity  | <u>544,766</u>      | <u>558,443</u>    |
| Total liabilities and stockholders' equity  | <u>\$ 717,818</u>   | <u>\$ 729,898</u> |

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

|  | <b>YEARS ENDED DECEMBER 31,</b> |                 |                |
|--|---------------------------------|-----------------|----------------|
|  | <b>2002</b>                     | <b>2001</b>     | <b>2000</b>    |
| Revenues:  |                                 |                 |                |
| Royalties  | \$ 40,421                       | \$ 30,604       | \$ 19,189      |
| License and other  | <u>5,952</u>                    | <u>13,796</u>   | <u>21,220</u>  |
| Total revenues   | <u>46,373</u>                   | <u>44,400</u>   | <u>40,409</u>  |
| Costs and expenses:  |                                 |                 |                |
| Research and development                                   | 57,978                          | 52,163          | 42,330         |
| General and administrative                                 | <u>19,093</u>                   | <u>15,724</u>   | <u>12,109</u>  |
| Total costs and expenses                                   | <u>77,071</u>                   | <u>67,887</u>   | <u>54,439</u>  |
| Operating loss   | (30,698)                        | (23,487)        | (14,030)       |
| Interest income  | 25,978                          | 35,135          | 22,647         |
| Interest expense   | (8,426)                         | (8,989)         | (7,965)        |
| Impairment loss on investment                              | <u>(1,366)</u>                  | <u>--</u>       | <u>--</u>      |
| Income (loss) before income taxes                          | (14,512)                        | 2,659           | 652            |
| Provision for income taxes                                 | <u>42</u>                       | <u>12</u>       | <u>5</u>       |
| Net income (loss)  | <u>\$ (14,554)</u>              | <u>\$ 2,647</u> | <u>\$ 647</u>  |
| Net income (loss) per share:                               |                                 |                 |                |
| Basic  | <u>\$ (0.16)</u>                | <u>\$ 0.03</u>  | <u>\$ 0.01</u> |
| Diluted  | <u>\$ (0.16)</u>                | <u>\$ 0.03</u>  | <u>\$ 0.01</u> |
| Shares used in computation of net income (loss) per share: |                                 |                 |                |
| Basic  | <u>88,865</u>                   | <u>87,624</u>   | <u>80,904</u>  |
| Diluted  | <u>88,865</u>                   | <u>92,889</u>   | <u>88,562</u>  |

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(In thousands, except per share and shares of common stock data)

|  | <b>Common Stock</b>            |  | <b>Additional<br/>Paid-In<br/>Capital</b> |
|--|--------------------------------|--|---|
|  | <b>Shares</b>                  | <b>Amount</b>  |   |
| Balance at December 31, 1999   | 77,127,036                     | \$ 772   | \$ 245,233                                |
| Follow-on public offering of common stock at \$59.2187 per share (net of underwriters discount of \$18,103 and offering expenses of approximately \$500) | 6,116,000                      | 61   | 343,517                                   |
| Issuance of common stock under employee benefit plans  | <u>3,910,264</u>               | <u>39</u>  | <u>22,504</u>                             |
| Balance at December 31, 2000   | 87,153,300                     | 872  | 611,254                                   |
| Issuance of common stock under employee benefit plans  | <u>1,346,001</u>               | <u>13</u>  | <u>12,840</u>                             |
| Balance at December 31, 2001   | 88,499,301                     | 885  | 624,094                                   |
| Issuance of common stock under employee benefit plans  | <u>679,566</u>                 | <u>7</u>   | <u>4,198</u>                              |
| Balance at December 31, 2002   | <u>89,178,867</u>              | <u>\$ 892</u>  | <u>\$ 628,292</u>                         |
|  | <b>Accumulated<br/>Deficit</b> | <b>Accumulated<br/>Other<br/>Comprehensive<br/>Income (Loss)</b> | <b>Total<br/>Stockholders'<br/>Equity</b> |
| Balance at December 31, 1999   | \$ (79,217)                    | \$ (2,045)   | \$ 164,743                                |
| Follow-on public offering of common stock at \$59.2187 per share (net of underwriters discount of \$18,103 and offering expenses of approximately \$500) | --                             | --   | 343,578                                   |
| Issuance of common stock under employee benefit plans  | --                             | --   | 22,543                                    |
| Comprehensive income:  |                                |  |   |
| Net income   | 647                            | --   | 647                                       |
| Unrealized gain on securities  | --                             | 2,633  | <u>2,633</u>                              |
| Total comprehensive income   |                                |  | <u>3,280</u>                              |
| Balance at December 31, 2000   | <u>(78,570)</u>                | <u>588</u>   | <u>534,144</u>                            |
| Issuance of common stock under employee benefit plans  | --                             | --   | 12,853                                    |
| Comprehensive income:  |                                |  |   |
| Net income   | 2,647                          | --   | 2,647                                     |
| Unrealized gain on securities  | --                             | 8,799  | <u>8,799</u>                              |
| Total comprehensive income   |                                |  | <u>11,446</u>                             |
| Balance at December 31, 2001   | <u>(75,923)</u>                | <u>9,387</u>   | <u>558,443</u>                            |
| Issuance of common stock under employee benefit plans  | --                             | --   | 4,205                                     |
| Comprehensive loss:  |                                |  |   |
| Net loss   | (14,554)                       | --   | (14,554)                                  |
| Unrealized loss on securities  | --                             | (3,328)  | <u>(3,328)</u>                            |
| Total comprehensive loss   |                                |  | <u>(17,882)</u>                           |
| Balance at December 31, 2002   | <u>\$ (90,477)</u>             | <u>\$ 6,059</u>  | <u>\$ 544,766</u>                         |

See accompanying notes



**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

|  | <b>YEARS ENDED DECEMBER 31,</b> |                   |                   |
|--|---------------------------------|-------------------|-------------------|
|  | <b>2002</b>                     | <b>2001</b>       | <b>2000</b>       |
| Cash flows from operating activities:  |                                 |                   |                   |
| Net income (loss)  | \$ (14,554)                     | \$ 2,647          | \$ 647            |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: |                                 |                   |                   |
| Depreciation and amortization  | 5,441                           | 4,782             | 3,570             |
| Amortization of convertible notes offering costs   | 721                             | 721               | 628               |
| Impairment loss on investment  | 1,366                           | --                | --                |
| Changes in assets and liabilities:   |                                 |                   |                   |
| Interest receivable  | 3,904                           | (4,522)           | (1,920)           |
| Other current assets   | (3,336)                         | (2,164)           | 4,739             |
| Other assets   | (643)                           | 105               | (4,233)           |
| Accounts payable   | 379                             | 187               | 185               |
| Accrued liabilities  | 1,713                           | 2,187             | 4,031             |
| Deferred revenue   | (62)                            | (1,355)           | (820)             |
| Total adjustments  | <u>9,483</u>                    | <u>(59)</u>       | <u>6,180</u>      |
| Net cash provided by (used in) operating activities  | (5,071)                         | 2,588             | 6,827             |
| Cash flows from investing activities:  |                                 |                   |                   |
| Purchases of marketable securities   | (79,954)                        | (485,483)         | (129,821)         |
| Maturities of marketable securities  | 283,500                         | 207,885           | 15,000            |
| Purchases of convertible note  | --                              | (30,000)          | --                |
| Purchase of land, property and equipment   | <u>(34,786)</u>                 | <u>(8,716)</u>    | <u>(3,355)</u>    |
| Net cash provided by (used in) investing activities  | 168,760                         | (316,314)         | (118,176)         |
| Cash flows from financing activities:  |                                 |                   |                   |
| Proceeds from issuance of capital stock, net of issuance costs                                     | 4,205                           | 12,853            | 366,121           |
| Proceeds from issuance of convertible notes  | --                              | --                | 150,000           |
| Payments on long-term debt   | <u>(432)</u>                    | <u>(400)</u>      | <u>(369)</u>      |
| Net cash provided by financing activities  | <u>3,773</u>                    | <u>12,453</u>     | <u>515,752</u>    |
| Net increase (decrease) in cash and cash equivalents   | 167,462                         | (301,273)         | 404,403           |
| Cash and cash equivalents at beginning of year   | <u>120,268</u>                  | <u>421,541</u>    | <u>17,138</u>     |
| Cash and cash equivalents at end of year   | <u>\$ 287,730</u>               | <u>\$ 120,268</u> | <u>\$ 421,541</u> |
| Supplemental cash flow data:   |                                 |                   |                   |
| Cash paid during the year for interest   | <u>\$ 8,957</u>                 | <u>\$ 8,989</u>   | <u>\$ 4,894</u>   |
| Non-cash activities:   |                                 |                   |                   |
| Exchange of assets for third party preferred stock   | <u>\$ 1,290</u>                 | <u>\$ --</u>      | <u>\$ --</u>      |

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2002**

## **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 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., Fremont Management, Inc. and PDL France SAS, after elimination of inter-company accounts and transactions.

### Reclassifications

Certain reclassifications of prior year amounts have been made to conform to the current presentation, including royalty revenue, license and other revenue and interest income.

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

We consider all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. 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

We currently recognize three types of revenues resulting from the licensing and use of our technology, and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use in drug development and production. Revenues, and their respective treatment for financial reporting purposes, are as follows:

#### *Upfront and License Maintenance Fees*

We generally recognize revenue from upfront fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Revenues recognized from upfront fees typically relate to patent license and patent rights agreements.

- Under patent license agreements, the licensee typically obtains a non-exclusive license to our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements.

- Under patent rights agreements, licensees currently purchase a research patent license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. All of the research is performed by the licensee, and therefore, upon delivery of the patent rights agreement, the earnings process is complete and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses. Subsequent to execution of the agreement, the licensee has the right to purchase patent licenses to certain designated targets, for which the licensee pays separate consideration at a later date. Such consideration is recognized upon exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.
- Under our humanization agreements, at times referred to in our previous filings as research and development agreements, the licensee typically pays an upfront fee for us to humanize an antibody. These upfront fees are recognized on a percent completion basis, as the humanization work is performed, which is typically over three to six months.
- Under patent license agreements and humanization agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

#### *Milestone Payments*

Certain agreements include milestone payments which are recognized as revenue when earned as part of a multi-element arrangement. Each element of the contract represents a separate earnings process and as such we recognize milestone amounts when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement and when payment is reasonably assured. Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones include delivery of a humanized antibody meeting a certain binding affinity and, at the customer's election, delivery of a cell line meeting certain criteria described in the original agreement. We recognize these milestones when we have no further performance obligations with respect to that milestone and the funding party confirms that the milestone stipulated in the agreement has been met.
- Patent license agreements and humanization agreements sometimes require our customers to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the customer's product. Because we have no obligations with respect to any of this activity, we record these milestone payments as revenue when received and we have confirmed that the milestone has been achieved.
- We may also receive certain milestone payments in connection with licensing technology to or from our partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when we or they achieve certain levels of development with respect to the licensed technology. These fees are recognized when we have no further performance obligations with respect to the applicable milestone and it is confirmed that the milestone stipulated in the agreement has been met.

#### *Royalties*

Under some of our agreements, we also receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from such licensees approximately one quarter in arrears; that is, generally at the end of the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we have adopted an accounting policy of recording the royalty revenue in the quarter it is reported to us (i.e., generally revenue is recognized one quarter following the quarter in which sales occurred). The majority of the Company's revenues were earned in the United States. Royalty revenues from MedImmune in 2002, 2001 and 2000 accounted for 41%, 33% and 24% of our total revenues, respectively. Royalty revenues from Genentech in 2002, 2001 and 2000 accounted for 38%, 27% and 19% of our total revenues, respectively.

### Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients, the completion of portions of the clinical trial, or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual cost of services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the patients continued participation in the trial. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable 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.

### Research and Development

Major components of research and development expenses consist of personnel costs, including salaries and benefits, clinical development performed by us and contract research organizations, preclinical work, pharmaceutical development, materials and supplies, third party research funding and overhead allocations consisting of various administrative and facilities related costs. All research and development costs are charged to expense as incurred.

### Net Income (Loss) Per Share

In accordance with Financial Accounting Standards Board (FASB) Statement No. 128, "Earnings Per Share", 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. The calculation of diluted net income per share also includes the dilutive effect of outstanding stock options in 2001 and 2000, but does not include the effect of outstanding convertible notes because the assumed conversion of these notes would be anti-dilutive. We incurred a net loss for the year ended December 31, 2002, and as such, we did not include the effect of outstanding stock options or outstanding convertible notes in the diluted net loss per share calculation, as their effect would be 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)

|                                     | <b><u>Years Ended December 31,</u></b> |                    |                    |
|-------------------------------------|--|--------------------|--------------------|
|                                     | <b><u>2002</u></b>                     | <b><u>2001</u></b> | <b><u>2000</u></b> |
| Numerator:                          |  |                    |                    |
| Net income (loss)                   | <u>\$ (14,554)</u>                     | <u>\$ 2,647</u>    | <u>\$ 647</u>      |
| Denominator:                        |  |                    |                    |
| Basic net income (loss) per share - |  |                    |                    |
| Weighted-average shares             | 88,865                                 | 87,624             | 80,904             |
| Dilutive potential common shares -  |  |                    |                    |
| Stock options                       | <u>--</u>                              | <u>5,265</u>       | <u>7,658</u>       |
| Denominator for diluted net income  |  |                    |                    |
| (loss) per share                    | <u>88,865</u>                          | <u>92,889</u>      | <u>88,562</u>      |
| Basic net income (loss) per share   | <u>\$ (0.16)</u>                       | <u>\$ 0.03</u>     | <u>\$ 0.01</u>     |
| Diluted net income (loss) per share | <u>\$ (0.16)</u>                       | <u>\$ 0.03</u>     | <u>\$ 0.01</u>     |

The total number of shares excluded from the calculations of diluted net income (loss) per share for outstanding convertible notes was 3,974,000 in 2002, 2001 and 2000. The total number of shares excluded from the calculation of diluted net loss per share for stock options was 12,310,000 in 2002, 5,263,000 in 2001 and 1,917,000 in 2000. Such securities, had they been dilutive, would have been included in the computations of diluted net income (loss) per share.

#### Comprehensive Income (Loss)

In accordance with FASB Statement No. 130, "Reporting Comprehensive Income", we are required to display comprehensive income (loss) and its components as part of our complete set of financial statements. 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, 2002, 2001 and 2000 is reflected in the Statements of Stockholders' Equity.

### Stock-Based Compensation

At December 31, 2002, we had six stock-based employee compensation plans, which are described more fully in Note 6. We account for our plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. No stock-based employee compensation cost is reflected in net income (loss), as all options granted under our plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income (loss) and earnings (loss) per share if we had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation, as amended by FAS 148, Accounting for Stock-Based Compensation – Transition and Disclosure* to stock-based employee compensation.

| (In thousands, except per share data)   | Year Ended December 31 |                    |                    |
|---|------------------------|--------------------|--------------------|
|   | 2002                   | 2001               | 2000               |
| Net income (loss), as reported  | \$ (14,554)            | \$ 2,647           | \$ 647             |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | <u>(11,842)</u>        | <u>(38,939)</u>    | <u>(13,300)</u>    |
| Pro forma net (loss)  | <u>\$(26,396)</u>      | <u>\$ (36,292)</u> | <u>\$ (12,653)</u> |
| Net income (loss) per share:  |                        |                    |                    |
| Basic—as reported   | <u>\$ (0.16)</u>       | <u>\$ 0.03</u>     | <u>\$ 0.01</u>     |
| Basic—pro forma   | <u>\$ (0.30)</u>       | <u>\$ (0.41)</u>   | <u>\$ (0.16)</u>   |
| Diluted—as reported   | <u>\$ (0.16)</u>       | <u>\$ 0.03</u>     | <u>\$ 0.01</u>     |
| Diluted—pro forma   | <u>\$ (0.30)</u>       | <u>\$ (0.41)</u>   | <u>\$ (0.16)</u>   |

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in each of 2002, 2001 and 2000, respectively: (a) no dividends; (b) expected volatility of 87%, 98% and 145%; (c) weighted-average risk-free interest rates of 3.91%, 4.72% and 6.14%; and (d) expected lives of 5 years.

### Segment and Concentrations Disclosure

In accordance with FASB Statement No. 131, "Disclosure About Segments of an Enterprise and Related Information", 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 primarily within the U.S.

### Derivative Instruments and Hedging Activities

In accordance with FASB issued Statement No. 133 "Accounting for Derivative Instruments and Hedging Activities", we are required to recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. We do not use or hold derivatives and therefore there is no effect on the results of operations or the financial position of the Company.

### Foreign Currency Translation

We use the U.S. dollar as our functional currency for our U.S. operations as well as the operations of our French subsidiary.

### Impairment Loss on Investment

In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately held drug discovery company, in exchange for 523,952 shares of Signature convertible preferred stock. The stock received was recorded at the net book value of the assets sold plus transaction costs incurred, which approximated \$1.3 million. In conjunction with this transaction, in December 2002, we accrued an additional \$0.2 million payable to Signature in connection with cash retention bonuses to designated key employees still employed by Signature after one year. Pursuant to the terms of the agreement, in exchange for these bonus payments we received in early 2003 an additional 149,701 shares of Signature convertible preferred stock, which was recorded as an increase in the carrying value of the preferred stock. Since the shares we received are not publicly traded, the value of the shares is difficult to estimate. As of December 31, 2002, we estimated that the fair value of our shares owned and to be received in early 2003 had declined to \$150,000 and that an impairment of our investment had occurred and that such impairment was other than temporary. Accordingly, we recorded an impairment charge of \$1.4 million in December 2002. The amount of the charge was based on the difference between the estimated fair value as determined by our management and our original cost basis in the shares of approximately \$1.6 million. If we deem the estimated fair value of the shares of Signature further impaired at the end of any future period, we may incur an additional impairment charge with respect to these shares.

### Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. See our "Clinical Trial Expenses" policy above. In addition, funded research and development paid to third parties is expensed on a straight-line basis over the period of performance. Our estimates and assumptions could differ significantly from the amounts which may actually be incurred.

### Land, 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)

|  | <b>December 31,</b> |                  |
|--|---------------------|------------------|
|  | <b>2002</b>         | <b>2001</b>      |
| Land   | \$ 10,743           | \$ 6,790         |
| Buildings and improvements                     | 22,198              | 22,001           |
| Leasehold improvements                         | 6,691               | 3,181            |
| Laboratory and manufacturing equipment         | 20,604              | 19,866           |
| Construction in-process                        | 26,754              | 5,910            |
| Computer and office equipment                  | 6,621               | 4,465            |
| Furniture and fixtures                         | 2,058               | 1,633            |
|  | 95,669              | 63,846           |
| Less accumulated depreciation and amortization | (24,867)            | (21,735)         |
|  | <u>\$ 70,802</u>    | <u>\$ 42,111</u> |

Depreciation and amortization expense for 2002, 2001 and 2000 were \$4.9 million, \$4.3 million and \$3.7 million, respectively.

Depreciation and amortization are 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        |

#### Capitalization of Interest Cost

We capitalized a portion of our interest on borrowings in connection with the renovation of our existing manufacturing facilities and the development and construction activities for our future manufacturing facility. Capitalized interest is added to the cost of the underlying assets and is amortized over the useful lives of the assets. Interest of \$0.5 million was capitalized for the year ended December 31, 2002. No interest was capitalized in 2001 and 2000.

#### Recent Accounting Pronouncements

In August 2001, the FASB issued Statement No. 143, "Accounting for Asset Retirement Obligations" (FAS 143). FAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated retirement costs. The Company is in the process of assessing the effect of adopting FAS 143, which will be effective for the Company's year ending December 31, 2003.

In June 2002, the FASB issued Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (FAS 146), which provides guidance related to accounting for costs associated with disposal activities covered by Statement No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets" or with exit or restructuring activities previously covered by EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." FAS 146 supersedes EITF Issue No. 94-3 in its entirety. FAS 146 requires that costs related to exiting an activity or to a restructuring not be recognized until the liability is incurred. FAS 146 will be applied prospectively to exit or disposal activities that are initiated after December 31, 2002.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. Our adoption of FIN 45 did not have a material impact on our results of operations and financial position.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" (FAS 148). FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional



disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options and have made disclosures in accordance with FAS 148.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A variable interest entity is a corporation, partnership, trust, or any other legal structures used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in research and development or other activities on behalf of another company. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The adoption of FIN 46 is not expected to have a material impact on our results of operations and financial position, because we do not have any transactions involving variable interest entities.

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

**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 daclizumab (marketed for prevention of kidney transplant rejection as Zenapax) for the potential treatment of autoimmune diseases, later amended to include asthma. 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 daclizumab in potential new autoimmune indications and will pay for these activities from our share of revenues. In Europe and certain other countries, Roche may choose to market daclizumab in autoimmune indications. In this case, we will receive a substantial portion of daclizumab revenue from these indications. For countries and indications for which Roche elects not to market, we will receive an exclusive license to market daclizumab and pay Roche a small royalty.

**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 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.

We have completed Phase I and Phase I/II clinical trials for the humanized anti-IL-4 antibody and are conducting 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, larger 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.

***Exelixis, Inc.*** In May 2001, we signed a collaborative agreement with Exelixis to discover and develop humanized antibodies for the diagnosis, prevention and treatment of cancer. We agreed to provide Exelixis with \$4.0 million in annual research funding for two or more years, and we purchased a \$30.0 million five year note convertible after the first year of the collaboration into Exelixis common stock. We received an exclusive, worldwide license to develop antibodies against certain targets identified by Exelixis that are involved in cell growth, cell death and proliferation. Exelixis has the right to co-fund development of antibodies resulting from the collaboration. Therefore we recognized the expense of research funding ratably over the periods for which it is performed. As of December 31, 2002, we have provided \$7.0 million in research funding to Exelixis of which we expensed \$4.0 million in 2002 and \$2.3 million in 2001. For antibody products we develop that Exelixis elects not to co-fund, we have agreed to make specified milestone payments and royalty payments on any product sales. We have notified Exelixis that we will not extend the research funding beyond the original two years.

***Igeneon AG.*** In July 2002, we signed an agreement with Igeneon AG, a European biotechnology company focused on cancer immunotherapies, for exclusive worldwide rights to develop and market HuABL364, a humanized antibody against the Lewis Y antigen. We received a licensing fee and milestone payments and may receive additional milestone payments and royalties on any product sales generated by the antibody.

#### *Humanization and Patent Licensing Arrangements*

***Wyeth.*** In December 1996, we entered into an agreement with Genetics Institute, now a wholly owned subsidiary of Wyeth, 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.

***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 milestone payments and are entitled to receive annual maintenance fees and royalties on any product sales.

**Celltech Group plc.** 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. In December 2001, Celltech obtained, pursuant to the exercise of certain of its rights under the agreement, a nonexclusive license for antibodies directed to tumor necrosis factor-alpha.

**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 paid us a signing and licensing fee, 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 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.

**MedImmune, Inc.** In December 2002, we entered into a patent rights agreement with MedImmune under our humanization patents for which they paid us an upfront fee. MedImmune can obtain up to three patent licenses for humanized antibodies upon payment of additional fees, as well as royalties on any product sales. MedImmune can obtain rights to obtain up to three additional patent licenses upon payment of additional fees.

**Other Patent License Agreements.** We have entered into patent license agreements with numerous other companies that are independently developing humanized antibodies, including Biogen, Chugai, Elan Pharmaceuticals, IDEC Pharmaceuticals, Medarex, Merck KgaA and Sankyo. In each license agreement, we granted a worldwide, exclusive or nonexclusive license under our patents to the other company for antibodies 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 have also entered into agreements to use our technology to humanize antibodies for other companies, including Ajinomoto, Mochida Pharmaceutical, Teijin, and Yamanouchi Pharmaceutical. In general, we received a licensing and signing fee and the right to receive additional payments upon the achievement of certain milestones and royalties on any product sales.

### 3. Accrued Liabilities

At December 31, 2002 and 2001 other accrued liabilities consisted of the following:

| (In thousands)          | <u>2002</u>     | <u>2001</u>     |
|-------------------------|-----------------|-----------------|
| Royalty expense         | \$ 385          | \$ 98           |
| Patent legal expense    | 230             | 176             |
| Construction in-process | 1,893           | 313             |
| Other                   | <u>2,068</u>    | <u>2,536</u>    |
| Total                   | <u>\$ 4,576</u> | <u>\$ 3,123</u> |

### 4. Commitments

We occupy leased facilities under agreements that expire in 2004, 2005 and 2009. We also have leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately \$1.3 million, \$0.9 million, and \$1.6 million for the years ended December 31, 2002, 2001 and 2000, respectively.

The total future minimum non-cancelable payments under these operating lease agreements are approximately as follows (in thousands):

|                          |                 |
|--------------------------|-----------------|
| Year Ending December 31, |                 |
| 2003                     | \$ 1,462        |
| 2004                     | 1,335           |
| 2005                     | 950             |
| 2006                     | 835             |
| 2007                     | 748             |
| Thereafter               | <u>891</u>      |
| Total                    | <u>\$ 6,221</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 estimated fair value, with unrealized gains and losses reported in accumulated other comprehensive income (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)   | <b>Available-for-Sale-Securities</b> |                                       |  |                                     |
|--|--------------------------------------|---------------------------------------|--|-------------------------------------|
|  | <b>Cost</b>                          | <b>Gross<br/>Unrealized<br/>Gains</b> | <b>Gross<br/>Unrealized<br/>Losses</b> | <b>Estimated<br/>Fair<br/>Value</b> |
| <b>December 31, 2002</b>   |                                      |                                       |  |                                     |
| Securities of the U.S.<br>Government and its agencies<br>maturing: |                                      |                                       |  |                                     |
| within 1 year  | \$ 50,935                            | \$ 556                                | \$ --                                  | \$ 51,491                           |
| between 1–3 years  | 121,257                              | 1,933                                 | --                                     | 123,190                             |
| U.S. corporate debt securities<br>maturing:                        |                                      |                                       |  |                                     |
| within 1 year  | 110,116                              | 2,444                                 | --                                     | 112,560                             |
| between 1–3 years  | <u>30,313</u>                        | <u>1,126</u>                          | <u>--</u>                              | <u>31,439</u>                       |
| Total marketable debt<br>securities                                | <u>\$ 312,621</u>                    | <u>\$ 6,059</u>                       | <u>\$ --</u>                           | <u>\$ 318,680</u>                   |
| <b>December 31, 2001</b>   |                                      |                                       |  |                                     |
| Securities of the U.S.<br>Government and its agencies<br>maturing: |                                      |                                       |  |                                     |
| within 1 year  | \$ 10,051                            | \$ 320                                | \$ --                                  | \$ 10,371                           |
| between 1–3 years  | 364,359                              | 4,648                                 | (421)                                  | 368,586                             |
| U.S. corporate debt securities<br>maturing:                        |                                      |                                       |  |                                     |
| within 1 year  | 5,112                                | 99                                    | --                                     | 5,211                               |
| between 1–3 years  | <u>141,138</u>                       | <u>4,741</u>                          | <u>--</u>                              | <u>145,879</u>                      |
| Total marketable debt<br>securities                                | <u>\$ 520,660</u>                    | <u>\$ 9,808</u>                       | <u>\$ (421)</u>                        | <u>\$ 530,047</u>                   |

During 2002, 2001 and 2000, 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

On August 22, 2000 and October 9, 2001, we effected two-for-one stock splits of our common stock, each 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 and September 18, 2001, respectively. Our stock began trading on a split-adjusted basis in 2000 as of August 23, 2000 and in 2001 as of October 10, 2001. The share and per share amounts in the accompanying financial statements and notes reflect the effect of these stock splits.

### Common Stock Reserved for Future Issuance

Shares of common stock of the Company reserved for future issuance at December 31, 2002 were as follows:

|                              |               |
|------------------------------|---------------|
| (In thousands)               |               |
| All stock option plans       | 20,650        |
| Employee Stock Purchase Plan | 1,183         |
| Convertible debt             | <u>3,974</u>  |
| Total                        | <u>25,807</u> |

### Stock Option Plans

#### *1991 Stock Option Plan*

In December 1991, the Board of Directors adopted the 1991 Stock Option Plan (1991 Plan). We reserved 16,000,000 shares of common stock for the grant of options under the 1991 Plan. At December 31, 2002, options to purchase 3,458,695 shares were outstanding under the 1991 Plan at prices ranging from \$3.41 to \$21.02. Options granted under the 1991 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. In the past, we have granted stock options to a limited number of non-employees (other than non-employee members of the Board of Directors). The compensation expense associated with these options was immaterial in all years presented.

At the 1999 Annual Meeting of Stockholders, stockholders approved the 1999 Stock Option Plan, including a provision whereby upon termination of the 1991 Plan, any shares remaining available for grant or which subsequently become available upon the termination of options outstanding under the 1991 Plan, if any, will be added automatically to the 1999 Stock Option Plan. As of December 31, 2002, 2,062,126 shares have been transferred to the 1999 Stock Option Plan.

#### *Outside Directors' Stock Option Plan*

In February 1992, the Board of Directors adopted the Outside Directors' Stock Option Plan (Directors' Plan). We reserved 800,000 shares of common stock for the grant of options under the Directors' Plan. Through December 31, 2002, the Company granted options to purchase 660,000 shares at exercise prices ranging from \$1.81 to \$11.22 per share, of which 100,000 shares were canceled.

At the 2002 Annual Meeting of Stockholders, stockholders approved that upon the termination of the Directors' Plan, any shares remaining available for grant or which would otherwise become available for grant upon the subsequent cancellation, termination or expiration of options outstanding will automatically become available for issuance under the 2002 Outside Directors Plan. As of December 31, 2002, 240,000 shares have been transferred to the 2002 Outside Directors Plan.

At December 31, 2002, options to purchase 224,000 shares were outstanding under the Directors' Plan. Options granted pursuant to the Directors' Plan vest monthly over five years. A total of 336,000 options were exercised under the Directors' Plan through December 31, 2002.

#### *1999 Nonstatutory Stock Option Plan*

In August 1999, the Board of Directors adopted the 1999 Nonstatutory Stock Option Plan (the Nonstatutory Option Plan) under which options may be granted to employees, prospective employees and consultants of the Company and any parent or subsidiary corporation. We reserved 4,000,000 shares of common stock for the grant of options under the Nonstatutory Option Plan.

In April 2001 and February 2003, the Board of Directors approved amendments to increase the shares reserved under the Nonstatutory Option Plan by 4,000,000 shares and 3,000,000 shares, respectively. The total number of shares reserved under the Nonstatutory Option Plan since its inception is 11,000,000.

As of December 31, 2002, 2,562,485 shares were available for grant.

Options may be granted under the Nonstatutory Option Plan with an exercise price established at the discretion of the Board of Directors, although all options granted to date have exercise prices equal to the market price of the Company's common stock on the date of grant. At December 31, 2002, options to purchase 4,668,767 shares were outstanding at a prices ranging from \$6.64 to \$56.84. 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. Certain options granted in August 1999 vested over a two year period beginning in September 1999. Options granted under the Nonstatutory Option Plan generally have a term of 10 years, although the Board of Directors may grant options with shorter or longer terms.

#### *1999 Stock Option Plan*

In April 1999, the Board of Directors adopted the 1999 Stock Option Plan (the 1999 Option Plan), which was approved by our stockholders in June 1999. We reserved 3,700,000 shares of common stock for the grant of options under the 1999 Option Plan.

In April and June 2001, respectively, the Board of Directors and stockholders approved an amendment to the Company's 1999 Option Plan to increase the number of shares reserved for issuance by a total of 4,000,000 shares. Upon termination of the 1991 Plan, any shares remaining available for grant or which subsequently become available upon the termination of options outstanding under the 1991 Plan, if any, will be added automatically to the 1999 Option Plan. As of December 31, 2002, 2,062,126 shares have been transferred to the 1999 Option Plan. The total number of shares reserved under the 1999 Option Plan since inception is 9,762,126.

As of December 31, 2002, 5,299,020 shares were available for grant.

At December 31, 2002, options to purchase 3,958,980 shares were outstanding at a prices ranging from \$6.64 to \$35.81. 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 vested over a two year period beginning in September 1999.

#### *2002 Outside Directors Plan*

In December 2001, the Board of Directors adopted the 2002 Outside Directors Plan (2002 Directors Plan) to replace the Company's Directors' Plan, subject to and effective upon its approval by the stockholders. We reserved 240,000 shares of common stock for the grant of options under the 2002 Directors Plan. In June 2002, at the 2002 Annual Meeting of Stockholders, our stockholders approved the 2002 Directors Plan including a provision whereby upon termination of the Directors' Plan, any shares remaining available for grant or which subsequently become available upon the termination of options outstanding under the Directors' Plan, if any, will be added automatically to the 2002 Directors Plan. As of December 31, 2002, 240,000 shares have been transferred to the 2002 Directors Plan.

Through December 31, 2002 the Company has not granted any shares against this plan. Options granted under the 2002 Directors Plan vest monthly over five years. The total number of shares reserved under the 2002 Directors Plan is 480,000 shares.

A summary of the status of our stock option plans at December 31, 2002, 2001 and 2000, and changes during the years ending those dates is presented below.

(In thousands, except exercise price data)

|  | 2002          |                                 | 2001          |                                 | 2000         |                                 |
|--|---------------|---------------------------------|---------------|---------------------------------|--------------|---------------------------------|
|  | Shares        | Weighted Average Exercise Price | Shares        | Weighted Average Exercise Price | Shares       | Weighted Average Exercise Price |
| Outstanding at beginning of year                               | 10,528        | \$18.40                         | 9,575         | \$13.90                         | 10,712       | \$ 5.89                         |
| Granted  | 3,427         | 13.46                           | 3,142         | 28.41                           | 3,413        | 28.14                           |
| Exercised  | (516)         | 5.63                            | (1,274)       | 8.29                            | (3,768)      | 5.69                            |
| Forfeited  | (1,129)       | 22.45                           | (915)         | 20.18                           | (782)        | 11.87                           |
| Outstanding at end of year                                     | <u>12,310</u> | 17.18                           | <u>10,528</u> | 18.40                           | <u>9,575</u> | 13.90                           |
| Exercisable at end of year                                     | <u>5,975</u>  |                                 | <u>3,799</u>  |                                 | <u>2,612</u> |                                 |
| Weighted average fair value of options granted during the year |               | <u>\$10.72</u>                  |               | <u>\$21.55</u>                  |              | <u>\$26.63</u>                  |

The following information applies to all stock options outstanding under our stock option plans at December 31, 2002:

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

| Range of Exercise Prices | Number Outstanding | Outstanding   |                                 | Exercisable        |                                 |
|--------------------------|--------------------|---|---------------------------------|--------------------|---------------------------------|
|                          |                    | Weighted Average Remaining Contractual Life (years) | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| \$ 3.41 - \$ 4.25        | 1,394              | 5.02  | \$ 4.18                         | 1,279              | \$ 4.17                         |
| \$ 4.28 - \$ 8.30        | 2,226              | 7.13  | 7.12                            | 1,160              | 6.18                            |
| \$ 8.55 - \$10.62        | 1,750              | 6.98  | 9.35                            | 757                | 9.60                            |
| \$ 10.94 - \$18.90       | 1,861              | 8.76  | 16.83                           | 327                | 14.08                           |
| \$ 19.97 - \$23.24       | 1,904              | 7.54  | 21.16                           | 1,058              | 21.05                           |
| \$ 23.46 - \$27.50       | 1,748              | 8.36  | 27.19                           | 713                | 27.25                           |
| \$ 27.83 - \$38.56       | 705                | 8.13  | 32.57                           | 318                | 32.95                           |
| \$ 38.78 - \$56.84       | <u>722</u>         | 7.95  | 43.53                           | <u>363</u>         | 44.12                           |
| Totals                   | <u>12,310</u>      |   | \$17.18                         | <u>5,975</u>       | \$15.50                         |

#### 1993 Employee Stock Purchase Plan

In February 1993, the Board of Directors adopted the 1993 Employee Stock Purchase Plan (Employee Purchase Plan). We reserved 2,400,000 shares of common stock for the purchase of shares by employees under the Employee Purchase Plan. At December 31, 2002, 1,183,361 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 2002, an aggregate of 163,369 shares were purchased by employees under the Employee Purchase Plan at prices of \$9.231 or \$7.225 per share.

## 7. Income Taxes

The provision for income taxes consists of the following:

|               | <b>Years Ended December 31,</b> |                    |                    |
|---------------|---------------------------------|--------------------|--------------------|
|               | <b><u>2002</u></b>              | <b><u>2001</u></b> | <b><u>2000</u></b> |
| Current:      |                                 |                    |                    |
| Federal       | \$ -                            | \$ -               | \$ -               |
| State         | 12                              | 12                 | 5                  |
| Foreign       | 30                              | -                  | -                  |
| Total Current | <u>\$ 42</u>                    | <u>\$ 12</u>       | <u>\$ 5</u>        |

A reconciliation of the income tax provision (benefit) at the statutory federal income tax rate compared to federal income taxes included in the accompanying statements of operations is as follows:

|  | <b><u>Year Ended December 31,</u></b> |                    |                    |
|--|---------------------------------------|--------------------|--------------------|
|  | <b><u>2002</u></b>                    | <b><u>2001</u></b> | <b><u>2000</u></b> |
| Computed at U.S. statutory rate            |                                       |                    |                    |
| At statutory rate                          | \$ (5,079)                            | \$ 930             | \$ 228             |
| Unutilized (utilized) net operating losses | 5,079                                 | (930)              | (228)              |
| State taxes                                | 12                                    | 12                 | 5                  |
| Foreign taxes                              | <u>30</u>                             | <u>--</u>          | <u>--</u>          |
| Total                                      | <u>\$ 42</u>                          | <u>\$ 12</u>       | <u>\$ 5</u>        |

As of December 31, 2002, we have federal and California state net operating loss carryforwards of approximately \$255.0 million and \$46.0 million, respectively. We also have federal and California state research and other tax credit carryforwards of approximately \$7.4 million and \$6.7 million, respectively. The federal net operating loss and credit carryforwards will expire at various dates beginning in the year 2003 through 2022, if not utilized. The California state net operating losses will expire at various dates beginning in 2004 through 2012, 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.

Deferred income taxes reflect the net effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our net deferred tax assets as of December 31 are as follows:

| (In thousands)                             | <u>2002</u>      | <u>2001</u>      |
|--|------------------|------------------|
| Deferred tax assets:                       |                  |                  |
| Net operating loss carryforwards           | \$ 89,410        | \$ 86,430        |
| Research and other credits                 | 11,910           | 11,390           |
| Deferred revenue                           | 20               | 40               |
| Capitalized research and development       | 8,090            | 6,960            |
| Other                                      | <u>730</u>       | <u>1,760</u>     |
| Total deferred tax assets                  | 110,160          | 106,580          |
| Valuation allowance for deferred tax asset | <u>(107,740)</u> | <u>(103,390)</u> |
| Total deferred tax assets                  | 2,420            | 3,190            |
| Deferred Tax Liabilities                   |                  |                  |
| Unrealized gains on investments            | <u>2,420</u>     | <u>3,190</u>     |
| Total deferred tax liabilities             | <u>2,420</u>     | <u>3,190</u>     |
| Net Deferred Tax Assets                    | <u>\$ --</u>     | <u>\$ --</u>     |

Because of our lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$4.4 million, \$11.4 million and \$56.8 million during 2002, 2001 and 2000, respectively.

Approximately \$69.0 million of the deferred tax assets at December 31, 2002 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 have appealed this decision. 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 and we have filed our

response to the European Patent Office. Oral hearings are scheduled to take place in October 2003. 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 received a decision from the Japanese Opposition Board in March 2001, supporting one aspect of the position of the opponents, and we filed a response in September 2001. In April 2002, the examiner issued a further Office Action maintaining the earlier decision of the Opposition Board, to which we filed an additional response in May 2002. We now await a final decision from the examiner. If the examiner maintains her earlier decision, we will have the opportunity to appeal to the Tokyo High Court. The patent will remain valid and enforceable during this appeal process. If this appeal is unsuccessful, we will then have an opportunity to appeal to the Japanese Supreme Court.

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, which have an approximate carrying amount of \$24.8 million, and is subject to the terms and covenants of the loan agreement.

At December 31, 2002 the maturities of principal payments under this term loan are approximately as follows (in thousands):

| <b>Year Ending December 31,</b> |                 |
|---------------------------------|-----------------|
| 2003                            | \$ 466          |
| 2004                            | 502             |
| 2005                            | 543             |
| 2006                            | 587             |
| 2007                            | 635             |
| Thereafter                      | <u>6,159</u>    |
| Total                           | <u>\$ 8,892</u> |

The fair value of the loan at December 31, 2002 is approximately \$9.7 million. The fair value of the remaining payments under the loan is estimated using discounted cash flow analyses, based on the Company's current incremental borrowing rate for similar types of borrowing arrangements.

## 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 at the holders' option into our common stock at a conversion price of \$37.75 per share, subject to adjustment as a result of certain events. 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, 2002 was \$2.1 million and \$1.3 million at December 31, 2001. The estimated fair value of the convertible subordinated notes at December 31, 2002 is \$123.0 million based upon publicly available pricing information for the notes.

## **11. Subsequent Events**

In February 2003, we announced the signing of a definitive merger agreement with Eos Biotechnology, Inc., a South San Francisco-based antibody discovery company, for approximately 4.3 million shares of our common stock. The acquisition is expected to close early in the second quarter of 2003. In connection with the merger, we expect to record a charge related to acquired in-process research and development. We will report the purchase accounting effects of the merger in our financial results for the period in which the transaction closes. Upon closing, we will have expanded our research personnel and added new capabilities in antibody target identification and validation, particularly in oncology. We also obtained two pre-clinical antibody product candidates, one of which is expected to initiate clinical investigation for potential treatment of solid tumors in the first half of 2003, and the second, in early 2004.

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, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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. at December 31, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 4, 2003

# **QUARTERLY FINANCIAL DATA (UNAUDITED)**

|   | <b>2002 Quarter Ended</b> |                            |                       |                        |
|---|---------------------------|----------------------------|-----------------------|------------------------|
|   | <b><u>December 31</u></b> | <b><u>September 30</u></b> | <b><u>June 30</u></b> | <b><u>March 31</u></b> |
| <b>Revenues:</b>  |                           |                            |                       |                        |
| Royalties   | \$ 7,263                  | \$ 5,991                   | \$ 13,491             | \$ 13,676              |
| License and other   | <u>3,450</u>              | <u>551</u>                 | <u>1,300</u>          | <u>651</u>             |
| Total revenues  | 10,713                    | 6,542                      | 14,791                | 14,327                 |
| <b>Costs and expenses:</b>  |                           |                            |                       |                        |
| Research and development  | 15,733                    | 14,306                     | 14,760                | 13,178                 |
| General and administrative  | <u>5,416</u>              | <u>4,735</u>               | <u>4,787</u>          | <u>4,155</u>           |
| Total costs and expenses  | <u>21,149</u>             | <u>19,041</u>              | <u>19,547</u>         | <u>17,333</u>          |
| Operating loss  | (10,436)                  | (12,499)                   | (4,756)               | (3,006)                |
| Interest income   | 5,843                     | 6,542                      | 6,455                 | 7,138                  |
| Interest expense  | (1,910)                   | (2,034)                    | (2,242)               | (2,240)                |
| Impairment loss on investment                                     | <u>(1,366)</u>            | <u>--</u>                  | <u>--</u>             | <u>--</u>              |
| Incom (loss) before income taxes                                  | (7,869)                   | (7,991)                    | (543)                 | 1,892                  |
| Provision for income taxes  | <u>15</u>                 | <u>--</u>                  | <u>16</u>             | <u>11</u>              |
| <b>Net income (loss)</b>  | <u>\$ (7,884)</u>         | <u>\$ (7,991)</u>          | <u>\$ (559)</u>       | <u>\$ 1,881</u>        |
| <b>Net income (loss) per share:</b>                               |                           |                            |                       |                        |
| Basic   | <u>\$ (0.09)</u>          | <u>\$ (0.09)</u>           | <u>\$ (0.01)</u>      | <u>\$ 0.02</u>         |
| Diluted   | <u>\$ (0.09)</u>          | <u>\$ (0.09)</u>           | <u>\$ (0.01)</u>      | <u>\$ 0.02</u>         |
| <b>Shares used in computation of net income (loss) per share:</b> |                           |                            |                       |                        |
| Basic   | <u>89,063</u>             | <u>88,999</u>              | <u>88,751</u>         | <u>88,645</u>          |
| Diluted   | <u>89,063</u>             | <u>88,999</u>              | <u>88,751</u>         | <u>91,750</u>          |

The sums of the quarters do not equal the annual amounts due to rounding.

|   | 2001 Quarter Ended |                     |                 |                 |
|---|--------------------|---------------------|-----------------|-----------------|
|   | <u>December 31</u> | <u>September 30</u> | <u>June 30</u>  | <u>March 31</u> |
| <b>Revenues:</b>  |                    |                     |                 |                 |
| Royalties   | \$ 5,631           | \$ 4,905            | \$ 10,462       | \$ 9,606        |
| License and other   | <u>1,300</u>       | <u>3,150</u>        | <u>2,221</u>    | <u>7,125</u>    |
| Total revenues  | 6,931              | 8,055               | 12,683          | 16,731          |
| <b>Costs and expenses:</b>  |                    |                     |                 |                 |
| Research and development  | 13,831             | 12,459              | 12,207          | 13,665          |
| General and administrative  | <u>4,318</u>       | <u>3,735</u>        | <u>4,052</u>    | <u>3,619</u>    |
| Total costs and expenses  | <u>18,149</u>      | <u>16,194</u>       | <u>16,259</u>   | <u>17,284</u>   |
| Operating loss  | (11,218)           | (8,139)             | (3,576)         | (553)           |
| Interest income   | 8,115              | 8,616               | 8,966           | 9,439           |
| Interest expense  | <u>(2,245)</u>     | <u>(2,248)</u>      | <u>(2,250)</u>  | <u>(2,248)</u>  |
| Income (loss) before income taxes                                 | (5,348)            | (1,771)             | 3140            | 6,638           |
| Provision for income taxes  | <u>--</u>          | <u>5</u>            | <u>--</u>       | <u>7</u>        |
| <b>Net income (loss)</b>  | <u>\$ (5,348)</u>  | <u>\$ (1,776)</u>   | <u>\$ 3,140</u> | <u>\$ 6,631</u> |
| <b>Net income (loss) per share:</b>                               |                    |                     |                 |                 |
| Basic   | <u>\$ (0.06)</u>   | <u>\$ (0.02)</u>    | <u>\$ 0.04</u>  | <u>\$ 0.08</u>  |
| Diluted   | <u>\$ (0.06)</u>   | <u>\$ (0.02)</u>    | <u>\$ 0.03</u>  | <u>\$ 0.07</u>  |
| <b>Shares used in computation of net income (loss) per share:</b> |                    |                     |                 |                 |
| Basic   | <u>88,103</u>      | <u>87,718</u>       | <u>87,444</u>   | <u>87,230</u>   |
| Diluted   | <u>88,103</u>      | <u>87,718</u>       | <u>93,184</u>   | <u>92,564</u>   |

The sums of the quarters do not equal the annual amounts due to rounding.

## **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 2002 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. CONTROLS AND PROCEDURES**

(a) Under the supervision and with the participation of our management, including our principal executive officer and principal accounting officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), within 90 days of the filing date of this report. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures are effective.



(b) There have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referenced in paragraph (a) above.

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K**

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

**99.1** 906 Certification for Chief Executive Officer

**99.2** 906 Certification for Principal Accounting Officer

(1) Index to financial statements

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

| <b>Item</b>                                       | <b>Page</b> |
|---|-------------|
| Consolidated Balance Sheets                       | —           |
| Consolidated Statements of Operations             | —           |
| Consolidated Statements of Stockholders' Equity   | —           |
| Consolidated Statements of Cash Flows             | —           |
| Notes to Consolidated Financial Statements        | —           |
| Report of Ernst & Young LLP, Independent Auditors | —           |

(2) All financial statement schedules are omitted because the information is inapplicable or presented in our Financial Statements or notes.

(3) The items listed on the Index to Exhibits on page 76 are incorporated herein by reference.

(b) Reports on Form 8-K.

None

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

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

## SIGNATURES

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

PROTEIN DESIGN LABS, INC.  
(Registrant)

By: /s/ Mark McDade  
Mark McDade,  
Chief Executive Officer

March 31, 2003  
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

| <b>Signature</b>                             | <b>Title</b>   | <b>Date</b>    |
|--|--|----------------|
| /s/ Mark McDade<br>(Mark McDade)             | Chief Executive Officer and Director<br>(Principal Executive Officer)                                  | March 31, 2003 |
| /s/ Robert L. Kirkman<br>(Robert L. Kirkman) | Vice President, Business Development<br>and Corporate Communications<br>(Principal Accounting Officer) | March 31, 2003 |
| <br>(Laurence Jay Korn)                      | Chairman of the Board of Directors   | March , 2003   |
| /s/ Jon S. Saxe<br>(Jon S. Saxe)             | Director   | March 31, 2003 |
| /s/ Cary L. Queen<br>(Cary L. Queen)         | Director   | March 31, 2003 |
| /s/ George M. Gould<br>(George M. Gould)     | Director   | March 31, 2003 |
| /s/ Max Link<br>(Max Link)                   | Director   | March 31, 2003 |
| /s/ Jürgen Drews<br>(Jürgen Drews)           | Director   | March 31, 2003 |
| /s/ L. Patrick Gage<br>(L. Patrick Gage)     | Director   | March 31, 2003 |

## CERTIFICATION

I, Mark McDade, certify that:

1. I have reviewed this annual report on Form 10-K of Protein Design Labs Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the periodic reports are being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report ("Evaluation Date"); and
  - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ Mark McDade  
Mark McDade  
Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Robert L. Kirkman, certify that:

1. I have reviewed this annual report on Form 10-K of Protein Design Labs Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the periodic reports are being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report ("Evaluation Date"); and
  - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ Robert L. Kirkman  
Robert L. Kirkman  
Vice President, Business  
Development and Corporate  
Communications  
(Principal Accounting Officer)

## INDEX TO EXHIBITS

| <b><u>Exhibit<br/>Number</u></b> | <b><u>Exhibit Title</u></b>  | <b><u>Page No.</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 Quarterly Report on Form 10-Q filed May 15, 2000.)   |                        |
| 3.3                              | Amended Certificate of Incorporation. (Incorporated by reference to Exhibit 3.3 to Annual Report on Form 10-K filed March 14, 2002).   |                        |
| 3.4                              | Amended and Restated Bylaws.   |                        |
| *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 Agreement. (Incorporated by reference to Exhibit 10.1 to Annual Report on Form 10-K filed March 31, 1996.)   |                        |
| *10.2                            | 1991 Stock Option Plan, as amended on October 17, 1996. (Incorporated by reference to Exhibit 10.2 to Annual Report on Form 10-K filed March 14, 2002).  |                        |
| *10.3                            | 1993 Employee Stock Purchase Plan, as amended on June 29, 2000. (Incorporated by reference to Exhibit 10.3 to Annual Report on Form 10-K filed March 14, 2002).  |                        |
| 10.4                             | 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.)   |                        |
| 10.5                             | 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.)   |                        |
| 10.6                             | 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.)                |                        |
| 10.7                             | 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.) |                        |
| *10.8                            | 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.)   |                        |
| 10.9                             | 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.)                                      |                        |
| 10.10                            | 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.)   |                        |
| 10.11                            | 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.)   |                        |
| 10.12                            | 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.)  |                        |

| <b><u>Exhibit<br/>Number</u></b> | <b><u>Exhibit Title</u></b>   | <b><u>Page No.</u></b> |
|----------------------------------|---|------------------------|
| *10.13                           | 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.)   |                        |
| *10.14                           | Outside Directors Stock Option Plan as amended on June 29, 2000 together with form of Nonqualified Stock Option Agreement. (Incorporated by Reference to Exhibit 10.36 to Annual Report on Form 10-K filed March 30, 2001.)   |                        |
| *10.15                           | Outside Directors Stock Option Plan as amended on October 18, 2001 together with forms of Nonqualified Stock Option Agreement and Amendment of Nonqualified Stock Option Agreement for Outside Director.  |                        |
| 10.16                            | 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.)                     |                        |
| 10.17                            | 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.)      |                        |
| 10.18                            | 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.)  |                        |
| 10.19                            | 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.)      |                        |
| 10.20                            | 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.)                       |                        |
| 10.21                            | 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.)                 |                        |
| 10.22                            | 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.)             |                        |
| 10.23                            | 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.) |                        |
| 10.24                            | 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.)                            |                        |
| *10.25                           | 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.)   |                        |

**Exhibit**

| <b><u>Number</u></b> | <b><u>Exhibit Title</u></b>   | <b><u>Page No.</u></b> |
|----------------------|---|------------------------|
| *10.26               | 1999 Stock Option Plan, as amended on June 14, 2001. (Incorporated by reference to Exhibit 10.27 to Annual Report on Form 10-K filed March 14, 2002).   |                        |
| 10.27                | 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.)   |                        |
| 10.28                | 1999 Nonstatutory Stock Option Plan as amended on December 14, 2000 and on April 25, 2001. (Incorporated by reference to Exhibit 10.27 to Annual Report on Form 10-K filed March 14, 2002).   |                        |
| 10.29                | Indenture Agreement between the Company and Chase Manhattan Bank And Trust Company, National Association, a national banking association, dated February 15, 2000. (Incorporated by Reference to Exhibit 10.33 to Annual Report on Form 10-K filed March 30, 2000.)   |                        |
| 10.30                | Registration Rights Agreement for the Company's 5.50% Convertible Subordinated Notes due February 15, 2007, dated February 15, 2000. (Incorporated by Reference to Exhibit 10.34 to Annual Report on Form 10-K filed March 30, 2000.)   |                        |
| 10.31                | 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.) |                        |
| 10.32                | Amendment No. 2 to Amended And Restated Agreement dated February 23, 2001 by and among the Company, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd. (Incorporated by Reference to Exhibit 10.38 to Annual Report on Form 10-K filed March 30, 2001.)   |                        |
| 10.33                | Amendment No. 1 to Amended And Restated Agreement dated February 23, 2001 between the Company and F. Hoffmann-La Roche Ltd. (Incorporated by Reference to Exhibit 10.39 to Annual Report on Form 10-K filed March 30, 2001.)  |                        |
| 10.34                | Collaboration Agreement between the Company and Exelixis, Inc., a Delaware corporation dated May 22, 2001 (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, 2001.)   |                        |
| 10.35                | Convertible Note between the Company and Exelixis, Inc., a Delaware corporation dated May 22, 2001. (Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed August 14, 2001.)   |                        |
| 10.36                | Note Purchase Agreement between the Company and Exelixis, Inc., a Delaware corporation dated May 22, 2001. (Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 14, 2001.)  |                        |
| 10.37                | Lease Agreement between the Company and St. Paul Properties, Inc., a Delaware corporation, dated May 31, 2001. (Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 14, 2001.)  |                        |
| 10.38                | Lease Agreement between the Company and John Arrillaga Survivor's Trust and the Richard T. Peery Separate Property Trust, a California general partnership, dated June 28, 2001. (Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed August 14, 2001.)  |                        |
| *10.39               | Executive Retention and Severance Plan adopted by the Company on October 10, 2001, together with forms of Participation Agreement and Release of Claims Agreement. (Incorporated by reference to Exhibit 10.40 to Annual Report on Form 10-K filed March 14, 2002).   |                        |
| *10.40               | 2002 Outside Directors Plan together with Form of Nonqualified Stock Option Agreement. (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10Q filed June 30, 2002).   |                        |
| *10.41               | Form of Notice of Grant of Stock Option under the 1999 Stock Option Plan. (Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10Q filed June 30, 2002).  |                        |
| *10.42               | Form of Notice of Grant of Stock Option under the 1999 Nonstatutory Plan. (Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10Q filed June 30, 2002).  |                        |

- \*10.43 Special Compensation and Continued Employment Agreement by and between the Company and Dr. Laurence J. Korn dated May 1, 2002. (Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10Q filed June 30, 2002).
- \*10.44 Stock Option Agreement by and between the Company and Mr. Douglas O. Ebersole dated April 25, 2002. (Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10Q filed June 30, 2002).
- \*10.45 Notice of Grant of Stock Option by and between the Company and Mr. Douglas O. Ebersole dated April 25, 2002. (Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10Q filed June 30, 2002).
- \*10.46 Offer Letter by and between the Company and Mr. Mark McDade dated October 24, 2002.
- \*10.47 Notice of Grant of Stock Option by and between the Company and Mr. Mark McDade dated October 24, 2002.
- \*10.48 Stock Option Agreement by and between the Company and Mr. Douglas O. Ebersole dated October 24, 2002.
- \*10.49 Notice of Grant of Stock Option by and between the Company and Mr. Douglas O. Ebersole dated October 24, 2002.
- 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.
- 99.1 906 Certification for Chief Executive Officer
- 99.2 906 Certification for Principal Accounting Officer

\* Management contract or compensatory plan or arrangement.