

# 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, 2003**

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 30, 2003, as reported on the NASDAQ National Market System, was approximately \$1,291,200,000.

As of January 30, 2004, the registrant had outstanding 93,936,069 shares of common stock.

#### DOCUMENTS INCORPORATED BY REFERENCE

None.

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 Humanizing Science are registered U.S. trademarks, and the PDL logo and HuZAF are trademarks of Protein Design Labs, Inc. Zenapax is a registered U.S. trademark of Hoffmann-La Roche and affiliates (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 patented antibody humanization technology is applied to promising mouse antibodies. By making certain modifications to the mouse antibody that make it more like a human antibody, our technology enhances the utility of such antibodies, while retaining their biological activity, for human therapeutic use. We believe our technology for the creation of humanized therapeutic monoclonal antibodies is the most widely validated in our industry. As of December 31, 2003, a total of six marketed products were licensed under our humanization patents and we are aware of at least approximately 40 humanized antibodies in clinical stage development worldwide by various pharmaceutical and biotechnology companies. Most of these humanized antibodies are potentially covered under patent agreements with PDL.

Since our founding in 1986, we have actively licensed our antibody humanization technology to, and performed humanization services for, pharmaceutical and biotechnology partners. To date, we have entered into numerous patent licensing agreements, and the resulting fees, milestones and related royalty revenues currently are the primary source of our revenues. In 2003, we recognized total royalties exceeding \$52 million on five licensed antibody products. Licensed antibody products for which we have recognized revenue in 2003 include Zenapax®, Mylotarg®, Synagis®, Herceptin® and Xolair®. Zenapax, Mylotarg and Synagis are marketed by Roche, Wyeth, and MedImmune, respectively, and Herceptin and Xolair are marketed by Genentech, Inc. (Genentech) and Genentech's partners. Additionally, Genentech has exercised licenses for its Raptiva™ and Avastin™ antibody products, which

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were approved, by the U.S. Food and Drug Administration (FDA) in October 2003 and February 2004, respectively. As royalty revenue is recognized one quarter following the quarter in which sales occurred, we will receive royalties on sales of Raptiva beginning in the first quarter of 2004 and on sales of Avastin in the second quarter of 2004.

We are leveraging our expertise in antibody humanization to become a fully integrated biopharmaceutical company that creates, develops, manufactures and in North America, markets, proprietary biopharmaceutical products. Toward that end, we currently have four antibodies in clinical development for various disease indications with a near-term emphasis on autoimmune diseases, in particular inflammatory bowel disease, or IBD, and cancer. For each product in clinical development, we conduct multiple activities, including preclinical studies, process development and antibody manufacturing at our facilities in Fremont, California and Plymouth, Minnesota. Revenues generated by our licensing activities and related royalties have contributed to our ability to significantly offset internal development costs associated with developing our proprietary antibody product candidates.

Based on the strength of our proprietary platform, the number of antibody programs we have in development and the flexibility provided by our current financial position, our goal for our existing pipeline is to initiate at least one pivotal clinical trial by 2005 and, if successful, to launch our first PDL-developed proprietary product into the North American market by the end of 2007. We currently believe that we would be able to achieve positive cash flow based upon revenues from our product sales. Since our goal is to launch our first product or products into the North American market by 2007, our ability to achieve this cash-flow positive position would not occur sooner than that, if we were successful.

### BUSINESS AND COMMERCIALIZATION STRATEGY

Our current business strategy is to transition from a company dependent on licensing activities, humanization services and royalties as the primary source of revenues to a commercial enterprise that derives the majority of its revenues from sales of its proprietary products.

During 2003, we established initiatives and implemented activities to further improve our capabilities in support of the longer-range objective of marketing a proprietary drug in North America by 2007. In research, we made significant progress in increasing productivity from our ongoing discovery efforts to derive a steady flow of new antibody candidates available for development. In clinical development, we have defined a clear set of product requirements for each step of the development process, with broader and more experienced teams managing these efforts.

As a result of our efforts to refine our clinical development programs, our near-term pipeline now is focused on the two most prevalent inflammatory bowel disease subtypes, ulcerative colitis and Crohn's disease. In terms of potential timeline for registration, our two most advanced clinical-stage programs are Nuvion (visilizumab) for potential treatment of severe steroid-refractory ulcerative colitis, and daclizumab for potential treatment of moderate-to-severe ulcerative colitis. Additionally, in 2003, we reacquired rights from Roche to market and manufacture the daclizumab (Zenapax®) humanized antibody in indications other than transplantation, and we obtained an option to acquire rights in transplant indications no later than 2007 and as early as 2005 at the election of Roche. We believe that the market potential for daclizumab could be expanded beyond transplantation through potential development of this already-marketed antibody in IBD and other autoimmune or inflammatory disease indications, such as multiple sclerosis (MS) and asthma.

We believe our current clinical development programs address areas of significant unmet medical need that could, at least in North America, effectively be serviced with a relatively small sales force. If our programs are successful in later stage trials, and subsequently gain regulatory approval for therapeutic use in the United States and Canada, we hope to create by 2007 a North American sales and marketing operation related to our core therapeutic focus in inflammatory bowel disease. We also

expect to develop a PDL sales and marketing capability in transplantation in connection with the anticipated reversion of rights to manufacture and market daclizumab, and we believe such infrastructure would be complementary to our potential marketing needs as they relate to Nuvion for severe ulcerative colitis.

We have retained worldwide rights to the products we are currently developing. While our goal is to market our products in North America, for all our products in development, we may out-license rights, even within the United States, to other biotechnology or pharmaceutical companies with respect to certain indications requiring specific expertise or large development and marketing efforts, such as MS or some oncology indications. In addition, we may receive upfront fees, milestone payments and/or other types of funding, in addition to possible royalties or other profit-sharing arrangements on any product sales by such marketing partners.

## PDL PRODUCTS IN CLINICAL STAGE DEVELOPMENT

The following table summarizes the potential therapeutic applications and development status for our clinical development programs. Not all clinical trials for each program are listed. The development and commercialization of our product candidates are subject to numerous risks and uncertainties, as noted in our "Risk Factors."

Antibody Product	Indication(s)	Status
Zenapax (daclizumab, anti-IL-2 receptor)	Prevention of acute kidney transplant rejection Moderate-to-severe ulcerative colitis Multiple sclerosis*	Marketed/Roche Phase II Phase I / II
Nuvion (visilizumab, anti-CD3)	Asthma	Phase II
HuZAF (fontolizumab, anti-gamma-interferon)	Severe steroid-refractory ulcerative colitis	Phase I / II
M200 (anti-a5b1 integrin)	Crohn's disease Advanced solid tumors	Phase II Phase I

\* Investigator-sponsored trial.

**Daclizumab (Zenapax, anti-IL-2 receptor).** The FDA approved daclizumab in December 1997 for the prevention of acute kidney transplant rejection, making it the first humanized antibody to be approved anywhere in the world. It has since been approved in Europe and a number of other countries. Our licensee, Roche, sells Zenapax in the United States, Europe and other territories for the kidney transplant indication and we receive royalties on Zenapax sales.

Effective October 2003, we amended our 1999 collaborative agreement with Roche and now have exclusive worldwide rights to market, develop, manufacture and sell daclizumab in all disease indications other than transplantation. Roche currently is expected to continue to market Zenapax in transplantation indications until 2007, although an earlier transfer to us of rights in transplantation may occur at Roche's election upon six months' written notice.

In connection with the new arrangement, we paid Roche \$80 million in cash for return of exclusive rights in indications other than transplantation, and we obtained an option to acquire rights in transplant indications no later than 2007 and as early as 2005 at the election of Roche. To effectuate the transfer of Zenapax in the transplantation indications, we will pay an additional exercise fee to Roche based on the average annual gross sales of Zenapax during the period from January 1, 2004,

through either the calendar quarter prior to the date of notice of the exercise, or Roche's notice of its decision to transfer the rights to us prior to our exercise date. If we do not receive transplantation rights, we would pay modest royalties to Roche on any sales in all diseases other than transplantation, and we would continue to receive royalties on sales of Zenapax in transplantation.

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 normal immune response as well as 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.

We are evaluating daclizumab in a Phase II clinical study, initiated in the second quarter of 2003, in patients with moderate-to-severe ulcerative colitis. This randomized, placebo-controlled Phase II clinical trial was fully enrolled by the end of December 2003 with more than 150 patients randomized, and we currently anticipate that results will be available by the end of the second quarter of 2004.

In addition to our work in ulcerative colitis, a Phase II trial of daclizumab in severe asthma is fully enrolled. We expect to report results from this trial in March 2004 at the American Academy of Allergy, Asthma & Immunology (AAAAI) meeting. This Phase II randomized, double blind, placebo-controlled clinical trial enrolled 116 patients who suffer from chronic, persistent asthma and whose disease is not well controlled with high doses of inhaled corticosteroids. Objectives of the study are to obtain safety and preliminary efficacy data.

In a pilot study conducted in 2002 and 2003 through the National Institutes of Health, daclizumab was evaluated in combination with interferon-beta therapy in patients with relapsing-remitting multiple sclerosis (MS) who had partially or completely failed to respond to interferon-beta therapy. In that study, daclizumab was well tolerated and led to a greater than 75% reduction in inflammatory activity in the majority of patients, as measured by reduction in contrast-enhanced MRI-scanned lesions. We believe that the resources and market expertise of a collaborative partner experienced in MS could facilitate the late-stage development and marketing of daclizumab in this indication. Consequently, we are seeking to establish a collaboration with such a partner for development of daclizumab in MS.

Daclizumab also is being evaluated in investigator-sponsored studies for uveitis, type I diabetes, aplastic anemia and the ocular manifestations of Behcet's disease. We are not currently planning to pursue registration for these indications; however, additional clinical studies may be conducted by our licensee, Roche, or by physician investigators.

**Nuvion (visilizumab, anti-CD3).** Visilizumab is in Phase I/II clinical studies in patients with severe ulcerative colitis that is refractory to treatment with intravenous steroids. This humanized non-FcR binding monoclonal antibody is directed at the CD3 antigen on activated T cells. Increasing evidence implicates T lymphocytes as the primary immune cells mediating the induction and progression of inflammatory bowel disease. While the mechanism of action of visilizumab in ulcerative colitis is still being characterized in ongoing studies, early research has demonstrated that visilizumab induces selective programmed cell death of activated, but not resting T cells *in vitro*, which may provide therapeutic benefit in ulcerative colitis.

In May 2003, we reported partial, preliminary results from a Phase I study in patients with severe ulcerative colitis. The clinical safety profile was reported as satisfactory to date, and evidence of activity was observed in the initial dose cohort of eight patients, given at 15 µg/kg on days 1 and 2. All eight patients responded to treatment and seven of eight achieved remission. The median duration of response was seven months. Following the initial cohort of eight patients, subsequent patients have received 10 µg/kg on days 1 and 2. A significant signal of clinical activity has been observed in the patients treated at this dose, and more than half of the patients monitored beyond day 60 have had a durable remission following treatment. The visilizumab Phase I study is now closed to further

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enrollment with 32 patients enrolled. An abstract describing this study has been accepted for oral presentation at the May 2004 Digestive Disease Week meeting.

Having seen a strong signal of activity in the initial Phase I study, we are exploring a range of doses to potentially improve further the risk/benefit profile of visilizumab in ulcerative colitis. We initiated a Phase I/II trial of visilizumab in the same refractory patient population in the fourth quarter of 2003. In this study, we expect to explore four dose levels from 5 µg/kg to 12.5 µg/kg given intravenously on days 1 and 2 as a bolus injection. Following the Phase I portion of the study, up to an additional 20 patients will be treated in the Phase II portion.

Because these severely ill patients have limited treatment options, we believe that the Phase I and Phase I/II studies may serve as the basis for discussions with regulatory agencies regarding the design of trials that may be appropriate for submission in support of a Biologics License Application (BLA) filing. We anticipate that such registrational trials could begin in the first half of 2005 and that the filing of a regulatory submission could occur by the end of 2006. The timing of such trials and regulatory filing are subject to significant uncertainties. We also plan to investigate other potential uses for Nuvion if we make additional progress in ulcerative colitis.

In June 2003, we discontinued our studies aimed at the treatment of steroid-refractory graft-versus-host disease (GvHD) following bone marrow transplantation as a potential indication for visilizumab. Accrual to a multi-institution Phase II trial, previously acknowledged as slow in accruing, was stopped. While most patients had improvement in symptoms of GvHD, the treatment with visilizumab was not, on average, associated with a significant prolongation of survival compared to historic controls.

**HuZAF (fontolizumab, anti-gamma interferon).** This humanized antibody has enrolled two Phase II studies in a total of approximately 300 patients with Crohn's disease, a form of inflammatory bowel disease. Fontolizumab 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 also completed a Phase I/II trial in patients with Crohn's disease. Data from the single-dose portion of this trial was difficult to interpret due to a high rate of response in the placebo group.

These two randomized, placebo-controlled, double blind Phase II trials are designed to better define the activity of this antibody in Crohn's disease. The first trial enrolled 201 patients and explores an initial intravenous dose of fontolizumab given as 1 mg/kg or 4 mg/kg, followed by additional lower subcutaneous doses. In the second trial, patients received up to two intravenous doses of fontolizumab given at 4 mg/kg or 10 mg/kg. A total of 133 patients have entered the study. We expect to report results from both Phase II trials of fontolizumab in Crohn's disease in May 2004 during the Digestive Disease Week meeting.

Results of a Phase I/II trial of subcutaneous administration of fontolizumab in psoriasis were reported in November 2003. We do not currently plan to pursue fontolizumab for a registration in psoriasis, but continue to perform exploratory studies that may be helpful in optimizing dosing regimens in other diseases.

In the future, we may initiate clinical trials of fontolizumab in other autoimmune diseases, including systemic lupus and rheumatoid arthritis.

**M200 (anti-a5b1 integrin antibody).** We obtained the anti-a5b1 integrin antibody program in connection with our April 2003 acquisition of Eos Biotechnology, Inc. (Eos). This chimeric antibody is in Phase I clinical studies for advanced solid tumors. M200 is a direct anti-endothelial cell antibody that inhibits angiogenesis. Agents that inhibit angiogenesis are intended to block formation of blood vessels in tumors, thereby leading to slower tumor growth, cell death or inhibition of metastasis. M200 targets

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the activated subset of endothelial cells. These activated cells are found in the lining of blood vessels undergoing angiogenesis, and by inhibiting the binding of fibronectin to a5b1 integrin receptors, angiogenesis is inhibited. *In vitro* studies have shown that the antibody inhibits angiogenesis, including vessel formation induced by vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF), as well as other pro-angiogenic growth factors. As a result, the antibody may prove effective in treating tumors in which one or more growth factors contribute to angiogenesis.

We are currently conducting a Phase I clinical trial of M200, initiated in May 2003, in patients with advanced solid tumors for whom there is no standard treatment. The primary study objective is to define the safety profiles associated with the antibody. The Phase I trial is expected to be completed by mid-2004, and Phase II trials are anticipated to begin by the end of 2004, again in patients with advanced solid tumors, including pancreatic or kidney cancers.

**PDL PRODUCTS IN PRECLINICAL STAGE DEVELOPMENT**

**F200 (anti-a5b1 integrin antibody fragment).** F200 is an anti-a5b1 integrin antibody fragment currently in preclinical development for certain ocular indications, including age-related macular degeneration. We currently anticipate that an Investigative New Drug application (IND) could be filed for this antibody in early 2005. However, we believe that it will facilitate the development and possible commercialization of this molecule if we obtain a committed and experienced ophthalmic development and marketing partner. Development progress may be affected by potential partnering discussions or commitment of resources to more advanced programs.

**Other Preclinical Programs.** We are evaluating a number of additional therapeutic antibody candidates, at earlier stages of development, that may be useful for the treatment of autoimmune diseases and cancer. These include antibodies to targets such as the chemokine IP10, that may be involved in inflammatory bowel diseases; Pr1, an antibody-drug conjugate that may be useful for the treatment of prostate cancer; numerous additional targets that may lead to therapeutics for the treatment of diseases such as ulcerative colitis, Crohn's disease, rheumatoid arthritis, breast cancer, ovarian cancer and lung cancer.

## RECENTLY TERMINATED CLINICAL PROGRAMS

**Anti-IL-4 Antibody.** We licensed the anti-IL-4 humanized antibody, for the potential treatment of asthma and allergy, from SmithKline Beecham, now GlaxoSmithKline plc (GSK), in 1999. We reported data in May 2003 from a Phase IIa clinical trial of the humanized anti-IL-4 antibody in steroid-naïve, mild/moderate asthma patients. The antibody was well tolerated, but did not demonstrate clinical benefit compared to placebo at either of the dose levels tested. Upon our decision to not conduct additional clinical studies of the humanized anti-IL-4 antibody, we returned the program to GSK.

**Anti-IL-12 Antibody.** Interleukin-12 (IL-12) is a cytokine with potential as a target in the treatment of a number of autoimmune diseases. Our Phase I trial in normal volunteers was completed; however, new data on the emerging role of IL-23 in MS led to a decision to cease further development of our antibody. In December 2003, we entered into a licensing agreement with Abbott Laboratories, Inc. (Abbott) that provides Abbott certain exclusive rights to intellectual property related to antibodies capable of binding to IL-12 or its receptor. The licensed rights are not related to our humanization technology. The Abbott antibody licensed under this arrangement is currently in Phase I/II clinical development. We received an upfront licensing fee, and may receive development milestone payments and royalties on future sales of antibodies developed by Abbott against IL-12. We initially licensed certain intellectual property related to anti-IL-12 therapy from Roche and will share with Roche a portion of all amounts received.

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## CURRENT SOURCES OF REVENUES

**Royalties.** We license our patents covering numerous humanized antibodies in return for license fees, annual maintenance payments and royalties on product sales. Seven of the eight humanized antibodies currently approved by the FDA are licensed under our patents and five of these licensed products generated royalties to PDL that were recognized in 2003: Genentech's Herceptin and Xolair; MedImmune's Synagis; Wyeth's Mylotarg; and Roche's Zenapax. Combined worldwide sales of these products exceeded \$1.3 billion in 2003. Additionally, Genentech has exercised licenses for its Raptiva™ and Avastin™ antibody products, which were approved by the FDA in October 2003 and February 2004, respectively. As royalty revenue is recognized one quarter following the quarter in which sales occurred, we will receive royalties on sales of Raptiva beginning in the first quarter of 2004 and on sales of Avastin in the second quarter of 2004.

**Patent licensing, humanization agreements and outlicensing.** 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.

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.

In addition, we are seeking to out-license marketing rights for certain antibodies in some geographical areas to other biotechnology or pharmaceutical companies, and may receive upfront fees, milestone payments and/or other types of funding, in addition to possible royalties or other profit-sharing arrangements on any product sales by our licensees.

## 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 irregular 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 antibodies have been developed as potential therapeutics to inhibit immune function, destroy cancer cells or neutralize viruses.

Although mouse monoclonal antibodies are relatively easy to generate, they have significant drawbacks as therapeutics. Mouse antibodies have a relatively short half-life in human patients, requiring them to be administered frequently. In addition, mouse 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 mouse 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 mouse antibody and renders it ineffective for further therapy. These problems have largely prevented mouse 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 mouse 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 40 humanized antibodies in clinical trials, including several antibodies addressing large markets. Fourteen human, humanized or chimeric antibodies have already been approved for marketing by the FDA, of which seven are humanized and licensed under our patents.

### *Our Antibody Technology Platform*

Our proprietary antibody technology platform has positioned us as a leader in the development of therapeutic antibodies that overcome many of the problems associated with mouse antibodies. Using our patented approach, "humanized" antibodies are designed to retain biological activity of mouse antibodies while incorporating human-like traits, which enhance the utility of such antibodies for human therapeutic use. Clinical trials and preclinical studies have shown that our humanized antibodies have the desired human-like antibody characteristics, low immunogenicity and a usefully long half-life, coupled with the important target-binding activity of a mouse-derived antibody.

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

Our antibody technology platform creates a humanized antibody designed by using our proprietary software to guide the choice of substitutions of amino acids from the original mouse antibody into the human antibody framework, based on structural information derived from the original mouse antibody. The construction of a humanized antibody starts with the identification of a mouse antibody that has demonstrated favorable results in laboratory, animal or human studies. A model of the mouse 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 key amino acids in the framework most responsible for maintaining the shape of CDRs. Software we developed as well as the experience of our computational chemists is important in this analysis. These key mouse amino acids are substituted into the human antibody framework along with mouse CDRs in order to maintain their ability to bind well to the target. The resulting humanized antibody retains most or all of the binding ability of the mouse antibody, but typically is between 85% and 95% human.

## **OUR RESEARCH**

Our research efforts are focused on creating and developing humanized antibodies for the treatment of autoimmune diseases, inflammatory conditions and cancer. Following our acquisition of Eos in April 2003, we significantly restructured and redefined our research to combine the target and biology expertise of Eos with the advanced protein engineering skills of PDL, with the aim of generating an average of one new antibody IND candidate per year after 2004. We have significant research activities aimed at the discovery of new antibodies and utilize various state-of-the-art research tools intended to optimize the efficiency of antibodies that may be useful for the treatment of certain diseases. These activities are intended to provide antibody product candidates for further preclinical

and clinical development in our core disease areas. We use a variety of sophisticated methods to discover these targets. In addition, we have obtained or in-licensed targets, or rights to targets or antibodies, through collaborative research agreements, from academic institutions or other biotechnology or pharmaceutical companies. We may in-license rights to additional targets or antibodies in the future.

We are also 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 preclinical 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 humans, 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 in California and Minnesota 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 believe our knowledge and capabilities in this area provide a significant degree of competitive advantage over those companies that currently lack such fully integrated operations. In particular, we have over a decade of manufacturing experience based upon a serum-free and protein-free production process, and we believe that this approach is a significant competitive advantage.

We manufacture antibodies for use as clinical trial material in an approximately 90,000 square-foot manufacturing facility in Plymouth, Minnesota, which we have leased since 1992. We currently manufacture visilizumab, fontolizumab and other preclinical antibodies in that facility. We renovated this facility in late 2002 and early 2003 to make it potentially licensable by regulatory agencies in the United States and other countries for supply of commercial antibodies. We completed initial validation of the renovated facility and resumed manufacturing of antibodies in the first half of 2003.

We are constructing a new commercial manufacturing facility in Brooklyn Park, Minnesota, approximately nine miles from our Plymouth location. Physical construction is expected to be completed late in 2004, which will be followed by validation and start-up activities. We currently expect to be able to produce antibodies for clinical use from this facility by 2006 and for commercial sale from this facility in 2007. Antibodies currently in our clinical-stage pipeline that may be made in this facility include visilizumab, fontolizumab, daclizumab, and the anti-a5b1 integrin antibody.

## HUMANIZATION AND PATENT LICENSING RIGHTS AGREEMENTS

We have entered into patent license agreements with numerous companies that are independently developing humanized antibodies, including Abbott Laboratories, Biogen Idec, Celltech, Chugai, Elan Pharmaceuticals, Genentech, Medarex, MedImmune, Merck KGaA, Sankyo, Seattle Genetics, 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 rights 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, GlaxoSmithKline (GSK), MedImmune, Millennium Pharmaceuticals and Tanox. Under these agreements, licensees currently purchase a

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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 fee, and rights to receive additional payments upon the achievement of certain milestones and royalties on any product sales.

We continue to pursue discussions with companies involved in antibody research and development and may enter into additional patent license, patent rights and humanization agreements from time to time.

In August 2003, we reported that Genentech had advised us that it had determined that the Xolair antibody product was not covered under the claims of our relevant antibody humanization patents. The companies subsequently conducted confidential discussions in an effort to resolve this issue and later expanded the scope of these discussions to include Genentech's Raptiva and Avastin antibody products. In December 2003, Genentech and we announced that the companies had concluded a definitive agreement which resolved a dispute relating to our existing patent licensing master agreement, in particular with respect to our antibody humanization patents and certain of Genentech's humanized antibodies. Under the terms of the agreement, Genentech exercised licenses under the patent licensing master agreement between the parties for Genentech's Xolair and Raptiva antibody products. These exercises resulted in payment of license exercise fees in excess of \$2 million to us, which we recognized as license revenue in the fourth quarter of 2003. We recognized royalty revenue from 2003 sales of Xolair beginning in the fourth quarter of 2003, and we will commence recognition of royalty revenue from Raptiva product sales in the first quarter of 2004.

In consideration of approximately \$1.1 million, Genentech exercised a license for its Avastin antibody product, which was approved by the FDA in February 2004. As a result, we will recognize license exercise fees of approximately \$1.1 million in the first quarter of 2004 and commence recognition of royalty revenue from Avastin product sales in the second quarter of 2004.

In connection with the December 2003 definitive agreement, we agreed to certain royalty reductions for significant levels of annual aggregate sales of Genentech products licensed under the master agreement. The revised royalty rate structure would apply reciprocally to any of our products licensed under the master agreement. The agreement resolves and settles both companies' disputes regarding infringement of the Xolair, Raptiva and Avastin products and the validity and enforceability of our patents. We also obtained additional rights to obtain non-exclusive, royalty-bearing licenses under certain of Genentech's antibody patents.

## ACQUISITION OF EOS

In April 2003, we completed the acquisition of Eos, an antibody discovery company, for approximately 4.2 million shares of our common stock. In conjunction with the merger, we recorded a charge of \$37.8 million related to acquired in-process research and development. This acquisition expanded our research and development personnel by approximately 41 people, and added new capabilities in antibody target identification and validation, particularly in oncology, as well as adding M200 and F200, a clinical and a preclinical program, respectively.

## MANUFACTURING AND FACILITIES

We manufacture our products for clinical development, other than M200. M200 is currently supplied by ICOS Corporation as part of a manufacturing agreement related to our acquisition of Eos. However, we intend to change over from ICOS supply to our own supply as soon as is reasonably practicable, subject to regulatory and physical constraints.

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We intend to continue to manufacture our potential products for use in preclinical and clinical trials, and to manufacture products for commercial use by 2007. We expect to use our manufacturing facilities in accordance with standard procedures that comply with appropriate regulatory standards.

We own two buildings comprising approximately 92,000 square feet of research and development and general office space in Fremont, California. We have an approximately \$8.5 million mortgage on these facilities. In addition, we lease approximately 72,000 square feet of adjacent research and development and general office space in Fremont, California. Our lease terms for these facilities will expire on February 28, 2006 and December 31, 2006.

In Plymouth, Minnesota, we lease approximately 90,000 square feet of manufacturing, laboratory and office space. The lease term will expire on February 28, 2009, subject to our option to extend the lease for an additional five-year term. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and we are building a new commercial manufacturing plant on this property that is currently pending completion and validation.

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 September 30, 2004.

In Menlo Park, California, we lease approximately 1,600 square feet of general office space. The lease term will expire on March 31, 2005.

We may obtain additional research and development and general office space in the future and may lease or acquire additional space as required.

## **PATENTS AND PROPRIETARY TECHNOLOGY**

We have been issued patents in the United States, Europe and Japan, which we believe cover many or most humanized antibodies. Some of these patents also cover other aspects of our antibody technology platform. We have filed similar patent applications in other countries. Our U.S. humanization patents, known generally as the Queen, et. al. patents, expire in 2013.

Our two humanization patents issued by the European Patent Office apply in the United Kingdom, Germany, France, Italy and 17 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. Five opponents, including Genentech, have withdrawn from the opposition proceedings.

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 subsequently appealed the Opposition Division's decision to the Technical Board of Appeal at the European Patent Office. In November 2003, the Technical Board of Appeal upheld our appeal and set aside the Opposition Division's initial decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. We believe that such claims, if upheld by the Opposition Division, would cover the production of many humanized antibodies.

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The nine-month opposition period for our second European antibody humanization patent ended in May 2000. Eight notices of opposition were filed with respect to this patent and we have filed our response with the European Patent Office. Oral hearings scheduled to take place in October 2003 were postponed and a subsequent hearing date has not yet been established.

Three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a final determination from the Japanese Patent Office examiner affirming the Opposition Board's earlier decision. We have appealed this decision to the Tokyo High Court. A hearing was held in April 2003. 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. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the 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.

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 that 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 cannot assure you that the patents we obtain or the unpatented proprietary technology we hold will afford us significant commercial protection.

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## **GOVERNMENT REGULATION**

The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, 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 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 United States, 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 United States, our collaborative partners and we are subject to foreign regulatory requirements and, if the particular product is manufactured in the United States, 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. In addition, as we build our commercial infrastructure to market our products in North America, our promotional materials and activities will also be governed by FDA regulations and guidelines.

Both before and after approval is obtained, a biological 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, 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 mouse, 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 antibody technology platform. 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, 2003, we had 549 full-time employees. Of the total, 157 employees were engaged in research and process development, 126 in clinical and regulatory, 112 in manufacturing, 83 in general and administrative functions, and 71 in quality assurance and compliance. 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

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Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read and 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 our current reports on Form 8-K and any other reports or filings we have filed with the SEC, including any amendment to those reports we have filed with, or furnished to, the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as practicable after we have electronically filed such material with, or furnished it to, the SEC, by contacting the Corporate Communications Department at our corporate offices by calling (510) 574-1406.

## RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Annual Report on Form 10-K, including the risk factors listed below. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock.

Keep these risk factors in mind when you read forward-looking statements contained in this Annual Report on Form 10-K and the documents incorporated by reference herein. These statements relate to our expectations about future events and time periods. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "intends," "plans," "believes," "anticipates," "expects," "estimates," "predicts," "potential," "continue" or "opportunity," the negative of these words or words of similar import. Similarly, statements that describe our reserves and our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Forward-looking statements involve risks and uncertainties, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements.

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

In general, our expenses have exceeded revenues. As of December 31, 2003, we had an accumulated deficit of approximately \$220.3 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 pursue clinical development of our potential products in new indications;

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- we invest in additional manufacturing capacity;
  - we build commercial infrastructure to market our products in North America;
  - 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.

**We have substantial outstanding indebtedness, which could adversely affect our financial condition and prevent us from fulfilling our obligations under our 2.75% \$250 million convertible notes.**

In connection with our sale of the 2.75% convertible notes, referred to as the Notes, in July 2003, we incurred \$250.0 million of indebtedness, set to mature in August 2023, although callable as early as 2010. Our total consolidated long-term debt as of December 31, 2003 was \$258.5 million and constituted approximately 37% of our total pro forma capitalization as of such date. The indenture relating to the Notes does not restrict our ability to incur additional indebtedness, including debt that is senior to the Notes.

The degree to which we are leveraged could have important consequences, because:

- it could affect our ability to satisfy our obligations under the Notes;
- a substantial portion of our cash flow from operations will be required to be dedicated to interest and principal payments and may not be available for operations, working capital, capital expenditures, expansion, acquisition or general corporate or other purposes;
- our ability to obtain additional financing in the future may be impaired;
- we may be more highly leveraged than some of our competitors, which may place us at a competitive disadvantage;
- our flexibility in planning for, or reacting to, changes in our business and industry may be limited; and
- it may make us more vulnerable in the event of a downturn in our business, our industry or the economy in general.

Our ability to make payments on and, if necessary, to refinance our debt, including the Notes, will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, business, financial, competitive, legislative, regulatory and other factors that are beyond our control.

We cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available in an amount sufficient to enable us to pay our debt, including the Notes, or to fund our other liquidity needs. We may need to refinance all or a portion of our debt, including the Notes, on or before maturity. We cannot assure you that we would be able to refinance any of our debt, including the Notes, on commercially reasonable terms or at all.

**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

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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 market launch of recently licensed 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; 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 paid to us in our first and second quarters than in other quarters. The seasonality of Synagis sales will 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 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

**Our humanization patents are being opposed and a successful challenge or refusal to take a license could limit our future revenues.**

Most of our current revenues are related to our humanization patents and the related licenses that third parties enter into with us for rights to those patents. If our rights are successfully challenged or third parties decline to take licenses for the patents, our future revenues would be adversely affected.

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 appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition 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 the opposition is successful, 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 United States. 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 opposition 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 opposition 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 were filed with respect to our second European antibody humanization patent and we have filed our response with the European Patent Office. Oral hearings, originally scheduled to take place in October 2003, have been postponed by the European Patent Office. No new date has been set for the hearings.

Also, three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a final determination from the Japanese Patent Office examiner affirming the Opposition Board's earlier decision. We have appealed this decision to the Tokyo High Court. A hearing was held in April 2003. 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. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the 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.

Our ability to maintain and increase our revenues from licensing is dependent upon third parties entering into new patent licensing arrangements, exercising rights under existing patent rights agreements, and paying royalties under existing patent licenses with us. To date, we have been successful in obtaining such licensing arrangements, and in receiving royalties on product sales, from parties whose products may be covered by our patents. However, we have experienced challenges in our licensing efforts, including the disagreement we had with Genentech in 2003 over whether its Xolair antibody product was covered under our humanization patents. There can be no assurance that we will continue to be successful in our licensing efforts in the future. Additionally, although we have reached an amicable settlement with Genentech that is intended to resolve such disagreements, Genentech or other companies may, in the future, seek to challenge our U.S. patents through litigation or patent office proceedings, such as re-examinations or interferences. If we experience difficulty in enforcing our patent rights through licenses, or if our licensees, or prospective licensees, challenge our antibody humanization patents, our revenues and financial condition could be adversely affected, and we could be required to undertake additional actions, including litigation to enforce our rights. Such efforts would increase our expenses and could be unsuccessful.

**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. For example, BTG International Limited (successor in interest to the Medical Research Council) recently has been issued a U.S. patent, to which we have a license, with claims that might be construed to overlap with our issued humanization patents. While the significance of this new U.S. patent is unclear, if it conflicts with our U.S. patents or patent applications, we may become involved in patent office or legal proceedings to determine which company was the first to invent the technology and 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.

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 that 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 appealed that decision, but the Technical Board of Appeal recently rejected the appeal. As a result, the decision revoking the patent is final; no further appeals are available. However, 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'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. In addition, Celltech was recently issued a second U.S. patent with claims that may be considered broader than its first U.S. 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. This agreement expires in December 2004. Notwithstanding this agreement, if our humanized antibodies were covered by Celltech's European or U.S. patents and if we need more than the three licenses under those patents currently available to us under the agreement, or we are unable to negotiate an extension of this agreement beyond December 2004 on terms that are acceptable to us, 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 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 Crohn's disease, the indication currently being investigated in our HuZAF (fontolizumab, anti-gamma interferon antibody) clinical trials. However, a European patent issued to Genentech in 1998 and a U.S. patent issued in 2003 do have claims to the use of anti-gamma interferon inhibitors, including antibodies, for treatment of inflammatory bowel disease, including Crohn's disease. 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 had, and may in the future have, clinical setbacks that prevent us from obtaining regulatory approval for our potential products. Most recently, in May 2003, we announced that we have discontinued additional clinical studies of the humanized anti-IL-4 antibody after data from a Phase IIa clinical trial of the antibody in steroid-naïve, mild/moderate asthma indicated that the anti-IL-4 antibody did not demonstrate clinical benefit compared to placebo at either of the dose levels tested.

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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 June 2003 we announced the discontinuance of studies aimed at the treatment of steroid-refractory graft-versus-host-disease following bone marrow transplantation with Nuvion after partial, preliminary results in a Phase II trial showed that Nuvion was not, on average, associated with a significant prolongation of survival relative to historic controls.

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 had 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 has been terminated and our current plan is not to further develop Nuvion for psoriasis. Development for Nuvion in severe steroid-refractory ulcerative colitis is ongoing.

In addition, we may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise because we have a relatively large number of potential products in clinical development. 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.

**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 in a timely manner in order 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, including those in clinical development;

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- 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.

**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 establish an internal marketing and sales group, contract for these services, or obtain the assistance of another company. Pursuant to the terms of our revised collaboration agreement with Hoffmann-La Roche Inc. (Roche), we have a reversion right, exercisable in 2006, but effective in 2007, to repurchase all rights, including marketing rights, in transplant indications, unless earlier elected by Roche. If we elect to exercise this right, or Roche elects to transfer such rights to us, we will be responsible for the marketing and commercialization of Zenapax in all indications worldwide. While Roche must notify us at least six months prior to a transfer of Zenapax to us, there can be no assurance that we will be able to establish marketing, sales and distribution capabilities for Zenapax in a timely manner. Further, we may not be able to establish such capabilities for our other products 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. If we are unsuccessful in 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, Roche and its affiliates are responsible for manufacturing Zenapax. In connection with the restructuring of our collaboration

agreement with Roche, we obtained the rights to manufacture Zenapax. We are responsible for manufacturing our other products for our own development, and will begin manufacturing clinical supplies of Zenapax following a transition period that we expect will extend to 2005. Our ability to successfully market and develop Zenapax, in particular in transplantation, depends upon our success in manufacturing Zenapax at commercial scale. We have not manufactured this product in the past and we will need to show comparability with material used by Roche. There can be no assurance that we will successfully and in a timely manner be capable of manufacturing Zenapax following the transfer of Zenapax to us by Roche.

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. Our collaborative partners and we 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.

We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture all of 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 have recently completed improvements to our existing manufacturing plant in order to manufacture initial commercial supplies of certain products, including Nuvion and Zenapax. 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 operate 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 are constructing 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 antibody technology platform. 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 our collaborative partners or we 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, markets Simulect® (basiliximab), a product competitive with Zenapax, in the United States and Europe. Novartis has acquired a significant interest in Roche.

**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 United States and other countries. In the United States, 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 United States, 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.

In addition, the FDA recently completed the transfer of regulatory responsibility, review and continuing oversight for many biologic therapeutic products, including antibody therapeutics, from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This transfer of responsibility could result in new regulatory standards, which could result in delays in development or regulatory approvals for our potential products. In addition, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured by Roche is comparable to the material we produce at our manufacturing facilities. New regulations resulting from the transfer of regulatory responsibility from CBER to CDER could make it more difficult for us to show comparability which could delay development and regulatory approval of Zenapax in new indications or reduce or interrupt commercial sales of Zenapax for the prevention of acute kidney transplant rejection.

For the marketing of pharmaceutical products outside the United States, our collaborative partners and we are subject to foreign regulatory requirements and, if the particular product is manufactured in the United States, 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. Additionally, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured by Roche does not differ significantly from the material we produce at our manufacturing facilities. Showing comparability between the material we produce before and after manufacturing changes, and in the case of Zenapax, between the material produced by Roche and the drug material produced by us, 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, and in the case of Zenapax, between the our material and the Roche 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 or an inability to immediately show comparability between the Roche material and our material 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 United States, 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 United States 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;
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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.

**We may not have the ability to raise the funds to repurchase the 2.75% \$250 million convertible notes on the repurchase date or to finance any repurchase offer required by the indenture.**

In August 2010, August 2013 and August 2018, respectively, holders of our \$250 million convertible notes (the Notes) may require us to repurchase all or a portion of their notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of notes to be repurchased in August 2013 and August 2018, at our option, in cash, shares of our common stock or a combination of cash and shares of our common stock. In addition, if a repurchase event occurs (as defined in the indenture), each holder of the Notes may require us to repurchase all or a portion of the holder's notes. We cannot assure you that there will be sufficient funds available for any required repurchases of these securities. In addition, the terms of any agreements related to borrowing which we may enter into from time to time may prohibit or limit our repurchase of notes or make our repurchase of notes an event of default under certain circumstances. If a repurchase event occurs at a time when a credit agreement prohibits us from purchasing the Notes, we could seek the consent of the lender to purchase the Notes or could attempt to refinance the debt covered by the credit agreement. If we do not obtain a consent, we may not purchase the Notes. Our failure to purchase tendered notes would constitute an event of default under the indenture, which might also constitute a default under the terms of our other debt. In such circumstances, our financial condition and the value of our securities could be materially harmed.

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

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of revenue recognition and may affect our financial position or results of operations. New

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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 National 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.**

In April 2003, we completed 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 issued 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 will 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;
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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 72,000 square feet of research and development and general office space in Fremont, California. Our lease terms will expire on February 28, 2006 and December 31, 2006.

In Plymouth, Minnesota, we lease approximately 90,000 square feet of manufacturing, laboratory and office space. Our lease terms will expire on December 31, 2004 and February 28, 2009, subject to our option to extend the leases for an additional five-year term. In March 2002, we purchased

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approximately 29 acres in Brooklyn Park, Minnesota and we continue 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 September 30, 2004.

In Menlo Park, California, we lease approximately 1,600 square feet of general office space. 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.

We own substantially all of the equipment used in our facilities. (See Note 7 to the consolidated financial statements.)

## ITEM 3. LEGAL PROCEEDINGS

We are 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 humanization patent. We appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition 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 the opposition is successful, 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 United States. 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 opposition 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 opposition 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 were filed with respect to our second European antibody humanization patent and we have filed our response with the European Patent Office. Oral hearings, originally scheduled to take place in October 2003, have been postponed by the European Patent Office. No new date has been set for the hearings.

Also, three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a

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final determination from the Japanese Patent Office examiner affirming the Opposition Board's earlier decision. We have appealed this decision to the Tokyo High Court. A hearing was held in April 2003. 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. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the 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.



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Provision for income taxes					
Net income (loss)	\$ (129,814)	\$ (14,554)	\$ 2,647	\$ 647	\$ (10,333)
Basic and diluted net income (loss) per share:	\$ (1.40)	\$ (0.16)	\$ 0.03	\$ 0.01	\$ (0.14)
Shares used in computation of net income (loss) per share:					
Basic	92,478	88,865	87,624	80,904	74,792
Diluted	92,478	88,865	92,889	88,562	74,792
December 31,					
2003                      2002                      2001                      2000                      1999					

#### CONSOLIDATED BALANCE SHEET DATA:

Cash, cash equivalents, marketable securities and restricted investments	\$ 504,993	\$ 606,410	\$ 650,315	\$ 661,173	\$ 137,237
Working capital	468,348	599,215	641,896	651,641	22,669
Total assets	742,030	717,818	729,898	704,980	182,551
Long-term obligations, less current portion	258,523	158,426	158,892	159,324	9,724
Accumulated deficit	(220,291)	(90,477)	(75,923)	(78,570)	(79,217)
Total stockholders' equity	448,331	544,766	558,443	534,144	164,743

Certain reclassifications of previously reported amounts have been made to conform to the presentation in the Consolidated Statement of Operations for the year ended December 31, 2003.

- (1) Represents acquired in-process research and development, which relates to the Eos acquisition and the purchase of certain technology from Roche that had not yet achieved technological feasibility. For a description of these charges, see Notes 2 and 4 to the Consolidated Financial Statements.
- (2) Includes charges associated with the early extinguishment of certain of our debt. For a description of these charges, see Note 12 to the Consolidated Financial Statements.
- (3) Represents non-cash charges related to the impairment of an equity investment. For a description of these charges, see Note 5 to the Consolidated 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

We are a recognized leader in the discovery and development of humanized monoclonal antibodies for the treatment of disease. All of our revenues are derived from licensing, humanization and royalty arrangements. As of December 31, 2003, we received royalties on five marketed products, with approximately 90% of our royalty revenues derived from the Herceptin antibody product marketed by Genentech and the Synagis antibody product marketed by MedImmune. We do not currently anticipate having proprietary marketed products prior to 2007. Accordingly, our revenues and related cash flows depend substantially on the success of our licensees and our ability to enter into new licensing and royalty arrangements.

#### Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of December 31, 2003, we had an accumulated deficit of approximately \$220.3 million. Our expenses will increase over the next several years because of the extensive resource commitments required to identify and develop antibody candidates, including the ongoing operating costs associated with our acquisition of Eos Biotechnologies, Inc. (see *Acquisition of Eos* below), to achieve regulatory approval and to 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. 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. Since our goal is to launch our first product or products into the North American market by 2007, our ability to achieve this cash-flow positive position would not occur sooner than that, if we were successful.

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.

#### *Acquisition of Eos*

In April 2003, we completed the acquisition of Eos Biotechnology, Inc. (Eos), a privately held South San Francisco-based antibody discovery company, in exchange for approximately 4.2 million shares of our common stock. The Eos acquisition 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 the antibody candidates (M200), which began clinical development in May 2003, targets potential treatment of solid tumors, and the second (F200) targets potential treatment of certain ocular indications.

The Eos acquisition was accounted for as an acquisition of assets rather than as a business combination as Eos was a development stage company that had not commenced its planned principal operations. Eos lacked the necessary elements of a business because it did not have completed products and, therefore, no ability to access customers. The Eos operating results have been included in our consolidated results of operations since April 5, 2003. In conjunction with this transaction, we recorded a charge of approximately \$37.8 million related to acquired in-process research and development in the second quarter of 2003.

The aggregate purchase price was \$38.8 million, consisting of the shares issued to the Eos stockholders valued at \$35.5 million (including the value of shares withheld to provide for tax liabilities of \$1.3 million), transaction costs of \$2.2 million and employee change of control costs of \$1.1 million. The shares issued in connection with this acquisition were valued at \$8.17 per share, which represented the average of the closing market price of our common stock a few days before and after the acquisition announcement date (February 4, 2003).

#### *Acquisition of Daclizumab*

Effective October 2003, we entered into an amendment to our collaboration agreement with Roche, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell Zenapax® (daclizumab) in all disease indications other than transplantation. Roche is currently expected to continue to market Zenapax in transplantation indications until 2007, although an earlier transfer to us of rights in transplantation may occur upon six months' written notice at Roche's election.

Under the new arrangement, we assumed worldwide responsibility for the development and, if successful, sales and marketing of daclizumab in all indications other than transplantation. We also have rights to manufacture daclizumab.

In connection with the new arrangement, we paid Roche \$80 million in cash for return of exclusive rights in indications other than transplantation, and we obtained an option to acquire rights in transplant indications (reversion right), exercisable by us in 2006, but effective in 2007 or as early as 2005 at the election of Roche. To effectuate the transfer of Zenapax in the transplantation indications,

we will pay an additional exercise fee to Roche based on the average annual gross sales of Zenapax during the period from January 1, 2004 through the calendar quarter prior to the date of notice of the exercise, or Roche's notice of its decision to transfer the rights to us prior to our exercise date. If we do not receive transplantation rights, we would pay modest royalties to Roche on any sales in all diseases other than transplantation, and would continue to receive royalties on sales of Zenapax in transplantation.

Of the \$80 million that we paid to Roche in October 2003, we recorded a charge to acquired in-process research and development totaling approximately \$48.2 million. We capitalized the remaining amount of \$31.8 million, which relates to core technology and the reversion right. We are amortizing the value of the core technology, \$16.0 million, over the term of the patents underlying the acquired technology. We will reclassify the reversion right asset, \$15.8 million, into core technology at the time when the rights to the technology revert back to us, which at our option will be no later than 2007, but could be as early as 2005 at the election of Roche. Upon reclassifying the reversion right asset to core technology, we will amortize the asset over the remaining term of the patents underlying the acquired technology.

### **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 development, use, sale and importation of humanized antibodies.

We enter into patent license and humanization agreements that may contain other elements, such as royalties and milestones related to the achievement of particular stages in product development. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element. We recognize revenue for delivered elements only when the fair values of undelivered elements are known, 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. Changes in the allocation of the contract value between deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract.

Under our humanization 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. We follow this method because we can reliably estimate the progress of each project based on information from our scientists. Due to our extensive experience in humanizing antibodies, coupled with the short-term nature of the humanization contracts, the likelihood that the actual progress is materially different than that reflected in our revenues at the end of any particular reporting period is low. Historically, revenues recognized have approximated actual progress under each humanization agreement.

## 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 ongoing 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, direct expenses related to each patient enrolled in a clinical trial are recognized on an estimated cost-per-patient basis as services are performed. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from contract research organizations (CROs), such as estimated costs per-patient, to calculate our accrual for direct clinical expenses at the end of each reporting period. For indirect expenses, which relate to site and other administrative costs to manage our clinical trials, we rely on information provided by the CRO, including costs incurred by the CRO as of a particular reporting date, to calculate our indirect clinical expenses. 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, which we confirm directly with the CRO. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred, however, our experience has been that our estimates at the end of any particular reporting period have been materially accurate.

## Intangible Assets

The valuation in connection with the initial purchase and the ongoing evaluation for impairment of intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. For example, we estimate future probability-adjusted cash flows and certain discount rates as well as assumed commercialization dates for future potential products. These estimations affect the allocation between charges to acquired in-process research and development and capitalization of intangible assets. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for intangible assets.

Once the values for intangible assets are established, we must test intangible assets with definite useful lives for impairment in accordance with Financial Accounting Standards Board (FASB) Statement No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." When we conduct our impairment tests for intangibles, factors that are considered important in determining whether impairment might exist include significant changes in our underlying business and product candidates or other factors specific to each asset being evaluated. Any changes in key assumptions about the business and its prospects, or changes in market conditions or other externalities, could result in an impairment charge and such a charge could have a material adverse effect on our consolidated results of operations.

## RESULTS OF OPERATIONS

Years ended December 31, 2003, 2002 and 2001

### Total Revenues

	Years Ended December 31,			Annual Percent Change	
	2003	2002	2001	2003 / 2002	2002 / 2001
	(In thousands)				
Total Revenues	\$ 66,686	\$ 46,373	\$ 44,400	44%	4%

Our total revenues for 2003 were \$66.7 million, a 44% increase from 2002 due to higher royalties and license fees when compared to 2002. Total revenues for 2002 were \$46.4 million, a 4% increase from 2001 due to higher royalties, partially offset by lower license and other revenues. These revenue changes are further discussed below.

	2003	2002	2001	2003 / 2002	2002 / 2001
(In thousands)					
<b>Revenues</b>					
Royalties	\$ 52,704	\$ 40,421	\$ 30,604	30%	32%
License and other	13,982	5,952	13,796	135%	(57)%

## Royalties

Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth were \$52.7 million in 2003 compared to \$40.4 million in 2002, an increase of 30% compared to an increase of 32% in 2002 from 2001. In 2003, the increase was primarily due to increased Herceptin sales reported by Genentech and higher Synagis sales reported by MedImmune. Royalty payments from MedImmune and Genentech accounted for 47% and 46%, respectively, of our royalty revenues during 2003. The increase in royalty revenues in 2002 when compared to 2001 was primarily due to higher third-party sales of Synagis and Herceptin. In 2002, royalty revenues from MedImmune and Genentech accounted for 47% and 43% of our royalty revenues, respectively. In 2001, royalty revenues from MedImmune and Genentech accounted for 48% and 39% of our royalty revenues, respectively.

We expect that in 2004, with the additional licensed products brought to market in late 2003 and the launch of Genentech's Avastin antibody product in 2004, we will continue to experience royalty revenue growth. We also continue to expect quarterly fluctuations in royalty revenues due to the seasonality of sales of Synagis.

## License and Other Revenues

	Years Ended December 31,		
	2003	2002	2001
(in thousands)			
<b>License and Other Revenues</b>			
Patent right and licensing	\$ 8,450	\$ 3,650	\$ 4,705
Humanization and other	5,532	2,302	9,091
Total License and Other Revenues	\$ 13,982	\$ 5,952	\$ 13,796

License and other revenues were \$14.0 million in 2003, an increase of 135% from 2002. License and other revenues were \$6.0 million in 2002, a decrease of 57% from 2001. 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 increase in license and other revenues in 2003 was primarily due to the fact that we entered into more patent licensing agreements in 2003 as compared with 2002 as well as higher milestone revenue in 2003 as compared with 2002. In 2003, we entered into six patent licensing agreements, compared to one patent rights and one patent licensing agreement in 2002. In addition, in 2003, we recognized \$2.5 million in milestone revenues, with no such comparable revenues in 2002.

The decrease in license and other revenues in 2002 from 2001 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 revenues 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 more than \$7.0 million in milestone and humanization revenues, with no such comparable revenues in 2002.

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

## Costs and Expenses

	Years Ended December 31,			Annual Percent Change	
	2003	2002	2001	2003 / 2002	2002 / 2001
(In thousands)					
<b>Costs and Expenses</b>					
Research and development	\$ 82,732	\$ 57,978	\$ 52,163	43%	11%
General and administrative	27,613	18,373	15,004	50%	22%
Acquired in-process research and development	85,993	—	—	—	—
Total costs and expenses	\$ 196,338	\$ 76,351	\$ 67,167	157%	14%



## Research and Development Expenses

Research and development expenses in 2003 were \$82.7 million, an increase of 43% from 2002. Research and development expenses in 2002 were \$58.0 million, an increase of 11% from 2001. 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 2003 was primarily due to an increase in personnel costs of approximately \$16.3 million, in large part resulting from an increase of research and development personnel of approximately 143 employees as a result of the acquisition of Eos, and the hiring of additional employees to pursue our expanding research and development programs. Also contributing to the increase were additional clinical development activities for our major research and development projects of approximately \$3.9 million and an increase in facility-related expenses of \$5.0 million, resulting from the expansion of our facilities in 2003. These increases in costs were partially offset by lower research and development funding provided to Exelixis of \$1.1 million.

The increase in 2002 was primarily related to an increase in research and development personnel headcount of approximately 38 employees and associated increase in personnel costs of approximately \$3.4 million, higher research and development funding provided to Exelixis of \$1.7 million, reflecting a

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full year of funding in 2002 compared to a partial year of funding in 2001, and higher preclinical studies' costs of \$0.8 million.

We expect our research and development expenses will continue to increase as we invest in manufacturing, advance our product candidates into later stages of development and add new product candidates. More specifically, the increase is expected to relate 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 as well as the further expansion of our research, preclinical, manufacturing and process development infrastructure.

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.

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Year Ended December 31,		
					2003	2002	2001
(In thousands)							
<b>Current Product Candidates</b>							
<b>Daclizumab</b>					\$ 17,737	\$ 7,778	\$ 8,329
	Asthma	Phase II	—	2004			
	Ulcerative colitis	Phase II	—	2004			
<b>HuZAF</b>					22,888	14,047	6,934
	Crohn's disease	Phase II	—	2004			
	Psoriasis	Phase I/II	—	Completed(1)			
<b>Nuvion</b>					9,134	4,001	4,658
	Steroid-refractory Graft vs. Host disease	Phase II	—	Completed(1)			
	Severe steroid-refractory Ulcerative colitis	Phase I/II	—	2004			
<b>Anti-a5b1 integrin Mab(2)</b>	Solid tumors	Phase I	—	2004	3,528	—	—
<b>Out-license Candidates(5)</b>							
<b>Anti-IL-4</b>	Asthma	Phase IIa	GlaxoSmithKline	Completed(3)	1,123	2,791	2,961
<b>Anti-IL-12</b>	Autoimmune diseases	Phase I	—	Completed(4)	286	2,526	5,058
<b>Remitogen</b>					474	2,766	3,532
	Non-Hodgkin's B-Cell lymphoma	Phase II	—	Completed			
	Solid tumors	Phase I	—	Completed			
<b>Zamyl</b>	Acute myeloid leukemia	Phase III	—	Completed	327	3,981	5,036
<b>Other(6)</b>					27,235	20,088	15,655
<b>Total Research and Development Expenses</b>					<b>\$ 82,732</b>	<b>\$ 57,978</b>	<b>\$ 52,163</b>

(1) Product is no longer being developed for this indication.

(2) Product acquired from Eos in April 2003.

(3) Product was returned to GlaxoSmithKline.

(4)

Target-related intellectual property outlicensed in December 2003.

(5) Further development of these products by PDL is not currently expected; some of these candidates are available for out-license.

(6) No single potential product included in "other" constitutes more than 5% of the total research and development expenses for the period presented.

The information in the column labeled "Estimated Completion of Phase" is our current 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. 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. 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 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.

### General and Administrative Expenses

General and administrative expenses in 2003 were \$27.6 million, an increase of 50% from 2002. In 2002, general and administrative expenses were \$18.4 million, an increase of 22% from 2001. General and administrative costs include costs of personnel, professional services, patent, consulting and other expenses related to our administrative functions and an allocation of facility costs. The increase in 2003 was primarily related to increased personnel and recruiting costs of \$5.2 million, higher legal costs related to our intellectual property, licensing and other contractual matters of \$1.7 million, increased facility-related costs of \$0.7 million, and stock-based compensation expense associated with the issuance of stock options to non-employees in 2003 of approximately \$0.3 million. 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. We expect that general and administrative expenses will continue to increase as we build infrastructure and support for expanded research and development capabilities.

### Acquired In-Process Research and Development

#### Eos Acquisition

In connection with the April 2003 acquisition of Eos, we recorded charges for acquired in-process research and development of \$37.8 million due to Eos' incomplete research and development programs that had not yet reached technological feasibility as of April 4, 2003 and had no alternative future use as of that date. A summary of these programs follows:

Program	Description	Status of Development	Value Assigned (in thousands)
Anti-angiogenesis (M200, Anti-a5b1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including pancreatic, non-small lung and colorectal cancers	IND filed December 2002; Phase I clinical trials initiated in June 2003	\$ 24,067
Ocular Neovascularization (F200, Anti-a5b1 Integrin Antibody)	Fab fragment of Anti-a5b1 Integrin Antibody for ocular indications, including age-related macular degeneration	IND filing expected in 2005*	\$ 13,767

\* Development progress may be affected by potential partnering discussions or commitment of resources to more advanced programs.

#### Acquisition of Zenapax® Rights from Roche

Effective October 2003, we entered into an amendment to our collaboration agreement with Roche, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell Zenapax (daclizumab) in all disease indications other than transplantation.

In connection with the new arrangement, we paid Roche \$80 million in cash for return of exclusive rights in indications other than transplantation, and we obtained an option to acquire rights in transplant indications (reversion right), exercisable by us in 2006, but effective in 2007 or as early as 2005 at the election of Roche.

Of the \$80 million that we paid to Roche in October 2003, we recorded a charge to acquired in-process research and development totaling approximately \$48.2 million. This amount relates to the rights to autoimmune indications for daclizumab that are currently being developed and tested in clinical studies, specifically to treat ulcerative colitis and asthma.

We are evaluating daclizumab in two Phase II clinical studies in patients with moderate-to-severe ulcerative colitis and asthma. These trials were fully enrolled by the end of December 2003, and we anticipate that results may be available in mid-year 2004.

The values of the acquired in-process research and development from both the Eos acquisition and the Roche arrangement were determined by estimating the related future probability-adjusted net cash flows, which were then discounted to present values using a rate of 15%. This discount rate is a significant assumption and is based on our estimated weighted average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from such projects were based on estimates of revenues and operating profits related to such projects considering the stage of development of each potential product acquired, the time and resources needed to complete each product, the estimated life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets. In determining the value of the acquired in-process research and development, the assumed commercialization dates used for the potential products ranged from 2008 to 2009 and 2007 to 2008 related to the Eos acquisition and the Roche arrangement, respectively.

Numerous risks and uncertainties exist with timely completion of development, including the uncertainty and timing of commencing human clinical trials and patient enrollment, as well as uncertainties related to the results of such studies, including interpretation of the data and obtaining FDA and other regulatory body approvals. The nature of the remaining efforts for completion of the acquired in-process research and development projects primarily consist of initiating clinical trials and studies, the cost, length and success of which are extremely difficult to determine. Feedback from regulatory authorities or results from clinical studies might require modifications or delays in later stage clinical trials or additional studies to be performed. The acquired products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals and the fact that the cost of sales to produce these products in a commercial setting has not been determined. If these programs cannot be completed on a timely basis, then our prospects for future revenue growth would be adversely impacted.

### Interest and Other Income, Interest Expense and Impairment Loss on Investment

	Years Ended December 31			Annual Percent Change	
	2003	2002	2001	2003 / 2002	2002 / 2001
	(In thousands)				
<b>Interest and Other Income, Interest Expense and Investment Impairment</b>					
Interest and other income, net	\$ 9,831	\$ 25,978	\$ 35,135	(62)%	(26)%
Interest expense	(9,770)	(9,146)	(9,709)	7%	(6)%
Impairment loss on investment	(150)	(1,366)	—	(89)%	—

Interest and other income, net was \$9.8 million in 2003, a decrease of 62% from 2002. In 2002, interest and other income was \$26.0 million, a decrease of 26% from 2001. In 2003, interest and other income, net consists of interest income of \$16.3 million, partially offset by early debt extinguishment charges of approximately \$6.5 million. Interest income decreased by \$9.7 million in 2003 when compared to 2002 primarily due to declining interest rates on our marketable securities. Interest income in 2002 was \$26.0 compared to \$35.1 million in 2001. Also in 2002, the decrease in interest earned was due largely to the decreased interest earned on our marketable securities' balances primarily as a result of lower market interest rates.

Interest expense in 2003, net of amounts capitalized, related to our 5.50% convertible subordinated notes that were redeemed in November 2003, our 2.75% convertible subordinated notes, a 7.64% term loan associated with the purchase our Fremont, California facilities, and notes payable assumed in our acquisition of Eos in the second quarter of 2003. Interest expense in 2002 related to our 5.50% convertible subordinated notes and a 7.64% term loan associated with the purchase our Fremont, California facilities. Interest expense in 2003 was \$9.8 million, an increase of 7% from 2002. Interest expense in 2002 was \$9.1 million, a decrease of 6% from 2001. Interest expense for 2003 increased slightly compared to the same period in 2002, due to increased interest expense resulting from the issuance of the 2.75% convertible notes in July 2003, including higher amortization of associated debt issuance costs, and the notes payable assumed from the Eos acquisition, partially offset by increased capitalized interest. Capitalized interest was \$2.2 million and \$0.5 million in 2003 and 2002, respectively, in connection with the renovation of our existing manufacturing facilities and the development activities for our future manufacturing facilities. The decrease in 2002 when compared to 2001 was the result of capitalizing \$0.5 million of our interest cost in 2002 in connection with the renovation of our existing manufacturing facilities and the development and construction activities for our future manufacturing facilities. No interest was capitalized in 2001.

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 therefore difficult to estimate. As of December 31, 2002, we estimated that the value of our investment in Signature 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. As of March 31, 2003, we estimated that our

investment in Signature had become fully impaired and that such impairment was other than temporary. Accordingly, we recorded an impairment charge of \$150,000 in March 2003.

## Income Taxes

We have recorded a tax provision of approximately \$73,000 for 2003 primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee, compared to \$42,000 for 2002. We do not expect to record any tax provision for federal income taxes during 2004 based upon our projected U.S. tax loss for 2004.

## 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, 2003, we had cash and cash equivalents, marketable securities and restricted investments in the aggregate of \$505.0 million, compared to \$606.4 million at December 31, 2002.

Net cash used in our operating activities in 2003 was approximately \$23.0 million compared with net cash used in operating activities of \$5.1 million in 2002. In 2003, the change in cash used in operating activities as compared to 2002 related primarily to the funding of greater operating expenses, increases in other current assets and other assets resulting from the transaction costs associated with the issuance of our 2.75% convertible notes, partially offset by an increase in accounts payable and accrued liabilities resulting from the construction of our new commercial manufacturing facility in Brooklyn Park, Minnesota. 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 our investment in Signature in 2002.

In 2003, net cash used in our investing activities was \$21.5 million, compared to cash provided by investing activities in 2002 of \$168.8 million. The change in 2003 was primarily the result of purchases of marketable securities associated with the issuance of our 2.75% convertible notes, as well as the purchase of intangible assets and increased purchases of property and equipment. Purchases of property and equipment in 2003 was primarily related to the development and construction activities for our manufacturing facility in Brooklyn Park, Minnesota. The purchase of intangible assets related to an amendment to our collaboration agreement with Roche, pursuant to which we paid Roche \$80 million in cash in return for exclusive worldwide rights to market, manufacture and sell daclizumab in all disease indications other than transplantation, resulting in a charge to in-process research and development of \$48.2 million and intangible assets of \$31.8 million. In 2002, purchases of land, property and equipment primarily consisted of land and equipment purchases in connection with the renovation of our existing Plymouth, Minnesota manufacturing facility as well as construction activities for our manufacturing facility in Brooklyn Park, Minnesota.

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, as a result of the investment of higher cash balances at the end of 2000 resulting from a follow-on offering in the third quarter of 2000. Also, the increase is attributable to higher capital expenditures in 2002, which primarily related to the renovation of our Plymouth, Minnesota manufacturing facility and development and construction activities and the purchase of land for our manufacturing facility in Brooklyn Park, Minnesota. Capital expenditures in

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2001 primarily consisted of equipment purchases and renovation of our Plymouth, Minnesota manufacturing facility.

Net cash provided by our financing activities in 2003 was \$98.5 million compared to \$3.8 million in 2002. The change in 2003 from 2002 was primarily the result of the proceeds totaling \$250 million from the issuance of our 2.75% convertible notes in July 2003, partially offset by the redemption of our 5.50% convertible notes in November 2003 in the aggregate of approximately \$154.1 million. The decrease in net cash provided by our financing activities in 2002 as compared to net cash provided by our financing activities of \$12.5 million in 2001 was primarily the result of a decrease in the exercise of outstanding stock options.

We estimate that our existing capital resources will be sufficient to fund our current level of operations for at least the next four years. Our future capital requirements will depend on numerous factors, including, among others, royalties from sales of products by third-party licensees, including Synagis, Herceptin, Xolair, Raptiva, Zenapax, Mylotarg and Avastin; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; interest income; 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 and qualifying 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 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 November 2003, we paid approximately \$155.9 million in cash to redeem our 5.5% convertible notes due February 15, 2007, including accrued interest of \$1.8 million and prepayment obligations of approximately \$4.1 million in connection with the redemption. In addition to the \$4.1 million in prepayment obligations for early extinguishment of these notes, we recorded a charge to write-off the unamortized balance of the original debt issuance costs of approximately \$2.4 million; these charges, totaling \$6.5 million, are included in interest and other income, net, in the Consolidated Statement of Operations.

In May 2001, we signed a collaborative agreement with Exelixis, Inc. 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 ended in June 2003. During the funding period, Exelixis performed certain genetic screens and other research activities intended to identify and validate targets for antibody therapeutics in

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 July 2003, we issued 2.75% convertible subordinated notes due August 16, 2023 in the aggregate with a principal amount of \$250.0 million. The 2.75% convertible notes are convertible into our common stock at a conversion price of \$20.14 per share, subject to adjustment in certain events and at the holders' option. Interest on the 2.75% convertible notes is payable semiannually in arrears on February 16 and August 16 of each year. The 2.75% convertible notes are unsecured and are subordinated to all our existing and future senior indebtedness and may be redeemed at our option, in whole or in part, beginning on August 16, 2008 at par value. In addition, in August 2010, August 2013 and August 2018, holders of our 2.75% convertible notes may require us to repurchase all or a portion of their notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For 2.75% convertible notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of notes to be repurchased in August 2013 and August 2018, at our option, in cash, shares of our common stock or a combination of cash and shares of our common stock. In the third quarter of 2003, we filed a shelf registration statement with the Securities and Exchange Commission covering the resale of the 2.75% convertible notes and the common stock issuable upon conversion of the notes.

We pledged a portfolio of U.S. government securities costing approximately \$20.8 million as security for the 2.75% convertible notes. These securities, and the earnings thereon, will be sufficient to pay the first six scheduled interest payments due on the notes. The pledged amount of \$20.8 million has been classified as restricted investments on our Consolidated Balance Sheet. The portion related to payments to be made within one year, \$7.4 million, is reflected on the Consolidated Balance Sheet within marketable securities and the portion related to payments to be made thereafter, \$13.4 million, is reflected on the Consolidated Balance Sheet as long-term restricted investments.

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. We have engaged Fluor Daniel (a division of Fluor Enterprises) to handle the engineering and certain procurement services for the new facility. In addition, we engaged Fluor Daniel to perform systems integration and assist in commissioning of the facility. As of December 31, 2003, under these arrangements, the aggregate contractual costs totaled approximately \$29.4 million, of which approximately \$5.5 million and \$0.9 million is remaining to be paid in 2004 and 2005, respectively. The design and project management work under this agreement was substantially completed in 2003, the construction support and systems integration is scheduled to be completed by the end of 2004, and the commissioning work is scheduled to be completed by mid-2005. In addition, we have entered into various commitments related to the manufacturing equipment and validation services required for the new facility with aggregate contractual costs of approximately \$36.0 million as of December 31, 2003, of which approximately \$18.8 million and \$3.1 million is remaining to be paid in 2004 and 2005, respectively. We have also signed agreements with McGough Construction for the construction management and certain construction services for the facility. Under those agreements as of December 31, 2003, the aggregate contractual costs totaled approximately \$94.0 million, of which approximately \$57.5 million remains to be paid in 2004. The facility construction is scheduled to be completed in late 2004.

Our contractual obligations under lease, debt, construction and research funding agreements for the next five years and thereafter as of December 31, 2003 are as follows:

	Payments Due By Period				
	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years	Total
	(In thousands)				
<b>Contractual Obligations(1)</b>					
Operating leases	\$ 2,531	\$ 4,242	\$ 1,532	\$ 131	\$ 8,436
Capital leases	183	—	—	—	183
Long-term debt	1,836	2,826	2,278	6,643	13,583
Convertible notes	6,875	13,750	13,750	263,750	298,125
Construction contracts	81,865	3,962	—	—	85,827
<b>Total contractual cash obligations</b>	<b>\$ 93,290</b>	<b>\$ 24,780</b>	<b>\$ 17,560</b>	<b>\$ 270,524</b>	<b>\$ 406,154</b>

- (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, or (b) any royalty payments from us to third parties as the amounts of such payments and / or likelihood of such payments are not known in any period presented above.

#### Recent Accounting Pronouncements

In November 2002, the FASB issued Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (Issue 00-21). Issue 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. Issue 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. Issue 00-21 also

addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. The provisions of Issue 00-21 applied to our revenue arrangements entered into after June 30, 2003. Our adoption of Issue 00-21 did not have a material impact on our results of operations or financial position.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities," (FIN 46). 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 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 for interim periods ending after March 15, 2004. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. Our adoption of FIN 46 is not expected to have a material impact on our results of operations or financial position.

In December 2003, the FASB revised FASB Statement No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits," (FAS 132) to improve financial statement disclosures for defined benefit plans. The standard requires that companies provide more details about their plan assets, benefit obligations, cash flows, benefit costs and other relevant information. For example, cash flow disclosures will include projections of future benefit payments and an estimate of contributions to be made in the next year to fund pension and other postretirement benefit plans. In addition to

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expanded annual disclosures, companies are required to report the various elements of pension and other postretirement benefit costs on a quarterly basis. FAS 132 is effective for fiscal periods ending after December 15, 2003. Our adoption of FAS 132, as revised in December 2003, is reflected in Note 13 to the Consolidated Financial Statements.

#### Off-Balance Sheet Arrangements

None.

#### 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, 2003 levels, the fair value of the portfolio would decline by approximately \$2.5 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, 2003, the aggregate fair values of our long-term debt and convertible subordinated notes were approximately \$8.5 million and \$290.0 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 2.75%. 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 our material debt obligations that are sensitive to changes in interest rates. The table presents principal amounts and related weighted average interest

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rates by year of expected maturity for our debt obligations. Our convertible notes may be converted to common stock prior to the maturity date.

Liabilities (000's)	2004	2005	2006	2007	2008	Thereafter	Total	Fair Value
<b>Long-term debt, including current portion</b>								
Fixed Rate	\$ 506	\$ 544	\$ 588	\$ 635	\$ 685	\$ 5,472	\$ 8,430	\$ 8,500*
Avg. Interest Rate	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	
<b>Convertible subordinated notes</b>								
Fixed Rate	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 250,000	\$ 250,000	\$ 290,000*

\* The fair value of the remaining payments under our long-term obligations is estimated using discounted cash flow analyses, based on our 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 per share data)

	December 31,	
	2003	2002
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 341,768	\$ 287,730
Marketable securities, including \$7.4 million of restricted investments at December 31, 2003	149,863	318,680
Other current assets	11,893	7,432
Total current assets	503,524	613,842
Land, property and equipment, net	155,513	70,802
Intangible assets, net	32,311	—
Restricted investments	13,362	—
Other assets	7,320	3,174
Convertible note receivable	30,000	30,000
Total assets	\$ 742,030	\$ 717,818
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,576	\$ 1,628
Accrued compensation	5,903	2,520
Accrued clinical trial costs	1,759	2,327
Accrued interest	3,204	3,071
Other accrued liabilities	19,351	4,576
Deferred revenue	161	38
Current portion of notes payable	537	—
Capital lease obligations	183	—
Current portion of other long-term debt	502	466
Total current liabilities	35,176	14,626
Convertible subordinated notes	250,000	150,000
Notes payable	595	—
Other long-term debt	7,928	8,426
Total liabilities	293,699	173,052
Commitments and contingencies (Notes 2 and 10)		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.01 per share, 250,000 shares authorized; 93,886 and 89,179 issued	939	892

and outstanding at December 31, 2003 and December 31, 2002, respectively

Additional paid-in capital	666,793	628,292
Accumulated deficit	(220,291)	(90,477)
Accumulated other comprehensive income	890	6,059
Total stockholders' equity	448,331	544,766
Total liabilities and stockholders' equity	\$ 742,030	\$ 717,818

See accompanying notes.

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**PROTEIN DESIGN LABS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

	Years Ended December 31,		
	2003	2002	2001
<b>Revenues:</b>			
Royalties	\$ 52,704	\$ 40,421	\$ 30,604
License and other	13,982	5,952	13,796
Total revenues	66,686	46,373	44,400
<b>Costs and expenses:</b>			
Research and development	82,732	57,978	52,163
General and administrative	27,613	18,373	15,004
Acquired in-process research and development	85,993	—	—
Total costs and expenses	196,338	76,351	67,167
Operating loss	(129,652)	(29,978)	(22,767)
Interest and other income, net	9,831	25,978	35,135
Interest expense	(9,770)	(9,146)	(9,709)
Impairment loss on investment	(150)	(1,366)	—
Income (loss) before income taxes	(129,741)	(14,512)	2,659
Provision for income taxes	73	42	12
Net income (loss)	\$ (129,814)	\$ (14,554)	\$ 2,647
<b>Net income (loss) per share:</b>			
Basic	\$ (1.40)	\$ (0.16)	\$ 0.03
Diluted	\$ (1.40)	\$ (0.16)	\$ 0.03
<b>Shares used in computation of net income (loss) per share:</b>			
Basic	92,478	88,865	87,624
Diluted	92,478	88,865	92,889

See accompanying notes.

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**PROTEIN DESIGN LABS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(In thousands, except shares of common stock data)



	Common Stock		Additional Paid-In Capital
	Shares	Amount	
Balance at December 31, 2000	87,153,300	\$ 872	\$ 611,254
Issuance of common stock under employee benefit plans	1,346,001	13	12,840
Balance at December 31, 2001	88,499,301	885	624,094
Issuance of common stock under employee benefit plans	679,566	7	4,198
Balance at December 31, 2002	89,178,867	892	628,292
Issuance of common stock under employee benefit plans	526,662	5	4,105
Issuance of common stock in connection with Eos acquisition	4,180,375	42	34,120
Issuance of common stock options to consultants for services	—	—	276
Balance at December 31, 2003	93,885,904	\$ 939	\$ 666,793

	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at December 31, 2000	\$ (78,570)	\$ 588	\$ 534,144
Issuance of common stock under employee benefit plans	—	—	12,853
Comprehensive income:			
Net income	2,647	—	2,647
Unrealized gains on securities	—	8,799	8,799
Total comprehensive income			11,446
Balance at December 31, 2001	(75,923)	9,387	558,443
Issuance of common stock under employee benefit plans	—	—	4,205
Comprehensive loss:			
Net loss	(14,554)	—	(14,554)
Change in unrealized gains on securities	—	(3,328)	(3,328)
Total comprehensive loss			(17,882)
Balance at December 31, 2002	(90,477)	6,059	544,766
Issuance of common stock under employee benefit plans	—	—	4,110
Issuance of common stock in connection with Eos acquisition	—	—	34,162
Issuance of common stock options to consultants for services	—	—	276
Comprehensive loss:			
Net loss	(129,814)	—	(129,814)
Change in unrealized gains on securities	—	(5,169)	(5,169)
Total comprehensive loss			(134,983)
Balance at December 31, 2003	\$ (220,291)	\$ 890	\$ 448,331

See accompanying notes.

**PROTEIN DESIGN LABS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Years Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net income (loss)	\$ (129,814)	\$ (14,554)	\$ 2,647

Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Acquired in-process research and development	85,993	—	—
Depreciation and amortization	8,407	5,441	4,782
Amortization of convertible notes offering costs	1,147	721	721
Amortization of intangible assets	941	—	—
Consultant stock-based compensation expense	276	—	—
Impairment loss on investment	150	1,366	—
Loss on early extinguishment of debt	6,538	—	—
Loss on disposal of fixed assets	455	—	—
Changes in assets and liabilities:			
Interest receivable	2,975	3,904	(4,522)
Other current assets	(3,770)	(3,336)	(2,164)
Other assets	(7,857)	(643)	105
Accounts payable	997	379	187
Accrued liabilities	10,474	1,713	2,187
Deferred revenue	123	(62)	(1,355)
<b>Total adjustments</b>	<b>106,849</b>	<b>9,483</b>	<b>(59)</b>
Net cash provided by (used in) operating activities	(22,965)	(5,071)	2,588
Cash flows from investing activities:			
Purchases of marketable securities	(110,049)	(79,954)	(485,483)
Maturities of marketable securities	278,000	283,500	207,885
Purchase of restricted securities	(20,822)	—	—
Purchase of convertible note	—	—	(30,000)
Cash acquired in acquisition of Eos	2,453	—	—
Purchase of intangible assets	(80,000)	—	—
Purchase of land, property and equipment	(91,118)	(34,786)	(8,716)
<b>Net cash provided by (used in) investing activities</b>	<b>(21,536)</b>	<b>168,760</b>	<b>(316,314)</b>
Cash flows from financing activities:			
Proceeds from issuance of common stock	4,110	4,205	12,853
Proceeds from issuance of convertible notes	250,000	—	—
Extinguishment of long-term convertible debentures	(154,125)	—	—
Payments on other long-term obligations	(1,446)	(432)	(400)
<b>Net cash provided by financing activities</b>	<b>98,539</b>	<b>3,773</b>	<b>12,453</b>
Net increase (decrease) in cash and cash equivalents	54,038	167,462	(301,273)
Cash and cash equivalents at beginning of year	287,730	120,268	421,541
Cash and cash equivalents at end of year	\$ 341,768	\$ 287,730	\$ 120,268
<b>Supplemental Disclosure of Noncash Financing and Investing Activities</b>			
Exchange of assets for third party preferred stock	\$ —	\$ 1,290	\$ —
<b>Cash Flow for Acquisition of Eos:</b>			
Assembled workforce	\$ 1,410	\$ —	\$ —
Other current assets acquired	691	—	—
Acquired in-process research and development	37,834	—	—
Property and equipment acquired	2,274	—	—
Liabilities assumed	(5,848)	—	—
Acquisition and transaction costs incurred	(4,652)	—	—
Common stock issued	(34,162)	—	—
<b>Supplemental Disclosure of Cash Flow Information</b>			
Cash paid during the year for interest	\$ 10,736	\$ 8,957	\$ 8,989

See accompanying notes.

PROTEIN DESIGN LABS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003

1. Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. (we, us, our, PDL or the Company) is a biotechnology company engaged in the development of humanized antibodies to prevent or treat various disease conditions. We currently have antibodies under development for autoimmune and inflammatory conditions, asthma and cancer. We hold 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 years amounts have been made to conform to the current year presentation.

### *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, cash equivalents 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.

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- 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, 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.

#### *Multiple Element Arrangements*

We enter into patent license and humanization agreements that may contain other elements, such as milestones related to reaching particular stages in product development and royalties. If we determine that separate elements exist under EITF 00-21, "Revenue Arrangements with Multiple Deliverables," we recognize revenue for delivered elements only when the fair values of undelivered elements are known, 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.
- 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 they or we achieve certain levels of development with respect to the

*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 recognize 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 ongoing 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 patient's 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 that 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.

*Interest and Other Income, Net*

Interest and other income, net, includes interest income earned on our marketable securities and other non-operating income and expenses. For the year ended December 31, 2003, the components of interest and other income, net, primarily include interest income on our marketable securities of \$16.3 million, partially offset by a \$6.5 million charge associated with the early extinguishment of our \$150 million 5.50% Convertible Notes in the fourth quarter of 2003 (see Note 12 for further details of our debt extinguishment). For the years ended December 31, 2002 and 2001, the amount was comprised solely of interest income on our marketable securities portfolio.

*Comprehensive Income (Loss)*

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 changes in unrealized gains and losses on our holdings of available-for-sale securities. Comprehensive income (loss) for the years ended December 31, 2003, 2002 and 2001 is reflected in the Consolidated Statements of Stockholders' Equity.

*Stock-Based Compensation*

At December 31, 2003, we had six stock-based employee compensation plans, which are described more fully in Note 14. 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.

	Year Ended December 31		
	2003	2002	2001
	(In thousands, except per share data)		
Net income (loss), as reported	\$ (129,814)	\$ (14,554)	\$ 2,647
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(19,255)	(11,842)	(38,939)
Pro forma net (loss)	\$ (149,069)	\$ (26,396)	\$ (36,292)

Net income (loss) per share:

Basic—as reported	\$	(1.40)	\$	(0.16)	\$	0.03
Basic—pro forma	\$	(1.61)	\$	(0.30)	\$	(0.41)
Diluted—as reported	\$	(1.40)	\$	(0.16)	\$	0.03
Diluted—pro forma	\$	(1.61)	\$	(0.30)	\$	(0.41)

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 2003, 2002 and 2001, respectively: (a) no dividends; (b) expected volatility of 72%, 87%, and 98%; (c) weighted-average risk-free interest rates of 2.90%, 3.91%, and 4.72%; and (d) expected lives of 5 years.

We account for stock options granted to non-employees at fair value using the Black-Scholes Option Valuation Model in accordance with EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Stock options granted to non-employees are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense over the service period in which the non-employee provides services to the Company.

#### *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 product revenue and have only one segment with facilities located primarily within the United States. The majority of our revenues are earned in the United States.

Revenues from Genentech in 2003, 2002 and 2001 accounted for 40%, 38%, and 27% of total revenues, and revenues from MedImmune in 2003, 2002 and 2001 accounted for 37%, 48%, and 33% of total revenues, respectively. No other revenue from any other source exceeded 10% of total revenues for all periods presented.

#### *Derivative Instruments*

In accordance with FASB 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 our operations or on our financial position.

#### *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. All foreign currency gains and losses are included in interest and other income, net, and have not been material.

#### *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. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred.

#### *Land, Property and Equipment*

Land, property and equipment are stated at cost less accumulated straight-line depreciation and amortization. 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	Shorter of asset life or 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 capitalize 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. Of total interest cost incurred of \$12.0 million and \$9.6 million during the years ended December 31, 2003 and 2002, we capitalized interest of \$2.2 million and \$0.5 million, respectively. No interest was capitalized in 2001.

#### *Intangible and Other Long-Lived Assets*

Intangible assets consist of assembled workforce, purchased core technology and a reversion right to purchase certain technology from Roche. In accordance with FAS No. 142, "Goodwill and Other Intangible Assets," we are amortizing our intangible assets with definite lives over their estimated useful lives and review them for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We are amortizing

the assembled workforce and core technology assets on a straight-line basis over their estimated useful lives, 2 and 10 years, respectively. We will reclassify the reversion right asset into core technology at that time when the rights to the technology revert back to us (see Note 2). Upon reclassifying the reversion right asset to core technology, we will amortize the asset over the remaining term of the patents underlying the acquired technology. Amortization of intangible assets is included primarily in research and

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development expenses in the Consolidated Statement of Operations. (See Note 8 for further details on intangible assets.)

In accordance with FASB Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," we identify and record impairment losses, as circumstances dictate, on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the discounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. No such impairments have been identified with respect to our long-lived assets, which consist primarily of property and equipment and the intangible assets discussed above.

#### *Postretirement Benefits*

In June 2003, we established a postretirement health care plan to offer medical benefits to certain of our former officers and their dependents. We account for these postretirement benefits in accordance with FASB Statement No. 106, "Employers' Accounting for Postretirement Benefits Other Than Pensions" and FASB Statement No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits."

#### *Recent Accounting Pronouncements*

In November 2002, the FASB issued EITF 00-21, "Revenue Arrangements with Multiple Deliverables" (Issue 00-21). Issue 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. Issue 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. Issue 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. The provisions of Issue 00-21 applied to our revenue arrangements entered into after June 30, 2003. Our adoption of Issue 00-21 did not have a material impact on our results of operations or financial position.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities," (FIN 46). 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 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 for interim periods ending after March 15, 2004. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. Our adoption of the remaining provisions FIN 46 in the first quarter of 2004 is not expected to have a material impact on our results of operations or financial position.

In December 2003, the FASB revised FASB Statement No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits," (FAS 132) to improve financial statement disclosures for defined benefit plans. The standard requires that companies provide more details about their plan assets, benefit obligations, cash flows, benefit costs and other relevant information. For example, cash flows will include projections of future benefit payments and an estimate of contributions to be made in the next year to fund pension and other postretirement benefit plans. In addition to expanded annual disclosures, companies are required to report the various elements of pension and other postretirement

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benefit costs on a quarterly basis. FAS 132 is effective for fiscal periods ending after December 15, 2003. Our adoption of FAS 132, as revised in December 2003, is reflected in Note 13.

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

**Roche.** Effective October 2003, we amended our 1999 collaboration agreement with Hoffmann-La Roche, Inc. and its affiliates (Roche), pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell Zenapax® (daclizumab) in all disease indications other than transplantation. Roche currently is expected to continue to market Zenapax in transplantation indications until 2007, although an earlier transfer to us of rights in transplantation may occur upon six months' written notice at Roche's election.

In connection with the new arrangement, we paid Roche \$80 million in cash for return of exclusive rights in indications other than transplantation, and we obtained an option to acquire rights in transplant indications (reversion right), exercisable by us in 2006, but effective in 2007 or as early as 2005 at the election of Roche. To effectuate the transfer of Zenapax in the transplantation indications, we will pay an additional exercise fee to Roche based on the average annual gross sales of Zenapax during the period from January 1, 2004 through the calendar quarter prior to the date of notice of the exercise, or Roche's notice of its decision to transfer the rights to us prior to our exercise date. If we do not receive transplantation rights, we would pay modest royalties to Roche on any sales in all diseases other than transplantation, and we would continue to receive royalties from Roche on sales of Zenapax in transplantation.

Of the \$80 million that we paid to Roche in October 2003, we recorded a charge to acquired in-process research and development totaling approximately \$48.2 million, representing technology that had not yet reached technological feasibility and that had no known future alternative uses. In particular, this amount relates to the rights to autoimmune indications for daclizumab that we are currently developing and testing in clinical studies, specifically to treat asthma and ulcerative colitis. These Phase II trials were fully enrolled by the end of December 2003, and we anticipate that results may be available in the first half of 2004.

We capitalized the remaining amount of \$31.8 million, which relates to core technology and the reversion right. We are amortizing the value of the core technology, \$16.0 million, over the term of the patents underlying the acquired technology. We will reclassify the reversion right asset, \$15.8 million, into core

technology at the time when the rights to the technology revert back to us, which at our option will be no later than 2007, but could be as early as 2005 at the election of Roche. Upon reclassifying the reversion right asset to core technology, we will amortize the asset over the remaining term of the patents underlying the acquired technology.

The value of the acquired in-process research and development was determined by estimating the related future probability-adjusted net cash flows, which were then discounted to a present value using a rate of 15%. This discount rate is a significant assumption and is based on our estimated weighted average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from such projects were based on estimates of revenues and operating profits related to such projects considering the stage of development of each potential product acquired, the time and resources needed to complete each product, the estimated life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets. In determining the value of the acquired in-process research and development, the assumed commercialization dates used for the potential products ranged from 2007 to 2008.

**GlaxoSmithKline plc.** In September 1999, we signed agreements with GlaxoSmithKline (GSK), involving two humanized antibodies for the possible treatment of asthma. We obtained a license to

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GSK's humanized anti-IL-4 antibody and granted an exclusive license under our antibody humanization patents to GSK for its humanized anti-IL-5 antibody. We also granted GSK options to obtain non-exclusive licenses under these patents for up to three additional antibodies.

In May 2003, we completed a Phase II trial of the humanized anti-IL-4 antibody in asthma patients. The antibody was well tolerated, but did not demonstrate clinical benefit compared to placebo at either of the dose levels tested. Accordingly, we will not conduct additional clinical studies of the humanized anti-IL-4 antibody and the program has been returned to GSK.

**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. We recognized the expense of our research funding ratably over the periods it was performed by Exelixis. As of December 31, 2003, we provided a total of \$8.0 million in research funding to Exelixis of which we expensed \$1.7 million in 2003, \$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 did not extend the research funding beyond the original two years, and as such, we did not fund any research expense to Exelixis beyond the second quarter of 2003.

**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. To date, we have received a licensing fee and milestone payments from Igeneon and in the future, we may receive additional milestone payments and royalties on any product sales generated by the antibody.

**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 licensing and signing fees totaling \$3.7 million 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 have since been receiving royalties on Herceptin sales. Further, in September 2003, Genentech and we mutually agreed to extend the master agreement for an additional 5-year term ending December 2008.

In December 2003, we signed a definitive agreement with Genentech, which resolved a dispute relating to our existing patent licensing master agreement, in particular with respect to our antibody humanization patents and certain of Genentech's humanized antibodies. Under terms of the agreement, Genentech exercised licenses under the patent licensing master agreement between the parties for Genentech's Xolair and Raptiva antibody products, which were approved by the FDA in the second and fourth quarters of 2003, respectively. These exercises resulted in payment of license exercise fees of \$2.2 million to us, which we recognized as license revenue in the fourth quarter of 2003. We recognized

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royalty revenue from third quarter 2003 sales of Xolair beginning in the fourth quarter of 2003, and we will commence recognition of royalty revenue from Raptiva product sales in the first quarter of 2004.

In consideration of approximately \$1.1 million, Genentech exercised a license for its Avastin antibody product, which was approved by the FDA in February 2004. As a result, we will recognize license exercise fees of approximately \$1.1 million in the first quarter of 2004 and commence recognition of royalty revenue from Avastin product sales in the second quarter of 2004.

In connection with the December 2003 definitive agreement, we agreed to certain royalty reductions for significant levels of annual aggregate sales of Genentech products licensed under the master agreement. The revised royalty rate structure would apply reciprocally to any of our products licensed under the master agreement. The agreement resolves and settles both companies' disputes regarding infringement of the Xolair, Raptiva and Avastin products and the validity and enforceability of our patents. We also obtained additional rights for non-exclusive, royalty-bearing licenses under certain of Genentech's antibody patents.

**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. In the fourth quarter of 2003, Millennium exercised one of its three patent licenses, and pursuant to the agreement, we received an additional patent license fee from Millennium.

**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.

**Actinium Pharmaceuticals, Inc.** In March 2003, we signed a licensing agreement with Actinium Pharmaceuticals, Inc. (API) that provides API certain development rights to Zamy1™, our SMART M195 humanized antibody against the CD33 antigen, present on the cancer cells of most patients with acute myeloid leukemia, the most common form of acute leukemia in adults. In connection with the signing of the agreement in the first quarter of 2003, we received an upfront licensing fee, and in the future we may receive development milestone payments and royalties on future sales generated by the antibody.

**Abbott Laboratories.** In December 2003, we signed a licensing agreement with Abbott Laboratories (Abbott) that provides Abbott certain exclusive rights to intellectual property related to antibodies capable of binding Interleukin-12 (IL-12) or its receptor. IL-12 is a cytokine with potential as a target in the treatment of a number of autoimmune diseases. The licensed rights are not related to our humanization technology. In connection with the agreement, we received an upfront licensing fee, and in the future we may receive development milestone payments and royalties on future sales of antibodies developed by Abbott against IL-12. We initially licensed certain intellectual property related to anti-IL-12 therapy from Roche and will share with Roche a portion of all amounts received.

**Other Patent License and Humanization Agreements.** We have entered into patent license and humanization agreements with numerous other companies that are independently developing humanized antibodies, including Biogen, Celltech Group plc, Chugai, Elan Pharmaceuticals, Eli Lilly and Company, Fujisawa Pharmaceuticals Co., IDEC Pharmaceuticals, Intermune Pharmaceuticals, Medarex, Merck KgaA, Progenics, Sankyo and Tanox. In each 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. 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, but does not include the effect of outstanding convertible notes because the assumed conversion of these notes would be anti-dilutive. We incurred net losses for the years ended December 31, 2002 and 2003, and as such, we did not include the effect of outstanding stock options or outstanding convertible notes in the diluted net loss per share calculations, as their effect would be anti-dilutive for both periods.

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:

	Years Ended December 31,		
	2003	2002	2001
	(In thousands, except basic and diluted net income (loss) per share)		
<b>Numerator:</b>			
Net income (loss)	\$ (129,814)	\$ (14,554)	\$ 2,647
<b>Denominator:</b>			
Basic net income (loss) per share—Weighted-average shares	92,478	88,865	87,624
Dilutive potential common shares—Stock options	—	—	5,265
Denominator for diluted net income (loss) per share	92,478	88,865	92,889
Basic net income (loss) per share	\$ (1.40)	\$ (0.16)	\$ 0.03
Diluted net income (loss) per share	\$ (1.40)	\$ (0.16)	\$ 0.03

The total number of shares excluded from the calculations of diluted net income (loss) per share for outstanding convertible notes was 16,389,450 in 2003 and 3,974,000 in 2002 and 2001. The total number of shares excluded from the calculation of diluted net loss per share for outstanding stock options was approximately 14,537,000 in 2003, 12,310,000 in 2002, and 5,263,000 in 2001. Such securities, had they been dilutive, would have been included in the computations of diluted net income (loss) per share.

### 4. Eos Acquisition



In April 2003, we completed the acquisition of Eos Biotechnology, Inc. (Eos), a development stage company. Eos was engaged in drug discovery of therapeutic antibodies based on information from the human genome. By applying a disease-based approach and a suite of proprietary discovery technologies, Eos identified antibodies that selectively and specifically target pathogenic cells.

This acquisition was completed to expand our development pipeline of potential products in oncology. Eos' portfolio consisted of two drug candidates, including Anti-a5b1 integrin antibody (M200), a function-blocking antibody that targets a specific integrin for solid tumors, including pancreatic, non-small lung and colorectal cancers and a Fab fragment of the Anti-a5b1 integrin antibody (F200) for ocular indications, including age-related macular degeneration. In 2003, we

initiated a Phase I clinical trial of M200 in patients with advanced solid tumors for whom there is no standard treatment.

In connection with this acquisition, we issued an aggregate of 4,180,375 shares of our common stock (net of approximately 151,000 shares that were withheld from Eos shareholders to provide for the Eos shareholder tax liabilities incurred in connection with receipt of the shares issued in the acquisition) in exchange for all outstanding shares of Eos preferred and common stock. The share issuances were exempt from registration pursuant to Section 3(a)(10) of the Securities Act of 1933, as amended. Certain shares issued will be held in escrow pursuant to the terms of the Agreement and Plan of Merger and Reorganization, as amended.

The Eos acquisition was accounted for as an acquisition of assets rather than as a business combination as Eos was a development stage company that had not commenced its planned principal operations. Eos lacked the necessary elements of a business because it did not have completed products and, therefore, no ability to access customers. The Eos operating results have been included in our consolidated results of operations since April 5, 2003.

The aggregate purchase price was \$38.8 million, consisting of the shares issued to the Eos stockholders valued at \$35.5 million (including the value of shares withheld to provide for tax liabilities of \$1.3 million), transaction costs of \$2.2 million and employee change of controls costs of \$1.1 million. The shares issued in connection with this acquisition were valued at \$8.17 per share, which represented the average closing market price of our common stock a few days before and after the acquisition announcement date (February 4, 2003).

Based upon an independent third-party valuation of the tangible and intangible assets acquired, we have allocated the total purchase price to the assets acquired and liabilities assumed as follows (in thousands):

Tangible assets acquired	\$ 5,418
Assembled workforce	1,410
Acquired in-process research and development	37,834
Liabilities assumed	(5,848)
	<u>\$ 38,814</u>

The \$1.4 million value assigned to the assembled workforce is being amortized over 2 years, the estimated useful life of the asset.

Approximately \$37.8 million of the purchase price was allocated to acquired in-process research and development due to Eos' incomplete research and development programs that had not yet reached

technological feasibility as of April 4, 2003 and had no alternative future use as of that date. A summary of these programs follows:

Program	Description	Status of Development	Value Assigned (in thousands)
Anti-angiogenesis (M200, Anti-a5b1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including pancreatic, non-small lung and colorectal cancers.	IND filed December 2002; Phase 1 clinical trials initiated in June 2003	\$ 24,067
Ocular Neovascularization (F200, Anti-a5b1 Integrin Antibody)	Fab fragment of Anti-a5b1 Integrin Antibody for ocular indications, including age-related macular degeneration.	IND filing in 2005*	\$ 13,767

\* Development progress may be affected by potential partnering discussions or commitment of resources to more advanced programs.

The value of the acquired in-process research and development was determined by estimating the related future probability-adjusted net cash flows, which were then discounted to a present value using a rate of 15%. This discount rate is a significant assumption and is based on our estimated weighted average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from such projects were based on estimates of revenues and operating profits related to such projects considering the stage of development of each potential product acquired, the time and resources needed to complete each product, the estimated life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target

markets. In determining the value of the acquired in-process research and development, the assumed commercialization dates used for the potential products ranged from 2008 to 2009.

## 5. 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.

As of March 31, 2003, we estimated that our investment in Signature had become fully impaired and that such impairment was other than temporary. Accordingly, in the first quarter of 2003 we

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recorded an impairment charge of \$150,000 to write off the residual book value of our investment in Signature at that date.

## 6. Marketable Securities and Restricted 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.

	Available-for-Sale Securities			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(In thousands)			
<b>December 31, 2003</b>				
Securities of the U.S. Government and its agencies maturing:				
within 1 year	\$ 28,909	\$ 50	\$ —	\$ 28,959
between 1-3 years	80,000	280	(25)	80,255
U.S. corporate debt securities maturing:				
within 1 year	29,994	504	—	30,498
between 1-3 years	10,070	81	—	10,151
Total marketable debt securities	\$ 148,973	\$ 915	\$ (25)	\$ 149,863
<b>December 31, 2002</b>				
Securities of the U.S. Government and its agencies maturing:				
within 1 year	\$ 50,935	\$ 556	\$ —	\$ 51,491
between 1-3 years	121,257	1,933	—	123,190
U.S. corporate debt securities maturing:				
within 1 year	110,116	2,444	—	112,560
between 1-3 years	30,313	1,126	—	31,439
Total marketable debt securities	\$ 312,621	\$ 6,059	\$ —	\$ 318,680

During 2003, 2002 and 2001, 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.

In July 2003, we issued 2.75% Convertible Subordinated Notes due August 16, 2023 with a principal amount of \$250.0 million (see Note 12 for further details). In connection with the issuance of these convertible notes, we pledged a portfolio of U.S. government securities as security, which, including the interest earned thereon, will be sufficient to pay the first six scheduled interest payments for the notes. The pledged amount, with a balance of approximately \$20.8 million at December 31, 2003, is classified as restricted investments on our balance sheet and consists of securities of the U.S. Government and its agencies. The portion related to payments to be made within one year, \$7.4 million, is reflected on the consolidated balance sheet within marketable securities, and the portion related to payments to be made thereafter, \$13.4 million, is reflected on the balance sheet as long-term restricted investments. The basis for the value of these restricted investments on the balance sheet is

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the amortized cost of the investments, which approximates the fair market values at December 31, 2003.

## 7. Land, Property and Equipment

Land, property, and equipment consisted of the following:

	December 31,	
	2003	2002
(In thousands)		
Land	\$ 10,743	\$ 10,743
Buildings and improvements	23,766	22,198
Leasehold improvements	18,887	6,691
Laboratory and manufacturing equipment	27,428	20,604
Construction-in-process	93,494	26,754
Computer and office equipment	11,278	6,621
Furniture and fixtures	2,540	2,058
	<u>188,136</u>	<u>95,669</u>
Less accumulated depreciation and amortization	(32,623)	(24,867)
	<u>\$ 155,513</u>	<u>\$ 70,802</u>

Depreciation and amortization expense for 2003, 2002 and 2001 was \$8.2 million, \$4.9 million, and \$4.3 million, respectively.

## 8. Intangible Assets

At December 31, 2003, our intangible assets consisted of the following (in thousands):

Assembled workforce	\$ 1,410
Core technology	16,053
Roche reversion right	15,788
	<u>33,251</u>
Total intangible assets	33,251
Less: Accumulated amortization	(940)
	<u>32,311</u>
Net intangible assets	\$ 32,311

Amortization expense for our intangible assets during 2003 was approximately \$940,000. The reversion right asset relates to our option to repurchase from Roche exclusive rights in remaining transplant indications of Zenapax. We will reclassify the reversion right asset into core technology at the time when the rights to the technology revert back to us (see Note 2). Upon reclassifying the reversion right asset to core technology, we will amortize the asset over the remaining term of the patents underlying the acquired technology.

For our assembled workforce and core technology intangible assets, the expected future annual amortization expense is as follows (in thousands):

	Assembled Workforce	Core Technology
<b>For the year ending December 31,</b>		
2004	\$ 705	\$ 1,646
2005	177	1,646
2006	—	1,646
2007	—	1,646
2008	—	1,646
Thereafter	—	7,411
	<u>882</u>	<u>15,641</u>
Total amortization expense	\$ 882	\$ 15,641

## 9. Accrued Liabilities

At December 31, 2003 and 2002, other accrued liabilities consisted of the following (in thousands):

2003	2002
------	------

Construction-in-process	\$	14,568	\$	1,896
Consulting and services		2,409		1,458
Other		2,374		1,222
Total	\$	19,351	\$	4,576

## 10. Commitments

We occupy leased facilities under agreements that expire in 2004, 2005, 2006 and 2009. We also have leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately \$2.3 million, \$1.3 million, and \$0.9 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Future payments under non-cancelable operating leases at December 31, 2003, are as follows:

<b>Year Ending December 31,</b>		
2004	\$	2,531
2005		2,344
2006		1,898
2007		753
2008		779
Thereafter		131
	\$	8,436

## 11. Long-Term Debt and Notes Payable

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

In connection with our acquisition of Eos in the second quarter of 2003, we assumed notes payable of \$2.3 million related to equipment and software purchases during 2001 and 2002. The equipment

loans bear interest at a weighted average rate of 10.2%, which payments are due in equal installments of interest and principal over a term of generally 4 years. The loans are secured by the equipment and software purchases made under the terms of the loans.

Future minimum payments under the facilities and equipment loans at December 31, 2003, together with the present value of those minimum payments, are as follows (in thousands):

<b>Year Ending December 31,</b>		
2004	\$	1,836
2005		1,583
2006		1,243
2007		1,139
2008		1,139
Thereafter		6,643
Total		13,583
Less amount representing interest		(4,021)
Present value of future payments		9,562
Less current portion		(1,039)
Non-current portion	\$	8,523

We believe that the fair values of the facility and equipment loans at December 31, 2003 approximated their carrying values as of this date. The fair values of the remaining payments under the loans are estimated using discounted cash flow analyses, based on our current incremental borrowing rates for similar types of borrowing arrangements.

## 12. Convertible Notes

In July 2003, we issued 2.75% Convertible Subordinated Notes due August 16, 2023 with a principal amount of \$250.0 million (Convertible Notes). The Convertible Notes are convertible into our common stock at a conversion price of \$20.14 per share, subject to adjustment in certain events and at the holders' option. Interest on the Convertible Notes is payable semiannually in arrears on February 16 and August 16 of each year. The Convertible Notes are unsecured and are subordinated to all our existing and future senior indebtedness. The Convertible Notes may be redeemed at our option, in whole or in part, beginning on August 16, 2008 at par value. In addition, in August 2010, August 2013 and August 2018, holders of our Convertible Notes may require us to repurchase all or a

portion of their notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For Convertible Notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of notes to be repurchased in August 2013 and August 2018, at our option, in cash, shares of our common stock or a combination of cash and shares of our common stock. In the third quarter of 2003, we filed a shelf registration statement with the Securities and Exchange Commission covering the resale of the Convertible Notes and the common stock issuable upon conversion of the Convertible Notes.

Issuance costs associated with the Convertible Notes aggregating \$8.3 million are included in other assets and are being amortized to interest expense over the term of the earliest redemption of the debt, or approximately seven years. The accumulated amortization at December 31, 2003 was \$0.5 million. The estimated fair value of the Convertible Notes at December 31, 2003 was approximately \$290 million based upon publicly available pricing information.

We pledged a portfolio of U.S. government securities costing approximately \$20.8 million as security for the Convertible Notes. (See Note 6.)

In February 2000, we issued 5.50% Convertible Subordinated Notes due February 15, 2007 with a principal amount of \$150 million (the 5.50% Convertible Notes). The 5.50% Convertible Notes were 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 these notes was payable semiannually in arrears on February 15 and August 15 of each year. The redemption price, set forth in the 5.5% Convertible Notes indenture, was 102.75% of the principal amount, or \$1,027.50 per \$1,000 of principal amount of the 5.5% Convertible Notes.

In November 2003, we paid approximately \$155.9 million in cash to redeem the 5.5% Convertible Notes, including accrued interest of \$1.8 million and prepayment obligations of approximately \$4.1 million in connection with the redemption. In addition to the \$4.1 million in prepayment obligations for early extinguishment of these notes, we recorded a charge to write-off the unamortized balance of the original debt issuance costs of approximately \$2.4 million; these charges, totaling \$6.5 million, are included in interest and other income, net, in the Consolidated Statement of Operations.

### 13. Postretirement Benefit Plan

In June 2003, we established a postretirement health care plan (the Plan), which covers medical, dental and vision coverage for certain of our former officers and their dependents. For the period from the inception of the Plan (June 1, 2003) through December 31, 2003, we have recognized, and accrued, net periodic postretirement benefit cost of approximately \$118,000. This expense includes service cost, interest cost, and amortization of prior service cost. In connection with the Plan, at December 31, 2003, the accumulated postretirement benefit obligation, the unamortized prior service cost, and the unrealized net actuarial loss were approximately \$1.0 million, \$773,000, and \$148,000, respectively.

We calculated the preceding information using an assumed discount rate of 6.5% and a measurement date of June 1, 2003. Further, we assumed the rate of increase in per capita costs of covered health care benefits to be 10% in 2004, decreasing gradually to 5.5% by the year 2009. A one percentage point change in the assumed health care cost trend rate would not have a material effect on the net periodic postretirement benefit cost or the postretirement benefit obligation at December 31, 2003.

In connection with the Plan, we expect to pay health care premiums aggregating approximately \$100,000 and \$2.1 million during the years 2004 through 2008, and during the years 2009 through 2030, respectively.

### 14. Stockholders' Equity

#### *Stock Split*

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. The share and per share amounts in the accompanying financial statements and notes reflect the effect of this stock split.

#### *Common Stock Reserved for Future Issuance*

Shares of our common stock reserved for future issuance at December 31, 2003 were as follows (in thousands):

All stock option plans	23,333
Employee stock purchase plan	974
Convertible debt	12,415
	<hr/>
Total	36,722
	<hr/>

#### *Stock Option Plans*

At December 31, 2003, we had six stock-based employee compensation plans, which are described more fully below. The exercise price of all stock options granted under our plans has been equal to the fair value of our common stock on the grant date and generally, the option term is ten years. 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 approximately \$276,000 in 2003, and it was immaterial in all other years presented.

#### *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. Options granted under the 1991 Plan generally vest at the rate of 25% 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.

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, are added automatically to the 1999 Stock Option Plan. During 2002, 1,717,694 shares, the remaining shares available for grant under the 1991 Plan, were transferred to the 1999 Stock Option Plan. As a result of stock options that subsequently terminated under the 1991 Plan, 361,630 additional shares have been transferred to and authorized for grant under the 1999 Stock Option Plan as of December 31, 2003.

#### *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. Options granted pursuant to the Directors Plan vest monthly over five years.

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. In 2002, the remaining 240,000 shares available for grant were transferred to the 2002 Outside Directors Plan.

#### *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.

Options may be granted under the Nonstatutory Option Plan with an exercise price and vesting period established at the discretion of the Board of Directors.

#### *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 our 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, are added automatically to the 1999 Option Plan. During 2002, 1,717,694 shares, the remaining shares available for grant under the 1991 Plan, were transferred to 1999 Stock Option Plan. As a result of stock options that subsequently terminated under the 1991 Plan, 361,630 additional shares have been transferred to and authorized for grant under the 1999 Stock Option Plan as of December 31, 2003.

Options may be granted under the 1999 Option Plan with an exercise price and vesting period established at the discretion of the Board of Directors.

#### *2002 Outside Directors Plan*

In December 2001, the Board of Directors adopted the 2002 Outside Directors Plan (2002 Directors Plan) to replace our 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. During 2002, 240,000 shares were transferred to the 2002 Directors Plan for a total of 480,000 shares authorized under this plan.

The 2002 Directors Plan provides for automatic annual grants to each outside director of options to purchase 12,000 shares of our common stock, vesting monthly over 12 months. Options must be granted under the 2002 Directors Plan with an exercise price equal to the market price of our stock on the grant date.

A summary of the status of our stock option plans at December 31, 2003, 2002 and 2001, and changes during the years ending those dates is presented below.

	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
(In thousands, except exercise price data)						
Outstanding at beginning of year	12,310	\$ 17.18	10,528	\$ 18.40	9,575	\$ 13.90
Granted	3,228	10.37	3,427	13.46	3,142	28.41
Exercised	(317)	6.75	(516)	5.63	(1,274)	8.29
Forfeited	(684)	21.65	(1,129)	22.45	(915)	20.18

Outstanding at end of year	14,537	15.69	12,310	17.18	10,528	18.40
Exercisable at end of year	8,230		5,975		3,799	
Weighted average fair value of options granted during the year	\$	7.27	\$	10.72	\$	21.55

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The following information applies to all stock options outstanding under our stock option plans at December 31, 2003:

Range of Exercise Prices	Outstanding			Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
(In thousands, except exercise prices and remaining contractual life data)					
\$ 3.88 - \$ 5.31	1,606	3.94	\$ 4.32	1,606	\$ 4.32
\$ 5.58 - \$ 7.83	1,590	6.89	7.20	725	6.63
\$ 7.84 - \$ 8.30	1,655	8.67	8.12	359	8.19
\$ 8.39 - \$ 9.66	1,723	6.59	9.19	881	9.47
\$ 9.66 - \$13.96	1,630	8.20	12.35	506	11.19
\$14.05 - \$18.90	1,616	8.53	17.73	611	18.39
\$20.48 - \$21.02	1,578	6.33	21.00	1,401	21.00
\$21.04 - \$23.49	292	7.82	22.29	156	22.29
\$23.63 - \$27.50	1,574	7.35	27.28	1,042	27.30
\$27.83 - \$56.84	1,273	7.05	38.55	943	39.08
<b>Totals</b>	<b>14,537</b>		<b>\$ 15.69</b>	<b>8,230</b>	<b>\$ 16.78</b>

To date, an aggregate of approximately 36,102,000 shares have been authorized for grant under our stock option plans and as of December 31, 2003, approximately 8,796,000 are available for grant.

#### 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, 2003, 973,287 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 2003, an aggregate of 210,074 shares were purchased by employees under the Employee Purchase Plan at prices of \$7.65 or \$11.87 per share. During 2002, an aggregate of 163,369 shares were purchased by employees under the Employee Purchase Plan at prices of \$9.23 or \$7.23 per share. During 2001, an aggregate of 72,923 shares were purchased by employees under the Employee Purchase Plan at prices of \$27.88 or \$34.17 per share.

#### 15. Income Taxes

The provision for income taxes consists of the following:

	Years Ended December 31,		
	2003	2002	2001
	(in thousands)		
<b>Current:</b>			
Federal	\$ —	\$ —	\$ —
State	18	12	12
Foreign	55	30	—
<b>Total Current</b>	<b>\$ 73</b>	<b>\$ 42</b>	<b>\$ 12</b>

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

Year Ended December 31,		
2003	2002	2001

(in thousands)

Computed at U.S. statutory rate			
At statutory rate	\$	(44,107)	\$ 930
Unutilized (utilized) net operating losses		31,243	(930)
Non deductible acquired in-process research and development		12,864	—
State taxes		18	12
Foreign taxes		55	—
<b>Total</b>	<b>\$</b>	<b>73</b>	<b>\$ 12</b>

As of December 31, 2003, we have federal and California state net operating loss carryforwards of approximately \$333.5 million and \$64.1 million, respectively. We also have federal and California state research and other tax credit carryforwards of approximately \$9.8 million and \$9.3 million, respectively. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in the year 2004 through 2023, if not utilized. The California state net operating losses will expire at various dates beginning in 2004 through 2013, if not utilized.

Utilization of the federal and California state net operating loss and tax 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 are as follows:

	December 31,	
	2003	2002
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 117,210	\$ 89,410
Research and other tax credits	15,940	11,910
Intangible assets	18,770	—
Deferred revenue	60	20
Capitalized research and development costs	10,610	8,090
Other	1,160	730
<b>Total deferred tax assets</b>	<b>163,750</b>	<b>110,160</b>
Valuation allowance	(163,400)	(107,740)
<b>Total deferred tax assets</b>	<b>350</b>	<b>2,420</b>
Deferred tax liabilities:		
Unrealized gains on investments	350	2,420
<b>Total deferred tax liabilities</b>	<b>350</b>	<b>2,420</b>
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

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Because of our history in the absence of earnings, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$55.7 million, \$4.4 million, and \$11.4 million during 2003, 2002 and 2001, respectively.

Approximately \$69.8 million of the deferred tax assets at December 31, 2003 relates to benefits of stock option deductions which, when recognized, will be allocated directly to contributed capital.

## 16. Legal Proceedings

We are 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 humanization patent. We have appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chain that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition 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 the opposition is successful, 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 United States. 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 opposition 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 opposition 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 were filed with respect to our second European antibody humanization patent and we have filed our response with the European Patent Office. Oral hearings, originally scheduled to take place in October 2003, have been postponed by the European Patent Office. No new date has been set for the hearings.

Also, three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a final determination from the Japanese Patent Office examiner affirming the Opposition Board's earlier decision. We have appealed this decision to the Tokyo High Court. A hearing was held in April 2003. 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.

With respect to these legal matters, we cannot predict with any certainty how they will ultimately be resolved. As any adverse outcomes are neither probable nor estimable at December 31, 2003, we have not reflected any charges for these matters in our consolidated results of operations.

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

Board of Directors and Stockholders  
Protein Design Labs, Inc.

We have audited the accompanying consolidated balance sheets of Protein Design Labs, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. 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, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 2, 2004

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### QUARTERLY FINANCIAL DATA (UNAUDITED)

	2003 Quarter Ended			
	December 31	September 30	June 30	March 31
	(in thousands, except per share data)			
<b>Revenues:</b>				
Royalties	\$ 8,896	\$ 8,758	\$ 17,905	\$ 17,145
License and other	4,717	567	3,096	5,602
Total revenues	13,613	9,325	21,001	22,747
<b>Costs and expenses:</b>				
Research and development	24,409	21,812	20,538	15,973
General and administrative	8,148	6,963	7,193	5,309
Acquired in-process research and development	48,159(1)	—	37,834(2)	—
Total costs and expenses	80,716	28,775	65,565	21,282
	(67,103)	(19,450)	(44,564)	1,465

Operating loss				
Interest and other income, net	)			
	(3,320)	4,291	4,188	4,672
Interest expense	(2,424)	(3,705)	(1,755)	(1,886)
Impairment loss on investment	—	—	—	(150)
Income (loss) before income taxes	(72,847)	(18,864)	(42,131)	4,101
Provision for income taxes	12	11	18	32
<b>Net income (loss)</b>	<b>\$ (72,859)</b>	<b>\$ (18,875)</b>	<b>\$ (42,149)</b>	<b>\$ 4,069</b>
<b>Net income (loss) per share:</b>				
Basic	\$ (0.78)	\$ (0.20)	\$ (0.45)	\$ 0.05
Diluted	\$ (0.78)	\$ (0.20)	\$ (0.45)	\$ 0.05
<b>Shares used in computation of net income (loss) per share:</b>				
Basic	93,764	93,665	93,301	89,182
Diluted	93,764	93,665	93,301	90,150

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

Certain reclassifications of previously reported amounts have been made to conform to the presentation in the Consolidated Statement of Operations for the year ended December 31, 2003.

- (1) Amount represents acquired in-process research and development related to the purchase of certain technology from Roche that has not yet achieved technological feasibility. For a description of these charges, see Note 2 to the Consolidated Financial Statements.
- (2) Amount represents acquired in-process research and development related to the Eos acquisition. For a description of these charges, see Note 4 to the Consolidated Financial Statements.
- (3) Amount includes charges of \$6.5 million incurred in connection with the early extinguishment of our \$150 million 5.50% Convertible Subordinated Notes due February 15, 2007. For a description of these charges, see Note 12 to the Consolidated Financial Statements.

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	2002 Quarter Ended			
	December 31	September 30	June 30	March 31
	(in thousands, except per share data)			
<b>Revenues:</b>				
Royalties	\$ 7,263	\$ 5,991	\$ 13,491	\$ 13,676
License and other	3,450	551	1,300	651
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	5,236	4,555	4,607	3,975
Total costs and expenses	20,969	18,861	19,367	17,153
Operating loss	(10,256)	(12,319)	(4,576)	(2,826)
Interest income	5,843	6,542	6,455	7,138
Interest expense	(2,090)	(2,214)	(2,422)	(2,420)
Impairment loss on investment	(1,366)	—	—	—
Income (loss) before income taxes	(7,869)	(7,991)	(543)	1,892
Provision for income taxes	15	—	16	11
<b>Net income (loss)</b>	<b>\$ (7,884)</b>	<b>\$ (7,991)</b>	<b>\$ (559)</b>	<b>\$ 1,881</b>

**Net income (loss) per share:**

Basic	\$	(0.09)	\$	(0.09)	\$	(0.01)	\$	0.02
Diluted	\$	(0.09)	\$	(0.09)	\$	(0.01)	\$	0.02

**Shares used in computation of net income (loss) per share:**

Basic		89,063		88,999		88,751		88,645
Diluted		89,063		88,999		88,751		91,750

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

Certain reclassifications of previously reported amounts have been made to conform to the presentation in the Consolidated Statement of Operations for the year ended December 31, 2003.

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2003, nor any change in other factors that could significantly affect our internal control over financial reporting subsequent to December 31, 2003, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART III****ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS**

Certain information concerning our current directors as of December 31, 2003, except as otherwise noted, is set forth below.

Director	Positions with the Company	Age	Director Since
Jürgen Drews, M.D.	Director	70	1997
Karen A. Dawes	Director	52	2003
L. Patrick Gage, Ph.D.	Director	61	2003
George M. Gould, Esq.	Director	66	1989
Laurence Jay Korn, Ph.D.	Director, Chairman of the Board	54	1986
Max Link, Ph.D.	Director	63	1993
Mark McDade	Chief Executive Officer, Director	48	2002
Cary L. Queen, Ph.D.	Senior Vice President, Director	53	1987
Jon S. Saxe, Esq.	Director	67	1989

*Karen A. Dawes* has served as a director of the Company since June 2003. She is currently Principal, Knowledgeable Decisions, LLC, a pharmaceutical consulting firm. She served from 1999 to 2003 as Senior Vice President and U.S. Business Group Head for Bayer Corporation's U.S. Pharmaceuticals Group. Prior to joining Bayer, she was Senior Vice President, Global Strategic Marketing, Wyeth, where she held responsibility for worldwide strategic marketing. She also served as Vice President, Commercial Operations for Genetics Institute, Inc., designing and implementing that company's initial commercialization strategy to launch BeneFIX and Neumega. Ms. Dawes began her pharmaceuticals industry career at Pfizer, Inc. where, from 1984 to 1994, she held a number of positions in Marketing, serving most recently as Vice President, Marketing of the Pratt Division. There she directed launches of Glucotrol/Glucotrol XL, Zolof, and Cardura. Ms. Dawes is also a director of Genaissance Pharmaceuticals, Inc.

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*Jürgen Drews, M.D.*, has been a director of the Company since February 1997. Dr. Drews has also served as a managing partner of the Health Innoventure Fund LLC of Bear, Stearns & Co. Inc. since January 2001. From March 1998 until December 2000, Dr. Drews served as a contributing advisor to OrbiMed Advisors LLC. Dr. Drews served as President, Global Research and as a member of the Executive Committee of the Roche Group from January 1996 to December 1997. From January 1991 to December 1995, Dr. Drews served as President, International Research and Development and as a member of the Executive Committee for the Roche Group. Prior to that time, Dr. Drews served as Chairman of the Research Board and member of the Executive Committee for F. Hoffmann-La Roche Ltd from April 1986 to December 1990. Dr. Drews served as Head of International Pharmaceutical Research and Development for Sandoz Ltd. from January 1982 to July 1985. Dr. Drews is also a director of MorphoSys GmbH, Genomics Pharmaceutical Company, Human Genome Sciences, Inc., Genaissance Pharmaceuticals, Inc., and Axxima Pharmaceuticals AG.

*L. Patrick Gage, Ph.D.*, has been a director of the Company since March 2003. From January 1997 until June 2002, Dr. Gage held various positions at Wyeth (formerly known as American Home Products). From March 1998 through June 2002, he served as President of Wyeth Research, a division of Wyeth, and from 2000 through June 2002 Dr. Gage also served as Senior Vice President, Science and Technology of Wyeth. From November 1989 through March 1998, Dr. Gage served as the head of Research and Development, then Chief Operating Officer and finally President of Genetics Institute, which was acquired by Wyeth in January 1997. Prior to that time, Dr. Gage held various positions in research management at Hoffmann-La Roche Inc. (Roche) over an 18-year period. Dr. Gage is also a Director of Neose Technologies and Chairman of the Dublin Molecular Medicine Centre in Ireland.

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

*Laurence Jay Korn, Ph.D.*, has been a director and Chairman of the Board of the Company since May 2002. From July 1986 until May 2002, Dr. Korn served as a director and Chairperson of the Board and from January 1987 until April 2002, Dr. Korn served as Chief Executive Officer. Previously, Dr. Korn headed a research laboratory and served on the faculty of the Department of Genetics at the Stanford University School of Medicine from March 1981 to December 1986. Dr. Korn received his Ph.D. from Stanford University and was a Helen Hay Whitney Postdoctoral Fellow at the Carnegie Institution of Washington and a Staff Scientist at the MRC Laboratory of Molecular Biology in Cambridge, England, before becoming an Assistant Professor at Stanford.

*Max Link, Ph.D.*, has been a director of the Company since June 1993. Dr. Link served as Chairman and Chief Executive Officer of Centerpulse Ltd. from March 2001 until its acquisition by Zimmer Holdings, Inc. in August 2003. He served as the Chief Executive Officer of Corange Ltd. from May 1993 to May 1994 and as the Chief Executive Officer of Boehringer Mannheim-Therapeutics, the worldwide pharmaceutical division of Corange (Boehringer Mannheim-Therapeutics), from October 1993 to May 1994. Dr. Link served as the Chairman of Sandoz Pharma Ltd. from April 1992 to April 1993. Dr. Link served in various management positions at Sandoz Ltd. and Sandoz Pharmaceuticals Corporation from October 1971 to April 1992. Dr. Link is also a director of Access Pharmaceuticals, Inc., Alexion Pharmaceuticals, Inc., Cell Therapeutics, Inc., CytRx Corp., Discovery Laboratories, Inc., Human Genome Sciences, Inc. and Celsion Corporation.

*Mark McDade*, has been a director of the Company since November 2002, when he joined the Company as Chief Executive Officer. From December 2000 until November 2002, he served as Chief Executive Officer of Signature BioScience, Inc. Prior to Signature, he was a co-founder and director of

Corixa Corporation. He served as Chief Operating Officer at Corixa from September 1994 through December 1998 and as President and Chief Operating Officer from January 1999 until his departure in late 2000. Before Corixa, he was Chief Operating Officer of Boehringer Mannheim-Therapeutics. Prior to Boehringer Mannheim-Therapeutics, he served in several positions at Sandoz Ltd., which included business development, product management and general management responsibilities. Mr. McDade currently serves on the board of directors of Valentis, Inc. Mr. McDade earned his M.B.A. from Harvard Business School.

*Cary L. Queen, Ph.D.*, has been a director of the Company since January 1987 and served as Vice President, Research, from April 1989 to August 2001 and as Senior Vice President from June 1993 until January 2004. Previously, Dr. Queen held positions at the National Institutes of Health from 1983 to 1986, where he studied the regulation of genes involved in the synthesis of antibodies. Dr. Queen received his Ph.D. in Mathematics from the University of California at Berkeley and subsequently served as an Assistant Professor of Mathematics at Cornell University.

*Jon S. Saxe, Esq.*, has been a director of the Company since March 1989. Mr. Saxe served as a consultant to the Company from June 1993 to December 1994 and again from May 2000 until January 2002. From May 1999 to April 2000, Mr. Saxe served as Senior Advisor to our Chief Executive Officer. From January 1995 to April 1999, Mr. Saxe served as President of the Company. He has also served as President of Saxe Associates since May 1993. Mr. Saxe is also a director of Incyte, Inc., Questcor Pharmaceuticals, Inc., First Horizon Pharmaceuticals, Inc., InSite Vision, Inc., SciClone Pharmaceuticals, Inc., ID Biomedical Corporation, VistaGen and Durect Corporation.

## Executive Officers

Certain information with respect to our executive officers as of December 31, 2003, except as otherwise noted, is set forth below. See "DIRECTORS" for information regarding Mr. McDade and Dr. Korn, two of our executive officers.

Name	Age	Position
Steven E. Benner, M.D., M.H.S.	44	Senior Vice President and Chief Medical Officer
Douglas O. Ebersole	48	Senior Vice President, Legal and Corporate Development and Secretary
Brett L. Schmidli	52	Senior Vice President, Technical Operations
Glen Y. Sato	44	Senior Vice President and Chief Financial Officer

Sergio Garcia-Rodriguez	42	Vice President, Legal, General Counsel and Assistant Secretary
Richard Murray, Ph.D.	45	Vice President, Research
Jaisim Shah	43	Vice President, Marketing
Laurie Torres	43	Vice President, Human Resources

*Steven E. Benner, M.D., M.H.S.*, has served as our Senior Vice President and Chief Medical Officer since November 2002. Dr. Benner joined the Company from the Pharmaceutical Research Institute of Bristol-Myers Squibb, having started there in 1995 as Associate Director, Clinical Oncology. He later served as Director and Group Director, Clinical Oncology before being named Executive Director, Clinical Oncology, in 1999. He was named Vice President, Licensing and Alliances in the Worldwide Medicines Group at Bristol-Myers Squibb in 2000, and assumed responsibilities as Global Development Champion and Vice President for Garenoxacin in 2002. He previously was Associate Professor of Medicine in the Division of Hematology/Oncology at The University of North Carolina at Chapel Hill,

and was Assistant Professor of Medicine in the Department of Thoracic/Head and Neck Medical Oncology at the University of Texas M.D. Anderson Cancer Center. He holds an M.H.S. degree in Clinical Epidemiology from The Johns Hopkins School of Hygiene and Public Health. He earned an M.D. degree from the University of Missouri-Columbia School of Medicine.

*Douglas O. Ebersole* has served as our Senior Vice President, Legal and Corporate Development since December 2002 and as Senior Vice President, Legal and Licensing from April 1999 until December 2002. Mr. Ebersole has served as our Secretary since July 1992. In addition, Mr. Ebersole served as our acting Chief Executive Officer from May 2002 until November 2002. Mr. Ebersole has also served in various other senior executive roles with the Company since joining PDL in July 1992. Prior to joining us, he served first as Associate General Counsel and later as General Counsel at NeXT Computer, Inc. Prior to joining NeXT in 1989, he was a partner in the corporate department of the law firm Ware & Freidenrich. Mr. Ebersole received his J.D. from Stanford Law School.

*Glen Y. Sato* has served as our Senior Vice President and Chief Financial Officer since May 2003. He joined PDL from Exelixis, Inc., where he had served as Senior Vice President, Chief Financial Officer and General Counsel since November 1999. Previous to Exelixis, he served in various legal and strategic planning positions at PDL, most recently as Vice President, Legal and General Counsel. During his previous tenure at PDL, Mr. Sato was responsible for SEC reporting and compliance, disclosure issues, intellectual property licensing and licensing strategy, general corporate counseling, insider trading compliance and intellectual property protection. Mr. Sato received his B.A. from Wesleyan University and his J.D. and MBA from University of California, Los Angeles.

*Brett L. Schmidli* has served as our Senior Vice President, Technical Operations since February 2002. Mr. Schmidli served as Director of Manufacturing Strategy at Eli Lilly & Company from 2000 to 2002 and was Chief Operating Officer and Director of Commercial Development—New Antidepressants there from 1998 to 2000. He served as a Director of Manufacturing and Product Development and a Director of Marketing within the Neuroscience Business Unit at Lilly from 1995 to 1998, and Director of Bioproducts Purification Development and Technical Services from 1992 to 1995. Mr. Schmidli previously was associated with Genetics Institute, Inc., serving in a number of management positions from 1982 to 1987 and as a senior consultant from 1987 to 1989. He received a bachelor's degree in Chemical Engineering from the Rose-Hulman Institute of Technology and an MBA from Indiana University.

*Sergio Garcia-Rodriguez* has served as our Vice President, Legal, General Counsel and Assistant Secretary since August 2001. From July 2000 until August 2001, Mr. Garcia-Rodriguez served as our Associate General Counsel. Prior to joining the Company, he served as International Counsel at DaimlerChrysler AG from 1996 to 2000 and previously was a partner in the law firm of Heller, Ehrman, White & McAuliffe. Mr. Garcia-Rodriguez received his J.D. degree from the University of California, Berkeley (Boalt Hall).

*Richard Murray, Ph.D.*, has served as our Vice President, Research since April 2003. Prior to joining the Company, Dr. Murray served as Vice President of Research at Eos Biotechnology, where he was also a co-founder of the company. He served in that role at Eos from February 1998 to April 2003, and was responsible for the discovery and transition of antibody-based therapeutic candidates from research to development. Prior to Eos, Dr. Murray was a staff scientist, then senior staff scientist at DNAX Research Institute. Dr. Murray received his Ph.D. from the University of North Carolina in Chapel Hill, with his work in the area of immuno-genetics.

*Jaisim Shah* has served as our Vice President, Marketing since August 2000. From July 1997 until July 2000, Mr. Shah served in various marketing management positions at Bristol Myers Squibb, most recently as Vice President, Marketing, for U.S. Pharmaceutical Group, Infectious Diseases and Vice President of Global Marketing. Prior to that time, from May 1991 until September 1993, he served as Product Director for biotech oncology products for the U.S. market for Roche Laboratories, a

subsidiary of Roche. From October 1993 until July 1997, he served as Global Business Leader for oncology and virology for F. Hoffmann-La Roche Ltd, based in Basel, Switzerland. He received his M.A. in International Economics from the University of Akron and an M.B.A. in Marketing from Oklahoma University.

*Laurie Torres* has served as our Vice President, Human Resources since joining the Company in November 2003. She previously served as Vice President of Human Resources for Genitope, a biotechnology company focused on the commercialization of patient-specific immunotherapies from the treatment of cancer, from 2000 to 2003. Ms. Torres was Senior Director of Human Resources for Heartport, Inc., a medical devices company specializing minimally invasive cardiac surgery, from 1998 to 2000, and Director of Employment there from 1997 to 1998. She served in various human resources positions at Genentech, Inc. from 1990 to 1997, after beginning her career in human resources at Hewlett-Packard, Inc. in 1985. Ms. Torres earned her B.A. from California State University, Hayward.

Our Board of Directors has a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, (the Exchange Act). The Audit Committee is comprised of the following directors: Max Link, George M. Gould and Karen A. Dawes. Our Board of Directors has determined that Max Link, Chair of the Audit Committee, is an audit committee financial expert as defined by Item 401(h) of Regulation S-K of the Exchange Act and is independent, as that term is used in Item 7(d)(e)(iv) of Schedule 14A under the Exchange Act.

## Code of Ethics

We have adopted a code of business conduct and ethics, and a policy providing for the reporting of potential violations of the code, for directors, officers (including our principal executive officer, principal financial officer and controller) and employees, known as the Code of Conduct and Policy Regarding Reporting of Potential Violations (the "Code of Conduct"). The Code of Conduct is available on our website at [http://www.pdl.com/governance/code\\_of\\_conduct.pdf](http://www.pdl.com/governance/code_of_conduct.pdf).

Additionally, stockholders may request a free copy of the Code of Conduct from:

Protein Design Labs, Inc.  
Attention: Investor Relations  
34801 Campus Drive  
Fremont, CA 94555  
(510) 574-1400

## SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Each director, executive officer, and beneficial owner of more than 10% of a registered class of equity securities of the Company who is subject to Section 16 of the Securities Exchange Act of 1934 is required by Section 16(a) of such act to report to the SEC by a specified date his or her transactions in our securities. To our knowledge, all reports relating to stock ownership and such other reports required to be filed during the year ended December 31, 2003, under Section 16(a) by our directors, executive officers and greater than 10% beneficial owners were timely filed, with the exception that one Form 4 reporting one transaction for Richard Murray. A timely filed Form 4 reporting this transaction was previously filed and amended to correct the number of shares acquired but the amendment under-reported the number of shares involved. A second amended Form 4 including the correct number of shares has been filed.

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## ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information concerning the compensation during the fiscal years ended December 31, 2003, 2002, and 2001, of our Chief Executive Officer, our four other most highly compensated executive officers whose salary and bonus exceeded \$100,000 for the fiscal year ended December 31, 2003 (collectively, the "Named Executive Officers"):

### SUMMARY COMPENSATION TABLE

Name and Principal Positions	Year	Annual Compensation(1)			Long-Term Compensation Awards	All Other Compensation(3) (\$)
		Salary (\$)	Bonus (\$)	Other Annual Compensation(2) (\$)	Securities Underlying Options (#)	
Mark McDade Chief Executive Officer	2003	500,844	500,000(4)	129,262	140,000	2,000
	2002	62,601	100,000(5)	—	900,000	—
	2001	—	—	—	—	—
Laurence Jay Korn Chairman of the Board(6)	2003	516,242	—	—	20,000	2,000
	2002	512,075	—	—	300,000	2,000
	2001	486,262	—	—	500,000	2,000
Steven E. Benner Senior Vice President and Chief Medical Officer(7)	2003	355,874	400,000(4)	15,139	60,000	2,000
	2002	50,578	125,000(5)	9,007	150,000	—
	2001	—	—	—	—	—
Douglas O. Ebersole Senior Vice President, Legal and Corporate Development	2003	329,151	150,000(8)	—	60,000	2,000
	2002	408,553	—	—	205,000	2,000
	2001	341,156	—	—	62,000	2,000
Brett Schmidli Senior Vice President, Technical Operations(9)	2003	338,169(10)	—	47,336	72,500	—
	2002	246,709	132,786(4)	15,772	162,500	—
	2001	—	—	—	—	—

(1) Compensation deferred at the election of the executive officer under our 401(k) Plan is included in the year earned. Includes life insurance premiums paid by the Company.

(2) Represents reimbursed relocation costs by the Company.

(3)

Reflects Company matching 401(k) contributions.

- (4) Represents a relocation bonus paid by the Company.
- (5) Represents a hiring bonus paid by the Company.
- (6) Dr. Korn resigned as Chief Executive Officer in April 2002 but continues to serve as an executive officer of the Company in his capacity as Chairman of the Board.
- (7) Steve E. Benner has been our Senior Vice President and Chief Medical Officer since November 2002.
- (8) Represents a performance bonus paid by the Company in 2003, authorized by the Compensation Committee in 2002, in recognition of Mr. Ebersole's performance as Chief Executive Officer in an acting capacity from April 2002 through November 2002.
- (9) Brett Schmidli has served as our Senior Vice President, Technical Operations since January 2002.
- (10) Includes forgiveness of \$2,260 of interest from a relocation and housing loan to Mr. Schmidli provided in connection with his joining the Company in January of 2002, as provided in the promissory note that was entered into at the time the loan was made.

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### Stock Options Granted in Fiscal 2003

The following table provides the specified information concerning grants of options to purchase our Common Stock made during the fiscal year ended December 31, 2003, to the Named Executive Officers:

#### OPTION GRANTS IN THE LAST FISCAL YEAR

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(4)	
	Number of Securities Underlying Options Granted(1,2)	% of Total Options Granted to Employees in Fiscal Year	Exercise Price (\$/Sh)(3)	Expiration Date	5% (\$)	10% (\$)
Mark McDade	70,000	2.17	7.83	4/11/13	344,697	873,530
	70,000	2.17	13.96	7/1/13	614,556	1,557,405
Laurence Jay Korn	10,000	0.31	7.83	4/11/13	49,242	124,790
	10,000	0.31	13.96	7/1/13	87,794	222,486
Steven E. Benner	30,000	0.93	7.83	4/11/13	147,727	374,340
	30,000	0.93	13.96	7/1/13	263,381	667,459
Douglas O. Ebersole	30,000	0.93	7.83	4/11/13	147,727	374,340
	30,000	0.93	13.96	7/1/13	263,381	667,459
Brett Schmidli	12,500	0.39	9.00	1/2/13	70,751	179,296
	30,000	0.93	7.83	4/11/13	147,727	374,340
	30,000	0.93	13.96	7/1/13	263,381	667,459

- (1) Options granted vest over a four year period at the rate of one fourth one year after the date specified at the time of grant (typically the hire date or an anniversary of the hire date) and  $\frac{1}{48}$  per month thereafter for each full month of the optionee's continuous employment with the Company. Only vested shares are exercisable. All outstanding options held by employees have terms of ten years.
- (2) Under the 1991 and 1999 Stock Option Plans, the Board retains some discretion to modify the terms of outstanding options; see "*Change of Control Arrangements, Termination of Employment Arrangements.*"
- (3) All options granted to employees were granted at market value on the date of grant.
- (4) Potential gains are net of exercise price, but before taxes associated with exercise. These amounts represent certain assumed rates of appreciation only, based on the Securities and Exchange Commission's rules. Actual gains, if any, on option exercises are dependent on the future performance of our Common Stock, overall market conditions and the optionee's continued employment through the vesting period. Any amounts reflected in this table may not necessarily be achieved. As an illustration of the effects such assumed appreciation would have on a stockholder's investment, one share of stock purchased at \$17.86 in 2003 (closing price as of December 31, 2003) would yield profits of \$11.23 per share at 5% appreciation per year over ten years or \$28.46 per share at 10% appreciation per year over the same period. The "potential realizable values" in this table are calculated using the exercise price of the stock options and assuming 5% or 10% appreciation per year from that price over the ten-year term of the options granted.

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The following table provides the specified information concerning exercises of options to purchase our Common Stock in the fiscal year ended December 31, 2003, and unexercised options held as of December 31, 2003, by the Named Executive Officers:

**AGGREGATE OPTION EXERCISES IN LAST FISCAL YEAR  
AND FISCAL YEAR END OPTION VALUES**

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options at 12/31/03		Value of Unexercised In-the-Money Options at 12/31/03 <sup>(1)</sup>	
			Unexercisable	Exercisable	Unexercisable	Exercisable
Mark McDade	—	—	796,250	243,750	7,248,850	2,330,250
Laurence Jay Korn	—	—	322,084	2,104,316	139,300	13,578,454
Steven E. Benner	—	—	169,375	40,625	1,407,744	367,656
Douglas O. Ebersole	—	—	179,086	385,590	907,747	1,939,009
Brett Schmidli	—	—	166,250	68,750	645,025	—

(1) Based on a value of \$17.86, which was the closing price of our Common Stock as of December 31, 2003.

**Compensation of Directors**

Each director who is not an employee of the Company (an "Outside Director") is authorized to receive cash compensation in the amount of \$3,000 each fiscal quarter, and an additional \$6,000 per year for each committee membership and may be reimbursed for expenses incurred in attending each Board and committee meeting. In addition, each member of each Board committee (other than the Stock Option Committee) was authorized to receive, for each committee on which he or she serves, an option under our 1999 Stock Option Plan to purchase 3,000 shares, vesting monthly over 12 months (subject to the optionee's continued service on the committee), at an exercise price equal to the fair market value of our Common Stock on the date of grant.

The Company's 2002 Outside Directors Stock Option Plan (the "2002 Directors Plan") provides for automatic initial grants of options to purchase 12,000 shares (the "Initial Option") of the Company's Common Stock to each person who first becomes an Outside Director (whether upon initial election or appointment to the Board or upon ceasing to be an employee while remaining or simultaneously becoming a director) and automatic annual grants to each Outside Director of options to purchase 12,000 shares (the "Annual Option") of the Company's Common Stock. Options under the 2002 Directors Plan are granted at the fair market value of the Company's Common Stock on the date of grant and vest monthly over 12 months, as long as the optionee continues to be a director. Vesting of options granted under the 2002 Directors Plan will not overlap with vesting of options previously granted by the Company to the Outside Directors. As such, an Outside Director who holds one or more options previously granted to him or her by the Company at the time he or she was an employee of the Company ("Prior Employee Options") that will continue to vest based upon the director's continued service to the Company as an Outside Director, will be granted an Initial Option only upon the date that such Prior Employee Options cease to vest. Such directors receive an Annual Option on the date of the annual meeting immediately following the date on which they received an Initial Option. Additionally, all Annual Options are subject to downward adjustment to insure that vesting of the Annual Options does not overlap with the vesting of any options previously granted by the Company to the Outside Directors.

Under the terms of the 2002 Directors Plan, in the event that (i) any person, entity or group becomes the beneficial owner of 40% or more of either the then outstanding Common Stock or the combined voting power of the Company's then outstanding securities entitled to vote generally in the election of directors; or (ii) the Company is party to a merger or consolidation which results in the holders of the voting securities of the Company outstanding immediately prior thereto failing to retain immediately after such merger or consolidation direct or indirect beneficial ownership of more than 50% of the total combined voting power of the securities entitled to vote generally in the election of directors of the Company or the surviving entity outstanding immediately after such merger or consolidation; or (iii) the sale or disposition of all or substantially all of the Company's assets or consummation of any transaction having similar effect (other than a sale or disposition to one or more subsidiaries of the Company), then options outstanding under the 2002 Directors Plan will become immediately exercisable and vested in full. The surviving, continuing, successor or purchasing corporation or parent corporation thereof may either assume the Company's rights and obligations under the outstanding options or substitute substantially equivalent options for such corporation's stock. Options that are not assumed, replaced or exercised will terminate.

**Compensation Committee Interlocks and Insider Participation**

During the fiscal year ended December 31, 2003, George M. Gould and Max Link served as members of the Compensation Committee of our Board of Directors. Neither of such Compensation Committee members was, during the fiscal year ended December 31, 2003, an officer or employee of PDL or any of its subsidiaries, was formerly an officer of PDL or its subsidiaries, or had any relationship requiring disclosure by PDL under any paragraph of Item 404 of Regulation S-K promulgated by the Securities and Exchange Commission.

**Change of Control Arrangements, Termination of Employment Arrangements**

**Stock Option Plans**

In the event of a sale of voting securities by our stockholders, a merger or consolidation to which we are a party, sale of all or substantially all of our assets, or liquidation or dissolution of the Company, following any of which the stockholders do not retain more than 50% of the total combined voting power of the stock of the Company or the acquiring corporation, the vesting of options held by full-time employees under our 1991 Stock Option Plan, 1999 Stock Option Plan and 1999 Nonstatutory Stock Option Plan will be accelerated by 25% of the total number of shares subject to such options if either (a) the acquiring corporation fails to assume the outstanding option or to substitute a substantially equivalent option for the acquiring corporation's stock, or (b) within one year following such transaction the option holder's employment is either terminated without cause or is constructively terminated.

**Executive Retention and Severance Plan**



We maintain the Executive Retention and Severance Plan (the "ERSP"), which provides certain severance and other benefits in connection with a change in control (as defined below) to our officers and key employees as designated by the Board or the Compensation Committee. At present, the ERSP covers all of our officers.

Under the ERSP, a change in control is deemed to have occurred in the event of (i) any acquisition of 40% or more of the Company's outstanding voting securities, (ii) any merger or consolidation involving the Company in which the Company's stockholders do not retain at least a majority of the total combined voting power of the Company or the combined entity, (iii) a sale or disposition of all or substantially all of the Company's assets to a third party or (iv) 50% or greater turnover among the members of the Company's Board over a period of two years or less. Upon a

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change in control, the ERSP provides for certain acceleration of the vesting of issued and outstanding stock options and shares of restricted stock held by participants. The extent of such vesting acceleration depends on a participant's position with the Company, and, with respect to a participant's outstanding Company stock options, whether such options are assumed in connection with the change in control. Upon a change in control, the vesting of all options and restricted stock held by each officer that serves on the Management Team, formerly the Executive Committee, will be subject to acceleration. The Management Team currently consists of Mr. McDade, Dr. Benner, Mr. Ebersole, Mr. Schmidli, Dr. Murray, Mr. Shah, Mr. Sato and Ms. Torres. Options and restricted stock held by the CEO, Mr. McDade, will become fully vested. Options and restricted stock held by other officers on the Management Team will generally become vested as to 50% of the shares subject to all future vesting installments, with the remaining unvested portion to continue vesting over the same period. If any participant's stock options are not assumed in connection with the change in control, and if it would provide the participant with a greater benefit than that described in the preceding sentence, a participant with less than two years of employment with the Company will be credited with an additional two years of employment for option vesting purposes, and a participant with two or more years of employment with the Company will become vested in full under his or her outstanding options.

The ERSP provides for severance benefits in the event of a participant's involuntary termination other than for "cause" or voluntary termination for "good reason" at any time within a specified time following a change in control, provided that, in the case of a person who was CEO at the time of the change in control, severance benefits accrue in the event of that person's termination for any reason during the time specified following the change in control. Under the ERSP, "cause" is defined to include theft, dishonesty or fraud, improper use of confidential information, gross negligence or willful misconduct in the performance of one's duties and conviction of a felony that materially impairs the participant's ability to perform his or her duties; "good reason" is defined to include a demotion or other material adverse change in assigned duties, a decrease in salary or targeted bonus amount, or a reduction in benefits compared to those granted to comparable employees. The applicable time periods following a change in control during which severance benefits could become payable is three years in the case of the CEO, two years in the case of any officer on the Management Team and one year in the case of all other participants.

Upon any termination of employment under the above circumstances, provided that the participant executes a prescribed release of claims against the Company, the participant is entitled to certain health and life insurance benefits for the applicable period, full vesting of all stock options and shares of restricted stock held by such participant and a lump sum severance payment equal to the equivalent of three years' salary and bonus in the case of a participant who was CEO at the time of the change in control, two years in the case of any officer on the Management Team and one year in the case of all other participants. For purposes of calculating the amount of such severance payment, salary is based on the participant's annual base salary immediately prior to termination or, if higher, immediately prior to the change in control, and bonus is based on the greatest of (i) the aggregate bonuses earned by the participant during the fiscal year preceding the change in control, (ii) the aggregate bonuses earned during the fiscal year preceding the termination, or (iii) the aggregate bonuses that would be earned during the current fiscal year, assuming attainment of 100% of applicable performance goals for that year.

The ERSP may not be terminated or amended without written approval by each participant affected by such termination or amendment.

#### **Other Termination of Employment Arrangements**

Pursuant to the terms of an offer letter between Mr. McDade and the Company, dated October 24, 2002, Mr. McDade was offered employment with the Company in the position of CEO. Pursuant to the terms of the offer letter, in the event that Mr. McDade's employment is terminated by

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us without "cause" (as defined in the ERSP), and upon his execution and delivery to us of a general release in a form reasonably satisfactory to the Company, Mr. McDade will be entitled to salary and bonus continuation at the same level as the most recently awarded bonus or at the maximum bonus rate if such termination occurs prior to his first bonus, but excluding other employment benefits, for one year from the date of such termination, or until Mr. McDade accepts a full time position with another company, whichever occurs first, less standard withholdings and deductions.

In connection with Dr. Laurence Korn's resignation as Chief Executive Officer of the Company in April 2002, we entered into a Special Compensation and Continued Employment Agreement (the "Continued Employment Agreement") with Dr. Korn pursuant to which Dr. Korn remained Chairman of the Board and responsible for certain other duties described in the Continued Employment Agreement. During the remainder of Dr. Korn's employment, Dr. Korn will be entitled to receive the same salary, benefits and vesting of stock options as before his resignation, provided that, after April 30, 2004, his salary will be subject to re-negotiation. Dr. Korn will also be entitled to continued administrative support. In the event of an Involuntary Termination (as such term is defined in the Continued Employment Agreement) of Dr. Korn's employment with the Company, Dr. Korn is entitled, upon execution of a general release in a form reasonably satisfactory to the Company, to certain benefits for the Specified Period (as defined below). If the Involuntary Termination had occurred less than one year after his resignation as CEO, the Specified Period would have been two years. If the Involuntary Termination occurs more than one year after the date of Dr. Korn's resignation as CEO, the Specified Period is one year. The benefits to which Dr. Korn will be entitled, for the Specified Period only, in the event of an Involuntary Termination include: salary at the same rate as immediately prior to the date of the Involuntary Termination, accelerated vesting of unvested options that would have become vested during the Specified Period and continuation of the benefits to which he was entitled prior to the Involuntary Termination (as further described in the Continued Employment Agreement).

On October 24, 2002, we entered into a Stock Option Agreement with Mr. Ebersole in connection with Mr. McDade accepting employment with us as CEO and replacing Mr. Ebersole who had been serving as CEO on an interim basis. Pursuant to the terms of the Agreement, Mr. Ebersole was granted an additional option to purchase 50,000 shares of Company Common Stock, pursuant to the 1999 Stock Option Plan. These options vest according to our standard four-year

vesting schedule pursuant to which one quarter of the shares underlying such options vest one year from the date of grant, and the remainder of such options vest one forty-eighth per month thereafter. In addition, such options will accelerate such that the option is fully vested and immediately exercisable if Mr. Ebersole is either (i) terminated without Cause, or (ii) resigns for Good Reason, each as defined in the Stock Option Agreement evidencing the option grant. The option is exercisable for the 12-month period following termination of Service for any reason, other than Cause. The foregoing capitalized terms are defined in the Stock Option Agreement evidencing the grant of the option to Mr. Ebersole.

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

The following table sets forth certain information regarding beneficial ownership of our Common Stock as of December 31, 2003, by (i) each person who is known by the Company, based on the records of our transfer agent and relevant documents filed with the U.S. Securities and Exchange Commission ("SEC"), to own beneficially more than 5% of the outstanding shares of our Common Stock, (ii) each member of the Board, (iii) the Named Executive Officers, and (iv) all members of our Board and our executive officers as a group. Unless otherwise specified, the address of each named individual is the address of the Company.

Name of Beneficial Owner or Group and Nature of Beneficial Ownership(1)	Amount of Beneficial Ownership	Percent of Common Stock Outstanding
FMR Corp.(2) 82 Devonshire Street Boston, MA 02109	10,656,594	11.35%
Delaware Management Holdings(3) 2005 Market Street Philadelphia, PA 19103	6,204,803	6.61%
Mark McDade(4)	281,250	*
Laurence Jay Korn, Ph.D.(5)	3,023,423	3.15%
Steven E. Benner, M.D., M.H.S.(4)	46,875	*
Douglas O. Ebersole(6)	418,913	*
Brett L. Schmidli(4)	96,250	*
Jürgen Drews, M.D.(4)	124,000	*
Karen A. Dawes(4)	9,250	*
L. Patrick Gage, Ph.D.(4)	15,000	*
George M. Gould, Esq.(7)	194,000	*
Max Link, Ph.D.(8)	100,000	*
Jon S. Saxe, Esq.(9)	397,182	*
Cary L. Queen, Ph.D.(10)	2,559,163	2.71%
All directors and executive officers as a group (17 persons)(11)	7,662,582	7.78%

\* Less than 1%

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

(2) Based solely on Schedule 13G as filed with the SEC, FMR Corp. has sole dispositive power with respect to all of the shares beneficially owned and sole voting power with respect to 1,631,350 of such shares.

(3) Based solely on Schedule 13G as filed with the SEC, Delaware Management Holdings has sole dispositive power with respect to all of the shares beneficially owned and sole voting power with respect to 6,189,135 of such shares.

(4) Consists of shares issuable upon the exercise of options which are currently exercisable, or which will become, exercisable within 60 days after December 31, 2003.

(5) Includes 2,170,565 shares issuable upon the exercise of options which are currently, or which will become exercisable within 60 days after December 31, 2003.

- (6) Includes 407,507 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2003.
- (7) Includes 162,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2003.
- (8) Includes 20,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2003.
- (9) Includes 369,502 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2003.
- (10) Includes 578,119 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2003. Also includes 11,700 shares held in trusts for the benefit of certain of Dr. Queen's relatives as to which Dr. Queen disclaims beneficial ownership and 3,900 shares held in trust for the benefit of Dr. Queen's daughter as to which Dr. Queen disclaims beneficial ownership.
- (11) Total includes all directors and officers who served in that capacity as of December 31, 2003 and 4,610,111 shares issuable upon the exercise of options beneficially owned by such directors and officers which are currently, or which will become, exercisable within 60 days after December 31, 2003.

### Equity Compensation Plan Information

The following table provides information as of December 31, 2003 concerning our equity compensation plans:

	(a)		(b)		(c)
	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity Compensation Plans Approved by Stockholders	7,893,152	\$	12.59		6,226,438(1)
Equity Compensation Plans Not Approved by Stockholders(2)	6,644,207	\$	19.37		3,542,540
<b>Total</b>	<b>14,537,359</b>	<b>\$</b>	<b>15.69</b>		<b>9,768,978</b>

- (1) Includes 973,287 shares available for future issuance under the Company's 1993 Employee Stock Purchase Plan.
- (2) See footnote 14 to the Financial Statements in the Company's Annual Report on Form 10-K for a description of the Company's 1999 Nonstatutory Stock Option Plan.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On April 4, 2003, we completed the acquisition of Eos in connection with which we hired two former executives of Eos, Richard Murray and Barbara Finck, as our Vice President, Research and Vice President, Clinical Development, respectively. Under the terms of the merger agreement between the Company and Eos, we issued an aggregate of approximately 4.3 million shares of our Common Stock to all Eos stockholders, including 65,820 and 31,456 shares issued to Dr. Murray and Dr. Finck, respectively. In our 2003 Proxy Statement, we reported that Dr. Murray had received 51,807 shares of PDL stock in connection with the merger, instead of the 65,820 shares that Dr. Murray actually received. The correct number of shares was reflected in the pro forma financial information furnished to the SEC on a Form 8 K/A on June 17, 2003. As of the closing date of the acquisition, the closing price of our Common Stock was \$7.78 per share.

### INDEBTEDNESS OF MANAGEMENT

In 2002, we lent an aggregate of \$150,000 to Mr. Brett Schmidli for the purchase of a home in Minnesota in connection with his commencement of employment with us at our Plymouth, Minnesota location. The loan is evidenced by two promissory notes executed prior to July 30, 2002, one for an amount of \$50,000 (the "Forgivable Loan") and one for an amount of \$100,000 (the "Repayable Loan"). Each of the Forgivable Loan and the Repayable Loan bears interest at the applicable federal rate, which refers to the minimum interest rate required to be charged on a loan to avoid the imputation of interest income under the Internal Revenue Code. The Internal Revenue Service publishes the applicable federal rate on a monthly basis. The interest rate for the Forgivable Loan is 4.52% and the interest rate for the Repayable Loan is 4.74%.

Pursuant to the terms of the Forgivable Loan, provided Mr. Schmidli remains a continuous, full-time employee of the Company, accumulated interest will be forgiven on each anniversary date of the loan, and, in addition, one-half of the principal amount will be forgiven on the second anniversary date of the loan and the remaining balance of the principal amount will be forgiven on the fourth anniversary date of the loan. The Forgivable Loan becomes immediately due and payable upon the termination of Mr. Schmidli's continuous full-time employment with the Company. The Repayable Loan is repayable as follows: (1) on each of the first and second anniversary dates of the loan, all then-accrued and unpaid interest is due; (2) on the third anniversary date of the loan, 50% of the principal as well as any then-accrued and unpaid interest is due; and (3) on the fourth anniversary date of the loan, the balance of all principal as well as any then-accrued and unpaid interest under the loan is due. All principal and interest accrued under the Repayable Loan becomes immediately due and payable upon the termination of Mr. Schmidli's continuous full-time employment with the Company.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Fees Paid to Ernst & Young

The following table sets forth the aggregate fees billed by Ernst & Young LLP for audit services rendered in connection with the consolidated financial statements and reports for 2003 and 2002 and

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for other services rendered during 2003 and 2002 on behalf of us and our subsidiaries, as well as all out-of-pocket costs incurred in connection with these services, which have been billed to us:

Fee Category:	2003	% of Total	2002	% of Total
		(in thousands)		
Audit Fees	\$ 507	86%	\$ 285	79%
Audit-Related Fees	22	4%	15	4%
Tax Fees	59	10%	36	10%
All Other Fees	—	—	25	7%
<b>Total Fees</b>	<b>\$ 588</b>		<b>\$ 361</b>	

**Audit Fees:** Audit fees consist of fees billed for professional services rendered for the audit of our consolidated financial statements and review of the interim condensed consolidated financial statements included in quarterly reports and services that are normally provided by Ernst and Young in connection with statutory and regulatory filings or engagements, and attest services, except those not required by statute or regulation. In 2003, audit fees include services related to the issuance of our 2.75% \$250 million Convertible Notes and the related filing of a Registration Statement on Form S-3 as well as the filing of our Form 8-K regarding the acquisition of Eos Biotechnologies. In 2002, audit fees include services provided to assist in our response to an SEC comment letter.

**Audit-Related Fees:** Audit-related fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit Fees." In 2003 and 2002, these services primarily relate to accounting consultations in connection with potential collaborations and patent licensing agreements.

**Tax Fees:** Tax fees consist of tax compliance/preparation and other tax services. In 2003 and 2002, tax compliance/preparation consists of fees billed for professional services related to federal and state tax compliance.

**All Other Fees:** "All Other Fees" consists of fees for all other services other than those reported above. In 2002, these fees are primarily related to real estate advisory services.

### Audit and Finance Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

The Audit Committee pre-approves all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. In February 2004, the Audit Committee adopted a policy for the pre-approval of services provided by the independent auditors. Under the policy, any pre-approval is detailed as to the particular service or category of services and is subject to a specific maximum level. For each proposed service, the independent auditor is required to provide detailed back-up documentation at the time of approval. The Audit Committee may delegate pre-approval authority to one or more of its members. Such a member must report any decisions to the Audit Committee at the next scheduled meeting.

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## PART IV

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

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

- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act, as amended.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act, as amended.
- 32.1 Certification by the Chief Executive Officer and the Chief Financial Officer of Protein Design Labs, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

- (1) Index to financial statements

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

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

Exhibit Number	Exhibit Title
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. (Incorporated by reference to Exhibit 3.4 to Annual Report on Form 10-K filed March 31, 2003).
4.1	Indenture between the Company and J.P. Morgan Trust Company, National Association, a national banking association, dated July 14, 2003. (Incorporated by Reference to Exhibit 4.1 to Registration Statement on Form S-3 filed September 11, 2003).
4.2	Registration Rights Agreement for the Company's 2.75% Convertible Subordinated Notes due 2023, between the Company and the Initial Purchasers dated July 14, 2003. (Incorporated by Reference to Exhibit 4.2 to Registration Statement on Form S-3 filed September 11, 2003).

*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 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.)
*10.7	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.)
10.8	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.)
10.9	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.)
*10.10	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.)
*10.11	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.)
*10.12	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. (Incorporated by reference to Exhibit 10.16 to Annual Report on Form 10-K filed March 14, 2002).
10.13	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.)

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- 10.14 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.)
  - 10.15 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.)
  - 10.16 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.)
  - \*10.17 1999 Stock Option Plan, together with forms of Incentive Stock Option Agreement and Nonstatutory Stock Option Agreement. (Incorporated by reference to Exhibit 10.31 to Registration Statement No. 333-87957 effective September 29, 1999.)
  - \*10.18 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).
  - 10.19 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.)
  - 10.20 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).
  - 10.21 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.)
  - 10.22 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.)
  - 10.23 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.)
  - 10.24 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.)
  - 10.25 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.)
  - 10.26 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.)

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- 10.27 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.)
  - \*10.28 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).
  - \*10.29 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 August 14, 2002).
  - \*10.30 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 August 14, 2002).
  - \*10.31 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 August 14, 2002).
  - \*10.32 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 August 14, 2002).
  - \*10.33 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 August 14, 2002).
  - \*10.34 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 August 14, 2002).

- \*10.35 Offer Letter by and between the Company and Mr. Mark McDade dated October 24, 2002. (Incorporated by reference to Exhibit 10.46 to Annual Report on Form 10-K filed March 31, 2003).
- \*10.36 Notice of Grant of Stock Option by and between the Company and Mr. Mark McDade dated October 24, 2002. (Incorporated by reference to Exhibit 10.47 to Annual Report on Form 10-K filed March 31, 2003).
- \*10.37 Stock Option Agreement by and between the Company and Mr. Douglas O. Ebersole dated October 24, 2002. (Incorporated by reference to Exhibit 10.48 to Annual Report on Form 10-K filed March 31, 2003).
- \*10.38 Notice of Grant of Stock Option by and between the Company and Mr. Douglas O. Ebersole dated October 24, 2002. (Incorporated by reference to Exhibit 10.49 to Annual Report on Form 10-K filed March 31, 2003).
- \*10.39 Offer Letter by and between the Company and Mr. Glen Sato dated April 9, 2003.
- \*10.40 Offer Letter by and between the Company and Ms. Laurie Torres dated September 10, 2003.
- 10.41 Manufacturing Agreement between the Company and ICOS Corporation, a Washington corporation, dated August 29, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10Q filed November 12, 2003).

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- 10.42 Amended and Restated Worldwide Agreement between the Company and Hoffmann-La Roche, a New Jersey corporation and F. Hoffmann-La Roche LTD of Basel Switzerland, dated October 1, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10Q filed November 12, 2003).
  - 10.43 Lease Agreement between the Company and Abgenix, Inc., a Delaware corporation, dated July 31, 2003. (Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10Q filed November 12, 2003).
  - 10.44 Amendment No. 2 to Sublease Agreement between the Company and FibroGen, Inc., a privately-held corporation, dated October 1, 2003. (Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10Q filed November 12, 2003).
  - 10.45 Amendment No. 1 to Patent Licensing Master Agreement between the Company and Genentech, Inc., dated as of September 18, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion).
  - 10.46 Amendment No. 2 to Patent Licensing Master Agreement between the Company and Genentech, Inc., dated as of December 18, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion).
  - 10.47 Amended No. 1 to the Herceptin License Agreement between the Company and Genentech, Inc., dated as of December 18, 2003.
  - 10.48 Patent License Agreement between the Company and Genentech, Inc., dated as of December 18, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion).
  - 10.49 Patent License Agreement between the Company and Genentech, Inc., dated as of December 18, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion).
  - \*10.50 Postretirement Healthcare Plan
    - 14 See Code of Ethics in Item 10: Executive Officers and Directors, of this Annual Report on Form 10-K.
    - 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.
    - 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act, as amended.
    - 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act, as amended.
    - 32.1 Certification by the Chief Executive Officer and the Chief Financial Officer of Protein Design Labs, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

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\* Management contract or compensatory plan or arrangement.

On December 12, 2003, we issued a press release regarding an agreement in principle to resolve a dispute relating to PDL's antibody humanization patents and certain of Genentech's humanized antibodies.

On December 22, 2003, we issued a press release announcing that PDL and Genentech concluded a definitive agreement which resolves their dispute relating to PDL's antibody humanization patents and certain of Genentech's humanized antibodies.

(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 3, 2004

\_\_\_\_\_  
 Date

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

Signature	Title	Date
/s/ MARK MCDADE _____ (Mark McDade)	Chief Executive Officer and Director (Principal Executive Officer)	March 3, 2004
/s/ GLEN SATO _____ (Glen Sato)	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2004
/s/ LAURENCE JAY KORN _____ (Laurence Jay Korn)	Chairman of the Board of Directors	March 3, 2004
/s/ JON S. SAXE _____ (Jon S. Saxe)	Director	March 4, 2004
/s/ CARY L. QUEEN _____ (Cary L. Queen)	Director	March 8, 2004
/s/ GEORGE M. GOULD _____ (George M. Gould)	Director	March 4, 2004
/s/ MAX LINK _____ (Max Link)	Director	March 8, 2004
/s/ JÜRGEN DREWS _____ (Jürgen Drews)	Director	March 8, 2004
/s/ L. PATRICK GAGE _____ (L. Patrick Gage)	Director	March 8, 2004
/s/ KAREN A. DAWES _____ (Karen A. Dawes)	Director	March 4, 2004



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April 9, 2003

Glen Y. Sato  
1470 Kings Lane  
Palo Alto, CA 94303

Dear Glen:

On behalf of Protein Design Labs, Inc., subject to approval by the PDL Board of Directors, I am pleased to extend to you an offer for the position of Senior Vice President and Chief Financial Officer, reporting to Mark McDade, Chief Executive Officer.

The monthly salary for this position is \$25,833.34 (\$310,000.00/annually). We offer our employees an attractive benefits package, including a comprehensive medical policy and dental plan, as well as life insurance coverage.

In addition, PDL is prepared to offer you a hiring bonus of \$100,000.00 payable and included with your first paycheck from PDL. If your employment with PDL is terminated for any reason prior to your first anniversary with PDL, the entire \$100,000.00 will be immediately due and payable to PDL. If your employment with PDL is terminated for any reason after your first anniversary and prior to your second anniversary, \$50,000.00 will be immediately due and payable to PDL.

Finally, in addition to our salary and benefits packages, I am pleased to offer to you options to purchase 250,000 shares of Protein Design Labs Common Stock under a PDL stock option plan. This offer is subject to the approval of the Board of Directors and your execution of our standard Stock Option Agreement. The options will vest over four years, with one-fourth of the options vesting after one year of employment and the remainder vesting in equal monthly increments over the remaining three years. The exercise price will be equal to the fair market value of the stock at the close of the market on the date you join PDL.

In the event that your employment is terminated by PDL without Cause (as defined in the ERSP) and if you execute and deliver to the Company, within thirty (30) days following such termination, a general release of all known and unknown claims against the Company existing as of the date of execution of the release, in a form reasonably satisfactory to the Company (which release shall also obligate you to refrain from soliciting employees, contractors, vendors, strategic partners, and customers to terminate their relationships with the Company), you will be entitled to (x) salary and bonus

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continuation at the same level as the most recently awarded bonus or at the maximum bonus rate if such termination occurs prior to your first bonus, but excluding other employment benefits, for six months or until you accept a full time position with another company, whichever occurs first, from the date of such termination, less standard withholdings and deductions; and (y) if such termination occurs prior to the end of your first year of employment, then the vesting of one-fourth of the Options (i.e., options to purchase 62,500 shares) will be accelerated as of the date of such termination.

For purposes of federal immigration law, you will be required to provide PDL documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire.

As a Protein Design Labs employee, you are free to resign at any time, just as Protein Design Labs is free to terminate your employment at any time, with or without cause.

To indicate your acceptance of our offer, please sign and date one copy of this letter in the space provided below and return it to Bernie Pangelinan, in the enclosed envelope by the date indicated below. This letter, along with an agreement relating to proprietary rights between you and PDL, sets forth the terms of your employment with PDL and supersedes any prior representations or agreements, whether written or oral. This letter may not be modified or amended except by a written agreement, signed by PDL and by you.

We are very excited at the prospect of your joining Protein Design Labs as a key contributor. This offer will remain open until April 14, 2003, at which time it will expire if not previously accepted. A start date will be determined by April 14, 2003, as well.

Sincerely,

/s/ Mark McDade  
Mark McDade  
Chief Executive Officer

/s/ Glen Y. Sato  
Glen Y. Sato

4/10/2003  
Date

September 10, 2003

Ms. Laurie Torres  
615 Church Street  
Half Moon Bay, CA 94019

Dear Laurie:

On behalf of Protein Design Labs, Inc., I am pleased to extend to you an offer for the position of Vice President, Human Resources reporting to me, PDL's Chief Executive Officer. Of course, your appointment as an officer of PDL is subject to approval by PDL's Board of Directors.

The monthly salary for this position is \$16,666.67 (\$200,000.00/annually). We offer our employees an attractive benefits package, including a comprehensive medical policy and dental plan, as well as life insurance coverage.

In addition, PDL is prepared to offer you a hiring bonus of \$35,000, plus an additional amount to compensate you for the tax liability you will incur as a result of receipt of the bonus such that the amount you will receive shall be \$35,000 (the "Bonus Amount"). Such Bonus Amount shall be payable and included with your first paycheck from PDL. If you voluntarily terminate your employment with PDL or if your employment is involuntarily terminated for cause prior to your second anniversary with PDL, the \$35,000 will be immediately due and payable to PDL as follows:

Termination prior to the first year anniversary	100% due and payable
Termination prior to the second year anniversary	50% due and payable
Termination following the second year anniversary	0% due and payable

Furthermore, in the event you move your primary residence, PDL agrees to provide you a relocation bonus of \$115,000.00, plus an additional amount to compensate you for the tax liability you will incur as a result of receipt of such amount such that the amount you will receive shall be \$115,000 (the "Relocation Amount"). Such Relocation Amount shall be used towards the purchase of a home in the Bay Area in closer proximity to PDL, and shall be paid only upon closing of your purchase of that home. The Relocation Amount must be used no later than November 3, 2004. If you voluntarily terminate your employment with PDL or if your employment is involuntarily terminated for cause prior to your second year anniversary, the \$115,000 will be immediately due and payable to PDL as follows:

Termination prior to the first year anniversary	100% due and payable
Termination prior to the second year anniversary	50% due and payable
Termination following the second year anniversary	0% due and payable

Finally, in addition to our salary and benefits packages, I am pleased to offer to you options to purchase 105,000 shares of Protein Design Labs Common Stock under a PDL stock option plan. This offer is subject to the approval of the Board of Directors (or an appropriate committee of the Board) and your execution of our standard Stock Option Agreement. The options will vest over four years, with one-fourth of the options vesting after one year of employment and the remainder vesting in equal monthly increments over the remaining three years. The exercise price will be equal to the fair market value of the stock at the close of the market on the date you join PDL.

For purposes of federal immigration law, you will be required to provide PDL documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire.

As a Protein Design Labs employee, you are free to resign at any time, just as Protein Design Labs is free to terminate your employment at any time, with or without cause.

To indicate your acceptance of our offer, please sign and date one copy of this letter in the space provided below and return it to Kurt Eggimann, in the enclosed envelope by the date indicated below. PDL agrees to not make public, without prior authorization from you, your acceptance of this offer. This letter, along with an agreement relating to proprietary rights between you and PDL, sets forth the terms of your employment with PDL and supersedes any prior representations or agreements, whether written or oral. This letter may not be modified or amended except by a written agreement, signed by PDL and by you.

We are very excited at the prospect of your joining Protein Design Labs as a key contributor starting November 3, 2003. This offer will remain open until September 15, 2003, at which time it will expire if not previously accepted.

Sincerely,

/s/ Mark McDade  
Mark McDade  
Chief Executive Officer

/s/ Laurie Torres  
Laurie Torres

9/12/2003  
Date

[...] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL PROVISIONS MARKED

EXHIBIT 10.45 (CONFIDENTIAL)

AMENDMENT NO. 1 TO THE PATENT LICENSING MASTER AGREEMENT

This AMENDMENT NO. 1 TO THE PATENT LICENSING MASTER AGREEMENT (the "Amendment"), is entered into as of September 18, 2003 by and between Genentech, Inc. ("GNE"), a Delaware corporation having offices at 1 DNA Way, South San Francisco, California 94080 and PROTEIN DESIGN LABS, INC., a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555 ("PDL") and amends that certain Patent Licensing Master Agreement dated September 25, 1998 (the "Agreement"). Except as expressly provided herein, capitalized terms shall have the meaning set forth in the Agreement.

RECITALS

- A. WHEREAS, GNE and PDL are parties to the Agreement; and
- B. WHEREAS, GNE and PDL desire to amend the Agreement to extend the period during which GNE may obtain nonexclusive license rights under the PDL Licensed Patents and PDL may obtain nonexclusive license rights under the GNE Licensed Patents.

AGREEMENT

NOW THEREFORE, the parties agree as follows:

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

1. AMENDMENT OF AGREEMENT.

Section 2.2 is amended to read in full as follows:

**2.2 Number of Licensed Antigens; Term of Rights.**

**(a) Limit on Number of Antigens.** Except as provided in Section 2.2(c), GNE's right to obtain licenses pursuant to Section 2.1 may be exercised for Antibodies directed against a maximum total of six (6) Antigens (provided that, GNE has already exercised a license with respect to the Antigen, HER-2, and therefore, has the right, except as provided otherwise in Section 2.2(c), to obtain licenses for Antibodies directed against five (5) additional Antigens),

**(b) Expiration of Rights to Elect.** Except as provided in Section 2.2(c), GNE's right to obtain licenses pursuant to Section 2.1 shall expire on December 31, 2008; provided that

GNE may elect to extend the expiration period for each license right under Section 2.1 not exercised by December 31, 2008 for an additional [...] year period by written notice and payment of the GNE Antigen Extension Fee to PDL prior to December 31, 2008 as provided in Section 3.4(a).

**(c) Double Up Right.** Upon written notice to PDL and payment of the GNE Double Up Fee at any time prior to [...], GNE may elect up to an additional [...] Antigens under Section 2.1 for a period of [...] years following the date of such notice; provided that rights to elect licenses with respect to the remaining [...] Antigens shall expire as of [...] unless otherwise extended pursuant to Section 2.2(b). By way of illustration and without limitation, if GNE elects to exercise its right hereunder but has exercised rights to licenses with respect to only [...] Antigens under Section 2.1 (including the license exercised by GNE with respect to the Antigen, HER-2) as of [...] (and has not extended the designation of the remaining [...] Antigens pursuant to Section 2.2(b)), then the cumulative number of Antigens subject to election by GNE under this Agreement through [...] shall be [...] Antigens.

Section 5.2 is amended to read in full as follows:

**5.2 Number of Licensed Antigens; Term of Rights.**

**(a) Limit of Number of Antigens.** Except as provided in Section 5.2(c), PDL's right to obtain licenses pursuant to Section 5.1 may be exercised for Antibodies directed against a maximum total of six (6) Antigens.

**(b) Expiration of Rights to Elect.** Except as provided in Section 5.2(c), PDL's right to obtain licenses pursuant to Section 5.1 shall expire on December 31, 2008, provided, however, that PDL may elect to extend the expiration period for each license right under Section 5.1 not exercised by December 31, 2008 for an additional [...] year period by written notice and payment of the PDL Antigen Extension Fee to GNE prior to December 31, 2008 as provided in Section 6.4(a).

**(c) Double Up Right.** Upon written notice to GNE and payment of the PDL Double Up Fee at any time prior to [...], PDL may elect up to an additional [...] Antigens under Section 5.1 for a period of [...] years following the date of such notice; provided that rights to elect licenses with respect to the first [...] Antigens shall expire as of [...] unless otherwise extended pursuant to Section 5.2(b). By way of illustration and without

limitation, if PDL elects to exercise its right hereunder but has exercised rights to licenses with respect to only [...] Antigens under Section 5.1 as of [...] (and has not extended the designation of the remaining [...] Antigens pursuant to Section 5.2(b)) then the cumulative number of Antigens subject to election by PDL under this Agreement through [...] shall be [...] Antigens.

2. **NO OTHER CHANGES.** On and after the date hereof, each reference in the Agreement to “this Patent Licensing Master Agreement,” “hereunder,” “hereof,” or words of like import referring to the Agreement, shall mean and be a reference to the

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Agreement as amended hereby. Except as specifically amended above, all other terms and conditions of the Agreement shall continue to be in full force and effect.

3. **PUBLIC DISCLOSURE.** Except as required by law or regulation, neither party shall publicly disclose the terms and conditions of this Amendment unless expressly authorized to do so by the other party, which authorization shall not be unreasonably withheld. In the event that disclosure shall be agreed upon then the parties will work together to develop a mutually acceptable disclosure.

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

Protein Design Labs, Inc.

Genentech, Inc.

By: /s/ Mark McDade  
Mark McDade

By: /s/ Joseph S. McCracken  
Joseph S. McCracken

Title: Chief Executive Officer

Title: VP Business & Market Development

[...] = **Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

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[...] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**CONFIDENTIAL PROVISIONS MARKED**

**EXHIBIT 10.46 (CONFIDENTIAL)**

**AMENDMENT NO. 2 TO THE PATENT LICENSING MASTER AGREEMENT**

This Amendment No. 2 to the Patent Licensing Master Agreement (“**Amendment**”) is entered into as of December 18, 2003 by and between Genentech, Inc. (“**GNE**”), a Delaware corporation having offices at 1 DNA Way, South San Francisco, California 94080 and Protein Design Labs, Inc. (“**PDL**”), a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555 (collectively, the “**Parties**”) and amends that certain Patent Licensing Master Agreement dated September 25, 1998 (including the form PDL License Agreement attached thereto as Exhibit C), as amended by Amendment No. 1 to the Patent Licensing Master Agreement dated September 18, 2003 (collectively the “**PLMA**”). Except as expressly provided herein, capitalized terms shall have the meanings set forth in the PLMA and references to Sections, Exhibits and Articles shall be deemed references to the PLMA.

**RECITALS**

WHEREAS, GNE and PDL are Parties to the PLMA; and

WHEREAS, in connection with the Parties’ execution of a settlement agreement of even date herewith (the “**Settlement Agreement**”), GNE and PDL desire to amend the PLMA (including, without limitation, the form PDL License Agreement attached thereto) to conform to the provisions of the Settlement Agreement.

NOW THEREFORE, the Parties agree as follows:

1. GNE and PDL agree that the effective date of this Amendment will be the Effective Date of the Settlement Agreement.
2. The PLMA is amended as follows:

A new Section 1.18 is added and shall read in full as follows:

**1.18 “GNE ROW Net Sales”** means Net Sales (as such term is defined under the form PDL License Agreement) of GNE Licensed Product(s) other than GNE US Net Sales.

A new Section 1.19 is added and shall read in full as follows:

1

**1.19 “GNE US Net Sales”** means Net Sales (as such term is defined under the form PDL License Agreement) of GNE Licensed Products(s) made, imported, used, offered for sale or sold in the United States.

A new Section 1.20 is added and shall read in full as follows:

**1.20 “PDL ROW Net Sales”** means Net Sales (as such term is defined under the GNE License Agreement) of PDL Licensed Product(s) other than PDL US Net Sales.

A new Section 1.21 is added and shall read in full as follows:

**1.21 “PDL US Net Sales”** means Net Sales (as such term is defined under the form GNE License Agreement) of PDL Licensed Products(s) made, imported, used, offered for sale or sold in the United States.

Section 2.3 is amended to read in full as follows:

**2.3 Procedure for Exercise of License Rights.** GNE shall provide PDL with written notice identifying the Antigen for which GNE desires to enter into a PDL License Agreement pursuant to the provisions of Section 2.1. Such written notice shall occur no later than ten (10) days following first regulatory approval of a product incorporating an Antibody directed against the relevant Antigen. Within fifteen (15) business days of the written notice, GNE shall pay the applicable License Exercise Fee specified in Section 3.2(a). PDL shall promptly review and respond in writing to the request by GNE for a license within ten (10) business days of receipt of the written request. PDL may deny GNE’s request for a license grant only if PDL has previously granted an exclusive or co-exclusive license or an unexpired option for an exclusive or co-exclusive license with respect to Antibodies to the identical Antigen or is then actively engaged in bona fide negotiations for such an exclusive or co-exclusive license or option for an exclusive or co-exclusive license; provided, however, that with respect to each of the GNE Named Antigens and [...], PDL shall provide GNE written notice prior to entering into an exclusive or co-exclusive license or option with any third party with respect to that GNE Named Antigen or [...] and shall permit GNE the opportunity to exercise its rights under Section 2.1 for a period not to exceed fifteen (15) days for a license for such GNE Named Antigen or [...] prior to the conclusion of an agreement with such third party for such a license or option. In the event that PDL denies GNE’s request, as set forth herein, for a PDL License Agreement, GNE’s right under Section 2.1 shall not be considered exercised. If PDL affirms GNE’s request or has not responded within ten (10) business days of receipt of GNE’s request under this Section 2.3(b), then GNE and PDL shall enter into a PDL License Agreement with respect to the Antigen. For the avoidance of doubt, if GNE has not given PDL notice of its desire to enter into a PDL License Agreement with respect to an Antigen within ten (10) days after first regulatory approval of a product incorporating an Antibody directed against such Antigen, GNE shall no longer have the right to exercise a PDL License Agreement with respect to

such Antibody under this Agreement, but GNE shall retain the right to exercise a PDL License Agreement with respect to a different Antibody directed at such Antigen. If, after GNE has exercised its license rights with respect to a particular Antigen and has entered into a PDL License Agreement pursuant to Section 2.1, GNE later has another product incorporating an Antibody that is directed against the same Antigen, then GNE must provide an additional written notice that such product is a GNE Licensed Product no later than ten (10) days following regulatory approval of such other product.

Section 4.1 is amended to read in full as follows:

#### 4.1 Royalties.

- (a) **GNE ROW Net Sales.** GNE will pay royalties to PDL under each executed PDL License Agreement (including the Herceptin License Agreement), notwithstanding any provision of such PDL License Agreement to the contrary, at the rate of [...] of GNE ROW Net Sales by GNE, its Affiliates and sublicensees and Roche of each GNE Licensed Product. Royalties for any GNE ROW Net Sales of any GNE Licensed Product sold prior to the effective date of such PDL License Agreement shall be paid in the first royalty payment under such PDL License Agreement.
- (b) **GNE US Net Sales.** GNE will pay royalties to PDL under each executed PDL License Agreement (including the Herceptin License Agreement), notwithstanding any provision of such PDL License Agreement to the contrary, on total annual GNE US Net Sales by GNE, its Affiliates and sublicensees and Roche for all GNE Licensed Product(s) at the following rates:

Total Annual GNE US Net Sales For All GNE Licensed Products	Royalty Rate
[...]	[...]
[...]	[...]
[...]	[...]
[...]	[...]

Such total annual GNE US Net Sales shall be calculated on a calendar year basis. Royalties for any GNE US Net Sales of any GNE Licensed Product sold prior to the effective date of such PDL License Agreement shall be paid in the first royalty payment under such PDL License Agreement, and shall be included in the total annual GNE US Net Sales for the calendar year in which such GNE US Net Sales occur.

- (c) In the case of a GNE Licensed Product that is a bispecific antibody, to the extent a license is required under the PDL Licensed Patents, each arm of such bispecific antibody shall require a separate license, provided that even if two licenses are required, the bispecific antibody shall be considered one GNE Licensed Product and bear the royalty applicable to one GNE Licensed Product. For example, if two licenses are required for a GNE Licensed Product that is a bispecific antibody that generates GNE ROW Net Sales, the royalty due on such sales of such GNE Licensed Product, even if two licenses are required, shall be [...] of GNE ROW Net Sales by GNE, its Affiliates and sublicensees and Roche.

Section 5.3 is amended to read in full as follows:

**5.3 Procedure for Exercise of License Rights.** PDL shall provide GNE with written notice identifying the Antigen for which PDL desires to enter into a GNE License Agreement pursuant to the provisions of Section 5.1. Such written notice shall occur no later than ten (10) days following first regulatory approval of a product incorporating an Antibody directed against the Antigen for which PDL desires to enter into a GNE License Agreement. Within fifteen (15) business days of the written notice, PDL shall pay the applicable License Exercise Fee specified in Section 6.2. GNE shall promptly review and respond in writing to the request by PDL for a license within ten (10) business days of receipt of the written request. GNE may deny PDL's request for a license grant only if GNE has previously granted an exclusive or co-exclusive license or an unexpired option for an exclusive or co-exclusive license with respect to Antibodies to the identical Antigen to either (a) a non-affiliate or (b) Roche under that certain agreement dated October 15, 1995, as such agreement is in effect on the Effective Date, or is then actively engaged in bona fide negotiations for such an exclusive or co-exclusive license or option for an exclusive or co-exclusive license; provided, however, that with respect to each of the PDL Named Antigens and [...], GNE shall provide PDL written notice prior to entering into an exclusive or co-exclusive license or option with any third party with respect to that PDL Named Antigen or [...] and shall permit PDL the opportunity to exercise its rights under Section 5.1 for a period not to exceed fifteen (15) days for a license for such PDL Named Antigen or [...] prior to the conclusion of an agreement with such third party for such a license or option. In the event that GNE denies PDL's request, as set forth herein, for a GNE License Agreement, PDL's right under Section 5.1 shall not be considered exercised. If GNE affirms PDL's request or has not responded within ten (10) business days of receipt of PDL's request under this Section 5.3, then PDL and GNE shall enter into a GNE License Agreement with respect to the Antigen. For the avoidance of doubt, if PDL has not given GNE notice of its desire to enter into a GNE License Agreement with respect to an Antigen within ten (10) days after first regulatory approval of a product incorporating an Antibody directed against such Antigen, PDL shall no longer have the right to exercise a GNE License Agreement with respect to such Antibody under this Agreement, but PDL shall retain the right to exercise a GNE License Agreement with respect to a different Antibody directed at such Antigen. If, after PDL has exercised its license rights with respect to a particular Antigen and has entered into

GNE License Agreement pursuant to Section 5.1, PDL later has another product incorporating an Antibody that is directed against the same Antigen, then PDL must provide an additional written notice that such product is a PDL Licensed Product no later than ten (10) days following regulatory approval of such other product.

Section 7.1 is amended to read in full as follows:

7.1 Royalties

- (a) PDL ROW Net Sales. PDL will pay royalties to GNE under each executed GNE License Agreement, notwithstanding any provision of such GNE License Agreement to the contrary, at the rate of [...] of PDL ROW Net Sales by PDL, its Affiliates and sublicensees of each PDL Licensed Product. Royalties for any PDL ROW Net Sales of any PDL Licensed Product sold prior to the effective date of such GNE License Agreement shall be paid in the first royalty payment under such GNE License Agreement.
(b) PDL US Net Sales. PDL will pay royalties to GNE under each executed GNE License Agreement, notwithstanding any provision of such GNE License Agreement to the contrary, on total annual PDL US Net Sales by PDL, its Affiliates and sublicensees of all PDL Licensed Product(s) at the following rates:

Table with 2 columns: Total Annual PDL US Net Sales For All PDL Licensed Products and Royalty Rate. Rows contain [...] values.

Such total annual PDL US Net Sales shall be calculated on a calendar year basis. Royalties for any PDL US Net Sales of any PDL Licensed Product sold prior to the effective date of such GNE License Agreement shall be paid in the first royalty payment under such GNE License Agreement, and shall be included in the total annual PDL US Net Sales for the calendar year in which such PDL US Net Sales occur.

This Section 7.1 (b) shall not apply to royalties payable on sales of a PDL Licensed Product if: (1) such PDL Licensed Product is directed to an Antigen that GNE has licensed to a third party under the GNE Licensed Patents prior to the effective date of this Amendment; (2) such third party license agreement for that Antigen contains a "Most Favored Licensee" provision (or its equivalent) that would be triggered by granting the royalty rates in this Section 7.1 to PDL; and (3) such third party license has not been terminated as of the effective date of the GNE License Agreement under which such Antigen is licensed to PDL. In such a case, PDL shall pay royalties to GNE at the rate of

[...] of PDL U.S. Net Sales by PDL, its Affiliates and sublicensees of such PDL Licensed Product.

- (c) In the case of a PDL Licensed Product that is a bispecific antibody, to the extent a license is required under the GNE Licensed Patents each arm of such bispecific antibody shall require a separate license, provided that even if two licenses are required, the bispecific antibody shall be considered one PDL Licensed Product and bear the royalty applicable to one PDL Licensed Product. For example, if two licenses are required for a PDL Licensed Product that is a bispecific antibody that generates PDL ROW Net Sales, the royalty due on such PDL Licensed Product that is a bispecific antibody, even if two licenses are required, shall be [...] of PDL ROW Net Sales by PDL, its Affiliates and sublicensees.

Section 11.6(d) is added to read as follows:

11.6(d) [...]

- 3. Exhibit C to the PLMA ("PLMA Exhibit C") is amended as follows:

Recital A of PLMA Exhibit C is amended to read in full as follows. The capitalized terms used in the following amended Recital A of the PLMA Exhibit C shall have the meanings set forth in such Exhibit C.

A. GNE and PDL have entered into a Patent Licensing Master Agreement effective September 25, 1998, as amended by Amendment No. 1 To The Patent Licensing Master Agreement dated September 18, 2003, and Amendment No. 2 To The Patent Licensing Master Agreement dated December 18, 2003 (the "Master Agreement"), pursuant to which GNE may enter into this Agreement with respect to a license under the "Queen Patents" for GNE's antibody products.

Section 3.04 of PLMA Exhibit C is amended to read in full as follows. The capitalized terms used in the following amended Section 3.04 of the PLMA Exhibit C shall have the meanings set forth in such Exhibit C.

3.04 The royalties payable to PDL under this PDL License Agreement shall be as set forth in Section 4.1 of the Master Agreement, except that in the event that GNE: (i) breaches its obligations under Sections 2.3 or 2.4 of the Settlement Agreement by and between PDL and GNE dated December 18, 2003 ("Settlement Agreement"); and (ii) fails to cure such breaches as provided under Section 4.2 of the Settlement Agreement, then PDL, at its sole discretion, may invoke its rights under Article 4 of the Settlement Agreement.

Section 3.05 of PLMA Exhibit C is amended to read in full as follows. The capitalized terms used in the following amended Section 3.05 of the PLMA Exhibit C shall have the meanings set forth in such Exhibit C.

3.05 Sales or other transfers of Licensed Products between and among GNE and any of its Affiliates, its sublicensees or Roche which are subsequently resold or to be resold by such Affiliates, sublicensees or Roche shall not be subject to royalty, but in such cases royalties shall accrue and be calculated on any subsequent sale or other transfer of such Licensed Products to a non-Affiliate. Genentech is obligated to pay royalties to PDL only once with respect to each unit of a Licensed Product.

Section 3.08(a) of PLMA Exhibit C is amended to read in full as follows. The capitalized terms used in the following amended Section 3.08(a) of the PLMA Exhibit C shall have the meanings set forth in such Exhibit C.



(a) GNE agrees to make written reports and royalty payments to PDL within sixty (60) days after the close of each calendar quarter during the term of this Agreement, beginning with the calendar quarter in which the date of first commercial sale or other transfer of a Licensed Product by GNE, its Affiliates, Sublicensees or Roche, provided that reports with respect to sales by sublicensees or Roche shall include only those sales as to which royalty reports were received by GNE during such calendar quarter. Sales of a Licensed Product occurring prior to the Effective Date shall be reported, and royalties on such sales shall be paid, in the first written report and royalty payment under this Agreement. These reports shall be certified by an officer of GNE and shall state for the calendar quarter in question: (1) identification of Net Sales of the Licensed Product on a country-by-country basis, (2) Net Sales in the Territory, (3) the quantities of Licensed Products sold or manufactured in such quarter in the Territory, (4) applicable offsets and (5) the net royalty due to PDL thereon pursuant to this Article 3. No later than at the time of the making of each such report, GNE shall make any payment due to PDL of royalties for the period covered by such report.

Section 7.02(d) of PLMA Exhibit C is amended to read in full as follows. The capitalized terms used in the following amended Section 7.02(d) of the PLMA Exhibit C shall have the meanings set forth in such Exhibit C.

(d) In the event that GNE: (i) breaches its obligations under Sections 2.3 or 2.4 of the Settlement Agreement and (ii) fails to cure such breach(es) as provided under Section 4.2 of the Settlement Agreement, then PDL, at its sole discretion, may invoke its rights under Article 4 of the Settlement Agreement.

4. No Other Conflicting Changes; Conflicting Provisions:

On and after the Effective Date, each reference in the PLMA to "this Agreement," "hereunder," "hereof," or words of like import referring to the PLMA, shall mean and be a reference to the PLMA as amended hereby. Except as specifically amended above, the PLMA is and shall continue to be in full force and effect. In the event of any conflict between the terms of this Amendment, the PLMA, the Herceptin License Agreement and the Settlement Agreement, the terms of the Settlement

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Agreement shall govern. In the event of any conflict between this Amendment, the PLMA and the Herceptin License Agreement, the terms of this Amendment shall govern.

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

**Protein Design Labs, Inc.**

**Genentech, Inc.**

By: /s/ Douglas O. Ebersole

By: /s/ Stephen Juelsgaard

Douglas O. Ebersole

Stephen  
Juelsgaard  
EVP &  
General  
Counsel

SVP, Legal & Corporate Development

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[...] = **Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

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**AMENDMENT NO. 1 TO THE HERCEPTIN LICENSE AGREEMENT**

This Amendment No. 1 To The Herceptin License Agreement (“**Amendment**”) is entered into as of December 18, 2003 by and between Genentech, Inc. (“**GNE**”), a Delaware corporation having offices at 1 DNA Way, South San Francisco, California 94080 and Protein Design Labs, Inc. (“**PDL**”), a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555 (collectively, the “**Parties**”) and amends that certain PDL License Agreement dated November 3, 1998 (the “**Herceptin License Agreement**”). Except as expressly provided herein, capitalized terms shall have the meanings set forth in the Herceptin License Agreement.

**RECITALS**

WHEREAS, GNE and PDL are Parties to the Herceptin License Agreement; and

WHEREAS, GNE and PDL are Parties to the Patent Licensing Master Agreement dated September 25, 1998, as amended by Amendment No. 1 To The Patent Licensing Master Agreement dated September 18, 2003 and Amendment No. 2 To The Patent Licensing Master Agreement of even date herewith (collectively the “**PLMA**”); and

WHEREAS, in connection with the Parties’ execution of a settlement agreement of even date herewith (the “**Settlement Agreement**”), GNE and PDL desire to amend the Herceptin License Agreement to conform to the provisions of the Settlement Agreement.

NOW THEREFORE, the Parties agree as follows:

1. GNE and PDL agree that the effective date of this Amendment will be the Effective Date of the Settlement Agreement.
2. The Herceptin License Agreement is amended as follows:

Section 3.04 is amended and supplemented as follows:

3.04 In further consideration of the rights and licenses granted under Article 2, GNE shall pay to PDL royalties on Net Sales of all GNE Licensed Products sold by GNE or its Affiliates or sublicensees or Roche in each country in the Territory as set forth in Section 4.1 of the PLMA.

3. No Other Conflicting Changes; Conflicting Provisions:

On and after the Effective Date, each reference in the Herceptin License Agreement to “this Agreement,” “hereunder,” “hereof,” or words of like import referring to the Herceptin License Agreement, shall mean and be a reference to the Herceptin License Agreement as amended hereby. Except as specifically amended above, the

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Herceptin License Agreement is and shall continue to be in full force and effect. In the event of any conflict, with respect to the subject matter herein, between the terms of this Amendment, the PLMA, the Herceptin License Agreement and the Settlement Agreement, the terms of the Settlement Agreement shall govern. In the event of any conflict, with respect to the subject matter herein, between this Amendment, the PLMA and the Herceptin License Agreement, the terms of this Amendment shall govern.

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

**Protein Design Labs, Inc.**

**Genentech, Inc.**

By /s/ Douglas O. Ebersole

By /s/ Stephen Juelsgaard

Title SVP, Legal & Corporate Development

Title EVP & General Counsel

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[...] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**CONFIDENTIAL PROVISIONS MARKED**

**EXHIBIT 10.48 (*CONFIDENTIAL*)**

**PDL LICENSE AGREEMENT**

**between**

**PROTEIN DESIGN LABS, INC.**

**and**

**GENENTECH, INC.**

This PDL License Agreement ("*Agreement*"), effective as of December 18, 2003 ("*Effective Date*"), is made by and between PROTEIN DESIGN LABS, INC., a Delaware corporation, having offices at 34801 Campus Drive, Fremont, CA 94555 (hereinafter "*PDL*") and GENENTECH, INC., a Delaware corporation, having offices at 1 DNA Way, South San Francisco, CA 94080 (hereinafter "*GNE*").

**RECITALS**

A. GNE and PDL have entered into a Patent Licensing Master Agreement effective September 25, 1998, as amended by Amendment No. 1 To The Patent Licensing Master Agreement dated September 18, 2003, and Amendment No. 2 To The Patent Licensing Master Agreement dated December 18, 2003 (the "*Master Agreement*"), pursuant to which GNE may enter into this Agreement with respect to a license under the "*Queen Patents*" for GNE's antibody products.

B. The Master Agreement provides GNE with the right to obtain a nonexclusive, worldwide, royalty-bearing license under the PDL Licensed Patents under the terms and conditions of this Agreement.

**AGREEMENT**

NOW THEREFORE, in consideration of the mutual covenants herein contained and intending to be legally bound, the parties agree as follows:

**1. DEFINITIONS**

All references to Exhibits, Articles and Sections shall be references to Exhibits, Articles and Sections of this Agreement. In addition, except as otherwise expressly provided herein, the following terms in this Agreement shall have the following meanings:

**1.01 "*Affiliate*"** means any corporation or other business entity controlled by, controlling, or under common control with another entity, with "*control*" meaning direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock of such corporation, or more than

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a fifty percent (50%) interest in the decision-making authority of such other unincorporated business entity; and a corporation in which the maximum amount of stock permitted by law to be held by another entity is beneficially owned by such other entity. Notwithstanding the foregoing, the term "*Affiliate*" under this Agreement with respect to GNE shall not include Roche Holdings, Inc., including its affiliated companies ("*Roche*"), until assignment of this Agreement to a member of such enterprise in accordance with Section 8.01.

**1.02 "*Antibody*"** means any antibody directed against an Antigen and shall include, without limitation, monospecific and bispecific antibodies (but only with respect to the Antigen for a bispecific antibody); less than full-length antibody forms such as Fv, Fab, and F(ab'), single-chain antibodies and antibody conjugates bound to a toxin, label or other moiety, as well as any and all such constructs directed against the Antigen.

**1.03 "*Antigen*"** means the target molecule: IgE as further identified on Exhibit B.

**1.04 "*Bulk Product*"** means Licensed Product supplied in a form other than Finished Product which can be converted into Finished Product.

**1.05 "*Combination Product(s)*"** means any product containing both a pharmaceutically active agent or ingredient which constitutes a Licensed Product and one or more other pharmaceutically active agents or ingredients which do not constitute Licensed Products.

**1.06 "*Europe*"** means the European Patent Convention Member Countries, including any successor organization and any additional countries that may join such organization from time to time during the term of this Agreement.

**1.07 "*Finished Product(s)*"** means any and all Licensed Products in form for use by an end user and not intended for further chemical or genetic manipulation or transformation.

**1.08 "*Licensed Product(s)*"** means an Antibody with respect to which GNE has either significant marketing rights or has done significant development (e.g., created, humanized or conducted preclinical or clinical development), the manufacture, import, use, offer to sell or sale of which would infringe, if not licensed under this Agreement, a Valid Claim.

**1.09 “Net Sales”** means the aggregate gross revenues, whether in cash or in kind, derived by or payable from or on account of the sale or other transfer of Finished Products by GNE, Affiliates of GNE, GNE’s sublicensees, Roche or Affiliates of GNE’s sublicensees to an independent third party not an Affiliate of GNE, a sublicensee of GNE, Roche, or an Affiliate of a sublicensee of GNE, less [...] to cover the following: (a) credits or allowances, if any, actually granted on account of price adjustments, recalls, rejection or return of items previously sold, (b) excise and sales taxes, duties or other taxes imposed on and paid with respect to such sales (excluding income or franchise taxes of any kind) and (c) outer packing, freight and freight insurance costs. For all Finished Product(s) used or consumed by others than GNE, GNE shall be entitled to deduct [...] from Net Sales in lieu of all other deductions such as taxes, shipping charges, packing, allowances and the like prior to calculating royalties due. If GNE or any of its Affiliates or sublicensees receive non-cash consideration for any Finished Product sold or otherwise transferred to an independent third party not Roche or an Affiliate of the seller or transferor, the fair market value of such non-cash consideration on the date of such transfer as known to GNE, or as reasonably estimated by GNE if unknown, shall be included in the definition of Net Sales. Net Sales shall not include Finished Products provided for bona fide

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clinical trial, evaluation, research or development purposes.

Net Sales for Bulk Products shall be calculated by multiplying the units of Finished Product to which such Bulk Product is reasonably anticipated to be converted by the established market price of the Finished Product on the date of sale of the Bulk Product. By way of example and without limitation, units of Finished Product may be measured in grams or doses, as appropriate.

The method of calculating Net Sales of materials in form other than Finished Product or Bulk Product that can be converted into Finished Product shall be established by good faith discussion between PDL and GNE prior to the first sale or transfer of any such material by GNE to a non-Affiliate.

**1.10 “Opposition Proceedings”** means the legal proceedings at the European Patent Office (“EPO”) initiated against EP patent 451,216B1 and terminating at the decision (oral and/or written) rendered by the Opposition Division (“OD”) of the EPO, but excluding any proceedings resulting from the filing of an appeal to the OD’s decision.

**1.11 “PDL Licensed Patents”** means the patents and patent applications identified on **Exhibit A**, and including any applications filed as of the Effective Date in the United States or any foreign jurisdiction. PDL Licensed Patents shall include U.S. or foreign patents or patent applications which claim priority to any application to which a listed U.S. Patent also claims priority. PDL Licensed Patents shall also include any foreign equivalents, addition, continuation, continuation-in-part or division of such patents or patent applications or any substitute applications therefor, any patent issued with respect to any such patent application, any reissue, extension or patent term extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent.

**1.12 “Territory”** means either (a) worldwide, or (b) [...].

**1.13 “Valid Claim”** means any claim in any PDL Licensed Patents which claim has neither expired or been disclaimed nor been held invalid or unenforceable by a court or other body of competent jurisdiction from which no appeal has been or may be taken.

## 2. LICENSE

**2.01 License Grant.** Subject to the fulfillment by GNE of all of the terms and conditions of this Agreement, PDL hereby grants to GNE and GNE hereby accepts a nonexclusive license in the Territory under the PDL Licensed Patents, including the right to grant sublicenses in accordance with Section 2.02, to make, have made, import, use, offer to sell and sell Licensed Products in the Territory. PDL shall be free at its discretion to enter into additional agreements with additional licensees at any time and on terms solely of its choosing.

**2.02 Limitation on Sublicenses; Notification.** GNE shall have the right to grant sublicenses of its rights under Section 2.01 with respect to Licensed Products, provided that GNE shall grant such sublicenses only in connection with the assignment or license by GNE to such sublicensee of the right to use, make, have made, sell or otherwise transfer the Licensed Products. GNE shall notify PDL of the identity of the sublicensee and scope of such sublicense promptly following the grant of a sublicense hereunder. Notwithstanding the assignment or grant of a sublicense by GNE hereunder, GNE shall remain obligated to pay all royalties due to PDL with respect to the sale of Licensed Products by its assignee or sublicensee. In addition, the grant of any sublicenses under Section 2.01 shall be on terms and conditions which are subject to and subordinate to

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the terms of this Agreement and GNE shall remain fully responsible to PDL for the performance of any and all such terms by its sublicensees.

**2.03 Updates to List of PDL Licensed Patents.** Upon written request of GNE (which request shall not be made more than once per calendar year), PDL agrees to provide a written update listing the PDL Licensed Patents, and such update shall constitute an amendment to **Exhibit A**. PDL may, at its option, furnish such update to GNE from time to time during the term of this Agreement as part of an update to the Master Agreement.

**2.04 No Other Rights.** GNE acknowledges and agrees that, except for the license expressly granted under Section 2.01, no rights to any other PDL patents or patent applications, or to any know-how, trade secrets or licenses are included in this Agreement or granted by implication, estoppel or otherwise.

**2.05 [...].**

## 3. PAYMENTS, ROYALTIES, REPORTS

**3.01 Signing Fee.** In consideration for the license granted by PDL under Article 2 of this Agreement, GNE shall pay to PDL, within fifteen (15) business days of the Effective Date of this Agreement, a nonrefundable signing and licensing fee in the sum of [...], increased annually beginning on January 1, 1999 and on each January 1 thereafter by an amount equal to the Consumer Price Index-U (or its successor) published by the U.S. Bureau of Labor Statistics (“CPI-

U”) for the prior year. GNE shall be entitled to deduct from the signing and licensing fee under this Agreement any amounts not previously credited and subject to credit under Section 3.03(a). All such deductions shall be documented with any payments hereunder.

**3.02 Annual Maintenance Fee.** In further consideration of the license granted under Article 2, within fifteen (15) business days of the [...] anniversary of the Effective Date and each anniversary thereafter, GNE shall pay PDL a nonrefundable annual maintenance fee in the amount of [...]. Such annual maintenance shall be [...] against royalties payable by GNE for the year with respect to which such annual maintenance fee is paid.

**3.03 Credits; Reductions.** [...]

(a) [...]

(b) [...]

**3.04 Royalties to PDL.** The royalties payable to PDL under this PDL License Agreement shall be as set forth in Section 4.1 of the Master Agreement, except that in the event that GNE: (i) breaches its obligations under Sections 2.3 or 2.4 of the Settlement Agreement by and between PDL and GNE dated December 18, 2003 (“Settlement Agreement”); and (ii) fails to cure such breaches as provided under Section 4.2 of the Settlement Agreement, then PDL, at its sole discretion, may invoke its rights under Article 4 of the Settlement Agreement.

**3.05 Royalties Payable Only Once; Sales Among Affiliates.** Sales or other transfers of Licensed Products between and among GNE and any of its Affiliates, its sublicensees or Roche which are subsequently resold or to be resold by such Affiliates, sublicensees or Roche shall not be subject to royalty, but in such cases royalties shall accrue and be calculated on any subsequent

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sale or other transfer of such Licensed Products to a non-Affiliate. Genentech is obligated to pay royalties to PDL is imposed only once with respect to each unit of a Licensed Product.

**3.06 Combination Products.** Net Sales in a particular country in the Territory, in the case of Combination Products for which the pharmaceutically active agent or ingredient constituting a Licensed Product and each of the other pharmaceutically active agents or ingredients not constituting Licensed Products have established market prices in that country in the Territory when sold separately, shall be determined by multiplying the Net Sales for each such Combination Product by a fraction, the numerator of which shall be the established market price for the Finished Product(s) contained in the Combination Product and the denominator of which shall be the sum of the established market prices for the Finished Product(s) plus the established market prices for the other pharmaceutically active agents or ingredients contained in the Combination Product. When such separate market prices are not established in that country in the Territory, then the parties shall negotiate in good faith to determine a fair and equitable method of calculating Net Sales in that country for the Combination Product in question.

**3.07 Currency Conversion.** All amounts payable to PDL under this Agreement shall be payable in U.S. Dollars by wire transfer to a bank account designated by PDL. In the case of royalties on Net Sales, all amounts payable shall first be calculated in the currency of sale and then converted into U.S. Dollars using the average of the daily exchange rates for such currency quoted by Citibank, N.A. for each of the last five (5) banking days of each calendar quarter.

**3.08 Reports.**

(a) **Current Reports.** GNE agrees to make written reports and royalty payments to PDL within sixty (60) days after the close of each calendar quarter during the term of this Agreement, beginning with the calendar quarter in which the date of first commercial sale or other transfer of a Licensed Product by GNE, its Affiliates, Sublicensees or Roche, provided that reports with respect to sales by sublicensees or Roche shall include only those sales as to which royalty reports were received by GNE during such calendar quarter. Sales of a Licensed Product occurring prior to the Effective Date shall be reported, and royalties on such sales shall be paid, in the first written report and royalty payment under this Agreement. These reports shall be certified by an officer of GNE and shall state for the calendar quarter in question: (1) identification of Net Sales of the Licensed Product on a country-by-country basis, (2) Net Sales in the Territory, (3) the quantities of Licensed Products sold or manufactured in such quarter in the Territory, (4) applicable offsets and (5) the net royalty due to PDL thereon pursuant to this Article 3. No later than at the time of the making of each such report, GNE shall make any payment due to PDL of royalties for the period covered by such report.

(b) **Termination Report.** For each Licensed Product, GNE also agrees to make a written report to PDL within ninety (90) days after the date on which GNE, its Affiliates or sublicensees last sell or otherwise transfer that Licensed Product in the Territory stating in such report the same information required by quarterly reports for all such Licensed Products made, sold or otherwise disposed of which were not previously reported to PDL.

(c) **Notification of Marketing Approval.** GNE agrees to notify PDL in writing within sixty (60) days after the date on which GNE, its Affiliates or sublicensees or Roche obtain marketing approval of a Licensed Product in any country in the Territory. Such notice shall specify the country in which marketing approval was obtained and the date of such approval.

**3.09 Inspection.** GNE agrees to keep, and to require any of its Affiliates or sublicensees to keep,

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clear, accurate and complete records for a period of at least three (3) years for each reporting period in which Net Sales occur showing the sales of Licensed Products in the Territory in sufficient detail to enable the royalties payable hereunder to be determined, and further agrees to permit its books and records, and to require any of its Affiliates or sublicensees to permit their books and records, to be examined by an independent accounting firm selected by PDL and reasonably satisfactory to GNE from time-to-time, but not more than once a year. Such examination is to be made at the expense of PDL, except in the event that the results of the audit reveal that GNE underpaid PDL by [...] or more, then GNE shall pay any deficiency plus interest for such overdue royalties in accordance with Section 3.11 hereof, and the audit fees shall be paid by GNE. Any such discrepancies will be promptly corrected by a payment or refund, as appropriate.

### 3.10 Withholding.

(a) **Fees.** The amounts payable under Sections 3.01 and 3.02 shall represent the actual proceeds to be received by PDL, net of any withholding or other taxes or levies that may be applicable to such payments. PDL agrees to reasonably cooperate with GNE in obtaining a refund of any withholding taxes or levies paid by GNE, if any, with respect to any payments to PDL hereunder. In the event that PDL is successful in obtaining any refund of tax withholding amounts paid by GNE under this Agreement, PDL agrees to promptly remit such refund amount to GNE.

(b) **Royalty Payments.** GNE may withhold from royalties due to PDL amounts for payment of any income or withholding tax that GNE has actually paid to any taxing authority with respect to royalty amounts due to PDL hereunder in the Territory. GNE shall promptly provide PDL with official tax receipts or other documentation sufficient to enable PDL to satisfy U.S. tax authorities with respect to PDL's application for a for-tax credit. GNE agrees to reasonably cooperate with PDL in obtaining a foreign tax credit in the U.S. with respect to royalties due to PDL on the sale or manufacture of Licensed Products.

**3.11 Interest on Overdue Royalties.** GNE shall be liable for interest on any overdue royalties, at the rate of ten percent (10%) per annum, or the highest rate allowed by law, whichever is less, commencing on the date such royalties are due until paid.

**3.12 Royalties to Third Parties.** GNE acknowledges and agrees that other licenses may be required from third parties with respect to the development, manufacture, importation, use, and sale of any Licensed Product under this Agreement, and that GNE shall be responsible for any royalties and other payments with respect to those license rights. In no event shall GNE have a right to credit against, reduce or otherwise offset any royalty or payment obligations to such third parties against royalty amounts payable to PDL under the this Agreement.

## 4. INFRINGEMENT OF PDL LICENSED PATENTS

**4.01 Suits.** PDL shall have no obligation hereunder to institute any action, suit or other proceeding against third parties for infringement of any PDL Licensed Patents or to defend any action, suit or proceeding brought by a third party which challenges or concerns the validity or enforceability of any PDL Licensed Patents in the Territory. Any monies recovered from alleged infringers shall be retained by PDL.

**4.02 Notification of Third Party Infringements.** GNE shall promptly notify PDL in writing of any actual or suspected infringement by third parties of any PDL Licensed Patent, which notification shall specify in reasonable detail the nature of such actual or suspected infringement

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of which GNE is aware and shall provide PDL with the available evidence, if any of such infringement.

## 5. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS; INDEMNIFICATION

**5.01 Representations of GNE.** GNE represents and warrants to PDL that:

(a) The execution, delivery and performance of this Agreement by GNE will not, with or without notice, the passage of time or both, result in any violation of, be in conflict with, or constitute a default under any material contract, obligation or commitment to which GNE is a party or by which it is bound, or to GNE's knowledge, violate any statute, rule or governmental regulation applicable to GNE.

(b) GNE has all requisite legal and corporate power and authority to enter into this Agreement on behalf of itself and its Affiliates and to carry out and perform its obligations under the terms of this Agreement.

**5.02 Representations of PDL.** PDL represents and warrants to GNE that:

(a) The execution, delivery and performance of this Agreement by PDL will not, with or without notice, the passage of time or both, result in any violation of, be in conflict with, or constitute a default under any material contract, obligation or commitment to which PDL is a party or by which it is bound, or to PDL's knowledge, violate any statute, rule or governmental regulation applicable to PDL.

(b) PDL has all requisite legal and corporate power and authority to enter into this Agreement and to carry out and perform its obligations under the terms of this Agreement.

**5.03 Disclaimers.** Nothing in this Agreement shall be construed as (a) a warranty or representation by PDL as to the validity, enforceability or scope of any PDL Licensed Patents; (b) a requirement that PDL file any patent application, or to secure any patent or patent rights, or maintain any patent in force, or to provide copies of patent applications to GNE or its Affiliates or sublicensees, or to disclose any inventions described or claimed in such patent applications; or (c) a warranty or representation by PDL that any Licensed Product made, used, imported, sold or otherwise disposed of under the license granted in this Agreement is or will be free from infringement of patents, copyrights, trademarks, trade secrets or other rights of third parties. GNE acknowledges and agrees that any royalties or payments that may be due to third parties in order for GNE to make, have made, import, use, sell or otherwise dispose of Licensed Products shall be the sole responsibility of GNE.

**5.04 No Other Warranties.** EXCEPT AS SPECIFICALLY SET FORTH IN ARTICLE 5, PDL MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO PDL LICENSED PATENTS OR ANY CELL LINES, ANTIBODIES OR LICENSED PRODUCTS DEVELOPED BY GNE UNDER THE LICENSE SET FORTH IN THIS AGREEMENT AND PDL FURTHER MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF OR PRACTICE UNDER PDL LICENSED PATENTS OR ANY CELL LINES, ANTIBODIES, LICENSED PRODUCTS OR OTHER MATERIALS DEVELOPED BY GNE UNDER THE LICENSE SET FORTH IN THIS AGREEMENT WILL NOT INFRINGE ANY THIRD PARTY RIGHTS.

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**5.05 Indemnification.** GNE shall at all times, during the term of this Agreement and thereafter, indemnify and hold harmless PDL and its Affiliates, sublicensees, directors, officers, agents and employees from any claim, proceeding, loss, expense, and liability of any kind whatsoever (including but not limited to those resulting from death, personal injury, illness or property damage and including legal expenses and reasonable attorneys' fees) arising out of or resulting from (a) any claim of patent infringement (direct or contributory) or inducing patent infringement with respect to the activities of GNE or its Affiliates or sublicensees, and (b) the development, manufacture, holding, use, testing, advertisement, sale or other disposition by GNE, its Affiliates or sublicensees, or any distributor, customer or representative thereof or any one in privity therewith, of any Licensed Product; provided, however, that PDL shall promptly notify GNE of such claim, proceeding, loss, expense or liability and GNE, at GNE's cost, shall have sole control over the defense, including settlement of any claim or action, with full cooperation from PDL.

## 6. CONFIDENTIALITY

The provisions of Article 9 of the Master Agreement are incorporated by reference as if set forth in their entirety herein.

## 7. TERM AND TERMINATION

**7.01 Term.** Unless earlier terminated as provided in this Article 7, this Agreement shall come into force on the Effective Date and shall continue until the last to expire of the PDL Licensed Patents. Thereafter, this Agreement shall terminate and all licenses or sublicenses granted hereunder shall become fully-paid licenses.

### 7.02 Termination.

(a) This Agreement may be terminated on sixty (60) days prior written notice by GNE.

(b) If GNE shall at any time default in the payment of any royalty, or the making of any report hereunder, or shall commit any material breach of any covenant or agreement herein contained or shall make any false report, and shall fail to have initiated and actively pursued remedy of any such default or breach within thirty (30) days after receipt of written notice thereof by the other party, PDL may, at its option, cancel this Agreement and revoke any rights and licenses herein granted and directly affected by the default or breach by notice in writing to such effect, but such act shall not prejudice PDL's rights to recover any royalty or other sums due at the time of such cancellation, it being understood, however, that if within thirty (30) days after receipt of any such notice GNE shall have initiated and actively pursued remedy of its default, then the rights and licenses herein granted shall remain in force as if no breach or default had occurred on the part of GNE, unless such breach or default is not in fact remedied within a reasonable period of time. If GNE disputes the existence of a default or material breach or making a false report or the failure to pursue a remedy or to remedy the default or breach, the provisions for resolution of a default shall be limited to those set forth in Section 11.6 of the Master Agreement.

(c) This Agreement may be terminated by either party upon the occurrence of any of the following which is not stayed or vacated within sixty (60) days of such occurrence: (i) petition in bankruptcy filed by or against the other party; (ii) adjudication of the other party as bankrupt or insolvent; (iii) appointment of a liquidator, receiver or trustee for all or a substantial part of the other party's property; or (iv) an assignment for the benefit of creditors of the other party.

(d) In the event that GNE: (i) breaches its obligations under Sections 2.3 or 2.4 of the Settlement Agreement and (ii) fails to cure such breach(es) as provided under Section 4.2 of the Settlement Agreement, then PDL, at its sole discretion, may invoke its rights under Article 4 of the Settlement Agreement.

**7.03 No Waiver.** The right of either party to terminate this Agreement as provided herein shall not be affected in any way by its waiver of any previous failure to perform hereunder or by its failure to take action with respect thereto.

**7.04 Survival.** Termination for any reason hereunder shall not affect any accrued rights or obligations of the parties arising in any manner under this Agreement as of the date of termination. In any event, the rights and obligations, including without limitation any accrued payment obligations, under Articles 3, 5 and 6 shall survive any termination of this Agreement.

## 8. MISCELLANEOUS

**8.01 Assignment.** This Agreement may not be assigned by either party without the prior written consent of the other, except that either may assign this Agreement without consent to a party which acquires all or substantially all of that portion of the business to which this Agreement pertains, whether by merger, sale of assets or otherwise. A merger or consolidation shall be deemed to constitute an assignment.

**8.02 Disputes.** The provisions of Section 11.6 of the Master Agreement are incorporated by reference as if set forth in their entirety herein.

**8.03 Severability.** If any provision of this Agreement is declared invalid by a court of law resort or by any court, the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof which relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement, in all other respects and all other jurisdictions, will remain in force; provided, however, that if the provision so invalidated is essential to the Agreement as a whole, then the parties shall negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original interest of the parties, and, failing such amendment, either party may submit the matter to a court of competent jurisdiction for resolution.

**8.04 Notices.** Any notice or report required or permitted to be given under this Agreement shall be in writing and shall be sent by expedited delivery or telecopied and confirmed by mailing as follows (or to such other address as may be specified in writing) and shall be effective three (3) days after such delivery:

If to PDL: Protein Design Labs, Inc.  
34801 Campus Drive  
Fremont, CA. 94555  
Attention: General Counsel

If to GNE: Genentech, Inc.  
1 DNA Way  
South San Francisco, California USA 94080  
Attn: Corporate Secretary

Facsimile number: (650) 225-8654

**8.05 Choice of Law.** The validity, performance, construction, and effect of this Agreement shall be governed by the laws of the State of California which are applicable to contracts between California residents to be performed wholly within California.

**8.06 Waiver.** None of the terms, covenants and conditions of this Agreement can be waived except by the written consent of the party waiving compliance.

**8.07 Force Majeure.** Neither party shall be responsible to the other for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof provided that such delay or non-performance is occasioned by a cause beyond the reasonable - control and without fault or negligence of such party, including, but not limited to earthquake, fire, flood, explosion, discontinuity in the supply of power, court order or governmental interference, act of God, strike or other labor trouble and provided that such party will inform the other party as soon as is reasonably practicable and that it will entirely perform its obligations immediately after the relevant cause has ceased its effect.

**8.08 Headings.** The captions used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits, or limitations.

**8.09 Entire Agreement.** This Agreement and the Master Agreement constitute the entire Agreement between the parties hereto with respect to the Antigen and supersede all previous Agreements, whether written or oral. In the event of any conflict between the terms of this Agreement and the Master Agreement with respect to the subject matter herein, the terms of this Agreement shall govern. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both parties.

**8.10 Counterparts.** This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date first above written.

By: /s/ Douglas O. Ebersole

Douglas O. Ebersole  
SVP, Legal & Corporate Development

By: /s/ Stephen Juelsgaard

Stephen  
Juelsgaard  
EVP &  
General  
Counsel

**Exhibit A**

**PDL Licensed Patents**

The following are patents and patent applications (also known as the "Queen et al. patents") issued and filed in certain countries in the world and licensed as part of the PDL Patent Rights under the Agreement. (As of: September 23, 2003)

1. The following issued U.S. patents and pending U.S. patent applications:

Patent No. 5,585,089, "Humanized Immunoglobulins," issued December 17, 1996.

Patent No. 5,693,761, "Polynucleotides Encoding Improved Humanized Immunoglobulins," issued December 2, 1997.

Patent No. 5,693,762, "Humanized Immunoglobulins," issued December 2, 1997.

Patent No. 6,180,370 "Humanized Immunoglobulins and Method of Making the Same", issued January 30, 2001.

[...].

2. The following patents and patent applications outside the U.S.:

Issue Date	Patent No.	Country	Title*
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Issued	9/29/00	AR 254487 V1	Argentina	“Novel Immunoglobulins, Their Production and Use”
Issued	7/12/94	647383	Australia	“
Issued	1/7/97	671949	Australia	“
Issued	1/24/96	AT 0451216	Austria	“
Issued	1/24/96	0451216	Belgium	“
Issued	8/25/99	0682040	Belgium	“
Issued	1/14/03	1101125-4	Brazil	“
Issued	10/27/97	61095	Bulgaria	“
Issued	8/13/02	2328851	Canada	“
Issued	8/20/02	2006865	Canada	“
Issued	4/11/00	40279	Chile	“
Issued	7/21/00	58770	China	“
Issued	11/4/99	P920500A	Croatia	“
Issued	12/02/02	174317	Denmark	“
Issued	1/24/96	0451216B1	Europe(1)	“
Issued	8/25/99	0682040 B1	Europe(1)	“
Issued	3/28/02	108797	Finland	“
Issued	1/24/96	FR0451216	France	“
Issued	8/25/99	FR0682040	France	“
Issued	1/24/96	DE 68925536.5	Germany	“

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Issued	8/25/99	DE 68929061.6	Germany	
Issued	1/24/96	DD 296 964	East Germany	“
Issued	1/24/96	GB 0451216	Great Britain	“
Issued	8/25/99	GB 0682040	Great Britain	“
Issued	1/5/93	1001050	Greece	“
Regist.	7/14/00	0682040	Hong Kong	
Issued	3/22/96	211174	Hungary	“
Issued	2/3/03	82755	Ireland	“
Issued	1/24/96	IT 0451216	Italy	“
Issued	8/25/99	IT 0682040	Italy	“
Issued	9/18/98	2828340	Japan(2)	“
Issued	1/24/96	LU 0451216	Luxembourg	“
Issued	8/25/99	LU 0682040	Luxembourg	“
Issued	2/18/92	92.2146	Monaco	“
Issued	1/24/96	NL 0451216	Netherlands	“
Issued	8/25/99	NL 0682040	Netherlands	“
Issued	10/20/97	231984	New Zealand	“
Issued	6/8/00	314793	New Zealand	“
Issued	7/9/01	19912385	Norway(3)	“
Issued	12/26/91	132068	Pakistan	“
Issued	5/17/96	29729	Philippines	“
Issued	10/20/95	92758	Portugal	“
Issued	2/10/99	2126046	Russia	“
Issued	1/24/96	SG 0451216	Singapore	“
Issued	5/22/01	78258	Singapore	“
Issued	2/28/99	8912489	Slovenia	“
Issued	10/31/90	89/9956	South Africa	“
Issued	11/23/98	178385	South Korea	“
Issued	1/24/96	2081974 T3	Spain	“
Issued	8/25/99	0682040	Spain	“
Issued	1/24/96	SE 0451216	Sweden	“
Issued	8/25/99	SE 0682040	Sweden	“
Issued	1/24/96	CH 0451216	Switzerland	“
Issued	8/25/99	CH 0682040	Switzerland	“
Issued	12/2/91	50034	Taiwan	“
Issued	5/19/93	13349	Uruguay	“
Issued	2/9/96	56455	Venezuela	“

Country

Application No.

Title\*

[...]

\*Exact titles may differ in different countries.

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(1) and corresponding European national patents issued therefrom.

- (2) registration date
- (3) this is the application number; have not received patent yet.

[...] = **Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

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[...] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**CONFIDENTIAL PROVISIONS MARKED**

**EXHIBIT 10.49 (CONFIDENTIAL)**

**PDL LICENSE AGREEMENT**

**between**

**PROTEIN DESIGN LABS, INC.**

**and**

**GENENTECH, INC.**

This PDL License Agreement (“*Agreement*”), effective as of December 18, 2003 (“*Effective Date*”), is made by and between PROTEIN DESIGN LABS, INC., a Delaware corporation, having offices at 34801 Campus Drive, Fremont, CA 94555 (hereinafter “*PDL*”) and GENENTECH, INC., a Delaware corporation, having offices at 1 DNA Way, South San Francisco, CA 94080 (hereinafter “*GNE*”).

**RECITALS**

A. GNE and PDL have entered into a Patent Licensing Master Agreement effective September 25, 1998, as amended by Amendment No. 1 To The Patent Licensing Master Agreement dated September 18, 2003, and Amendment No. 2 To The Patent Licensing Master Agreement dated December 18, 2003 (the “*Master Agreement*”), pursuant to which GNE may enter into this Agreement with respect to a license under the “*Queen Patents*” for GNE’s antibody products.

B. The Master Agreement provides GNE with the right to obtain a nonexclusive, worldwide, royalty-bearing license under the PDL Licensed Patents under the terms and conditions of this Agreement.

**AGREEMENT**

NOW THEREFORE, in consideration of the mutual covenants herein contained and intending to be legally bound, the parties agree as follows:

**1. DEFINITIONS**

All references to Exhibits, Articles and Sections shall be references to Exhibits, Articles and Sections of this Agreement. In addition, except as otherwise expressly provided herein, the following terms in this Agreement shall have the following meanings:

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**1.01 “Affiliate”** means any corporation or other business entity controlled by, controlling, or under common control with another entity, with “control” meaning direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock of such corporation, or more than a fifty percent (50%) interest in the decision-making authority of such other unincorporated business entity; and a corporation in which the maximum amount of stock permitted by law to be held by another entity is beneficially owned by such other entity. Notwithstanding the foregoing, the term “Affiliate” under this Agreement with respect to GNE shall not include Roche Holdings, Inc., including its affiliated companies (“*Roche*”), until assignment of this Agreement to a member of such enterprise in accordance with Section 8.01.

**1.02 “Antibody”** means any antibody directed against an Antigen and shall include, without limitation, monospecific and bispecific antibodies (but only with respect to the Antigen for a bispecific antibody); less than full-length antibody forms such as Fv, Fab, and F(ab’), single-chain antibodies and antibody conjugates bound to a toxin, label or other moiety, as well as any and all such constructs directed against the Antigen.

**1.03 “Antigen”** means the target molecule: CD11a as further identified on Exhibit B.

**1.04 “Bulk Product”** means Licensed Product supplied in a form other than Finished Product which can be converted into Finished Product.

**1.05 “Combination Product(s)”** means any product containing both a pharmaceutically active agent or ingredient which constitutes a Licensed Product and one or more other pharmaceutically active agents or ingredients which do not constitute Licensed Products.

**1.06 “Europe”** means the European Patent Convention Member Countries, including any successor organization and any additional countries that may join such organization from time to time during the term of this Agreement.

**1.07 “Finished Product(s)”** means any and all Licensed Products in form for use by an end user and not intended for further chemical or genetic manipulation or transformation.

**1.08 “Licensed Product(s)”** means an Antibody with respect to which GNE has either significant marketing rights or has done significant development (e.g., created, humanized or conducted preclinical or clinical development), the manufacture, import, use, offer to sell or sale of which would infringe, if not licensed under this Agreement, a Valid Claim.

**1.09 “Net Sales”** means the aggregate gross revenues, whether in cash or in kind, derived by or payable from or on account of the sale or other transfer of Finished Products by GNE, Affiliates of GNE, GNE’s sublicensees, Roche or Affiliates of GNE’s sublicensees to an independent third party not an Affiliate of GNE, a sublicensee of GNE, Roche, or an Affiliate of a sublicensee of GNE, less [...] to cover the following: (a) credits or allowances, if any, actually granted on account of price adjustments, recalls, rejection or return of items previously sold, (b) excise and sales taxes, duties or other taxes imposed on and paid with respect to such sales (excluding income or franchise taxes of any kind) and (c) outer packing, freight and freight insurance costs. For all Finished Product(s) used or consumed by others than GNE, GNE shall be entitled to deduct [...] from Net Sales in lieu of all other deductions such as taxes, shipping charges, packing, allowances and the like prior to calculating royalties due. If GNE or any of its Affiliates or sublicensees receive non-cash consideration for any Finished Product sold or

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otherwise transferred to an independent third party not Roche or an Affiliate of the seller or transferor, the fair market value of such non-cash consideration on the date of such transfer as known to GNE, or as reasonably estimated by GNE if unknown, shall be included in the definition of Net Sales. Net Sales shall not include Finished Products provided for bona fide clinical trial, evaluation, research or development purposes.

Net Sales for Bulk Products shall be calculated by multiplying the units of Finished Product to which such Bulk Product is reasonably anticipated to be converted by the established market price of the Finished Product on the date of sale of the Bulk Product. By way of example and without limitation, units of Finished Product may be measured in grams or doses, as appropriate.

The method of calculating Net Sales of materials in form other than Finished Product or Bulk Product that can be converted into Finished Product shall be established by good faith discussion between PDL and GNE prior to the first sale or transfer of any such material by GNE to a non-Affiliate.

**1.10 “Opposition Proceedings”** means the legal proceedings at the European Patent Office (“EPO”) initiated against EP patent 451,216B1 and terminating at the decision (oral and/or written) rendered by the Opposition Division (“OD”) of the EPO, but excluding any proceedings resulting from the filing of an appeal to the OD’s decision.

**1.11 “PDL Licensed Patents”** means the patents and patent applications identified on **Exhibit A**, and including any applications filed as of the Effective Date in the United States or any foreign jurisdiction. PDL Licensed Patents shall include U.S. or foreign patents or patent applications which claim priority to any application to which a listed U.S. Patent also claims priority. PDL Licensed Patents shall also include any foreign equivalents, addition, continuation, continuation-in-part or division of such patents or patent applications or any substitute applications therefor, any patent issued with respect to any such patent application, any reissue, extension or patent term extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent.

**1.12 “Territory”** means either (a) worldwide, or (b) [...].

**1.13 “Valid Claim”** means any claim in any PDL Licensed Patents which claim has neither expired or been disclaimed nor been held invalid or unenforceable by a court or other body of competent jurisdiction from which no appeal has been or may be taken.

## 2. LICENSE

**2.01 License Grant.** Subject to the fulfillment by GNE of all of the terms and conditions of this Agreement, PDL hereby grants to GNE and GNE hereby accepts a nonexclusive license in the Territory under the PDL Licensed Patents, including the right to grant sublicenses in accordance with Section 2.02, to make, have made, import, use, offer to sell and sell Licensed Products in the Territory. PDL shall be free at its discretion to enter into additional agreements with additional licensees at any time and on terms solely of its choosing.

**2.02 Limitation on Sublicenses; Notification.** GNE shall have the right to grant sublicenses of its rights under Section 2.01 with respect to Licensed Products, provided that GNE shall grant such sublicenses only in connection with the assignment or license by GNE to such sublicensee

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of the right to use, make, have made, sell or otherwise transfer the Licensed Products. GNE shall notify PDL of the identity of the sublicensee and scope of such sublicense promptly following the grant of a sublicense hereunder. Notwithstanding the assignment or grant of a sublicense by GNE hereunder, GNE shall remain obligated to pay all royalties due to PDL with respect to the sale of Licensed Products by its assignee or sublicensee. In addition, the grant of any sublicenses under Section 2.01 shall be on terms and conditions which are subject to and subordinate to the terms of this Agreement and GNE shall remain fully responsible to PDL for the performance of any and all such terms by its sublicensees.

**2.03 Updates to List of PDL Licensed Patents.** Upon written request of GNE (which request shall not be made more than once per calendar year), PDL agrees to provide a written update listing the PDL Licensed Patents, and such update shall constitute an amendment to **Exhibit A**. PDL may, at its option, furnish such update to GNE from time to time during the term of this Agreement as part of an update to the Master Agreement.

**2.04 No Other Rights.** GNE acknowledges and agrees that, except for the license expressly granted under Section 2.01, no rights to any other PDL patents or patent applications, or to any know-how, trade secrets or licenses are included in this Agreement or granted by implication, estoppel or otherwise.

**2.05 [...]**

## 3. PAYMENTS, ROYALTIES, REPORTS

**3.01 Signing Fee.** In consideration for the license granted by PDL under Article 2 of this Agreement, GNE shall pay to PDL, within fifteen (15) business days of the Effective Date of this Agreement, a nonrefundable signing and licensing fee in the sum of [...], increased annually beginning on January 1, 1999 and on each January 1 thereafter by an amount equal to the Consumer Price Index-U (or its successor) published by the U.S. Bureau of Labor Statistics (“CPI-U”) for the prior year. GNE shall be entitled to deduct from the signing and licensing fee under this Agreement any amounts not previously credited and subject to credit under Section 3.03(a). All such deductions shall be documented with any payments hereunder.

**3.02 Annual Maintenance Fee.** In further consideration of the license granted under Article 2, within fifteen (15) business days of the [...] anniversary of the Effective Date and each anniversary thereafter, GNE shall pay PDL a nonrefundable annual maintenance fee in the amount of [...]. Such annual maintenance shall be [...] against royalties payable by GNE for the year with respect to which such annual maintenance fee is paid.

**3.03 Credits; Reductions.** [...]

(a) [...]

(b) [...]

**3.04 Royalties to PDL.** The royalties payable to PDL under this PDL License Agreement shall be as set forth in Section 4.1 of the Master Agreement, except that in the event that GNE: (i) breaches its obligations under Sections 2.3 or 2.4 of the Settlement Agreement by and between PDL and GNE dated December 18, 2003 ("Settlement Agreement"); and (ii) fails to cure such

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breaches as provided under Section 4.2 of the Settlement Agreement, then PDL, at its sole discretion, may invoke its rights under Article 4 of the Settlement Agreement.

**3.05 Royalties Payable Only Once; Sales Among Affiliates.** Sales or other transfers of Licensed Products between and among GNE and any of its Affiliates, its sublicensees or Roche which are subsequently resold or to be resold by such Affiliates, sublicensees or Roche shall not be subject to royalty, but in such cases royalties shall accrue and be calculated on any subsequent sale or other transfer of such Licensed Products to a non-Affiliate. Genentech is obligated to pay royalties to PDL is imposed only once with respect to each unit of a Licensed Product.

**3.06 Combination Products.** Net Sales in a particular country in the Territory, in the case of Combination Products for which the pharmaceutically active agent or ingredient constituting a Licensed Product and each of the other pharmaceutically active agents or ingredients not constituting Licensed Products have established market prices in that country in the Territory when sold separately, shall be determined by multiplying the Net Sales for each such Combination Product by a fraction, the numerator of which shall be the established market price for the Finished Product(s) contained in the Combination Product and the denominator of which shall be the sum of the established market prices for the Finished Product(s) plus the established market prices for the other pharmaceutically active agents or ingredients contained in the Combination Product. When such separate market prices are not established in that country in the Territory, then the parties shall negotiate in good faith to determine a fair and equitable method of calculating Net Sales in that country for the Combination Product in question.

**3.07 Currency Conversion.** All amounts payable to PDL under this Agreement shall be payable in U.S. Dollars by wire transfer to a bank account designated by PDL. In the case of royalties on Net Sales, all amounts payable shall first be calculated in the currency of sale and then converted into U.S. Dollars using the average of the daily exchange rates for such currency quoted by Citibank, N.A. for each of the last five (5) banking days of each calendar quarter.

**3.08 Reports.**

(a) **Current Reports.** GNE agrees to make written reports and royalty payments to PDL within sixty (60) days after the close of each calendar quarter during the term of this Agreement, beginning with the calendar quarter in which the date of first commercial sale or other transfer of a Licensed Product by GNE, its Affiliates, Sublicensees or Roche, provided that reports with respect to sales by sublicensees or Roche shall include only those sales as to which royalty reports were received by GNE during such calendar quarter. Sales of a Licensed Product occurring prior to the Effective Date shall be reported, and royalties on such sales shall be paid, in the first written report and royalty payment under this Agreement. These reports shall be certified by an officer of GNE and shall state for the calendar quarter in question: (1) identification of Net Sales of the Licensed Product on a country-by-country basis, (2) Net Sales in the Territory, (3) the quantities of Licensed Products sold or manufactured in such quarter in the Territory, (4) applicable offsets and (5) the net royalty due to PDL thereon pursuant to this Article 3. No later than at the time of the making of each such report, GNE shall make any payment due to PDL of royalties for the period covered by such report.

(b) **Termination Report.** For each Licensed Product, GNE also agrees to make a written report to PDL within ninety (90) days after the date on which GNE, its Affiliates or sublicensees last sell or otherwise transfer that Licensed Product in the Territory stating in such report the same

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information required by quarterly reports for all such Licensed Products made, sold or otherwise disposed of which were not previously reported to PDL.

(c) **Notification of Marketing Approval.** GNE agrees to notify PDL in writing within sixty (60) days after the date on which GNE, its Affiliates or sublicensees or Roche obtain marketing approval of a Licensed Product in any country in the Territory. Such notice shall specify the country in which marketing approval was obtained and the date of such approval.

**3.09 Inspection.** GNE agrees to keep, and to require any of its Affiliates or sublicensees to keep, clear, accurate and complete records for a period of at least three (3) years for each reporting period in which Net Sales occur showing the sales of Licensed Products in the Territory in sufficient detail to enable the royalties payable hereunder to be determined, and further agrees to permit its books and records, and to require any of its Affiliates or sublicensees to permit their books and records, to be examined by an independent accounting firm selected by PDL and reasonably satisfactory to GNE from time-to-time, but not more than once a year. Such examination is to be made at the expense of PDL, except in the event that the results of the audit reveal that GNE underpaid PDL by [...] or more, then GNE shall pay any deficiency plus interest for such overdue royalties in accordance with Section 3.11 hereof, and the audit fees shall be paid by GNE. Any such discrepancies will be promptly corrected by a payment or refund, as appropriate.

**3.10 Withholding.**

(a) **Fees.** The amounts payable under Sections 3.01 and 3.02 shall represent the actual proceeds to be received by PDL, net of any withholding or other taxes or levies that may be applicable to such payments. PDL agrees to reasonably cooperate with GNE in obtaining a refund of any withholding taxes or levies paid by GNE, if any, with respect to any payments to PDL hereunder. In the event that PDL is successful in obtaining any refund of tax withholding amounts paid by GNE under this Agreement, PDL agrees to promptly remit such refund amount to GNE.

(b) **Royalty Payments.** GNE may withhold from royalties due to PDL amounts for payment of any income or withholding tax that GNE has actually paid to any taxing authority with respect to royalty amounts due to PDL hereunder in the Territory. GNE shall promptly provide PDL with official tax receipts or other documentation sufficient to enable PDL to satisfy U.S. tax authorities with respect to PDL's application for a for-tax credit. GNE agrees to reasonably cooperate with PDL in obtaining a foreign tax credit in the U.S. with respect to royalties due to PDL on the sale or manufacture of Licensed Products.

**3.11 Interest on Overdue Royalties.** GNE shall be liable for interest on any overdue royalties, at the rate of ten percent (10%) per annum, or the highest rate allowed by law, whichever is less, commencing on the date such royalties are due until paid.

**3.12 Royalties to Third Parties.** GNE acknowledges and agrees that other licenses may be required from third parties with respect to the development, manufacture, importation, use, and sale of any Licensed Product under this Agreement, and that GNE shall be responsible for any royalties and other payments with respect to those license rights. In no event shall GNE have a right to credit against, reduce or otherwise offset any royalty or payment obligations to such third parties against royalty amounts payable to PDL under the this Agreement.

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#### 4. INFRINGEMENT OF PDL LICENSED PATENTS

**4.01 Suits.** PDL shall have no obligation hereunder to institute any action, suit or other proceeding against third parties for infringement of any PDL Licensed Patents or to defend any action, suit or proceeding brought by a third party which challenges or concerns the validity or enforceability of any PDL Licensed Patents in the Territory. Any monies recovered from alleged infringers shall be retained by PDL.

**4.02 Notification of Third Party Infringements.** GNE shall promptly notify PDL in writing of any actual or suspected infringement by third parties of any PDL Licensed Patent, which notification shall specify in reasonable detail the nature of such actual or suspected infringement of which GNE is aware and shall provide PDL with the available evidence, if any of such infringement.

#### 5. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS; INDEMNIFICATION

**5.01 Representations of GNE.** GNE represents and warrants to PDL that:

(a) The execution, delivery and performance of this Agreement by GNE will not, with or without notice, the passage of time or both, result in any violation of, be in conflict with, or constitute a default under any material contract, obligation or commitment to which GNE is a party or by which it is bound, or to GNE's knowledge, violate any statute, rule or governmental regulation applicable to GNE.

(b) GNE has all requisite legal and corporate power and authority to enter into this Agreement on behalf of itself and its Affiliates and to carry out and perform its obligations under the terms of this Agreement.

**5.02 Representations of PDL.** PDL represents and warrants to GNE that:

(a) The execution, delivery and performance of this Agreement by PDL will not, with or without notice, the passage of time or both, result in any violation of, be in conflict with, or constitute a default under any material contract, obligation or commitment to which PDL is a party or by which it is bound, or to PDL's knowledge, violate any statute, rule or governmental regulation applicable to PDL.

(b) PDL has all requisite legal and corporate power and authority to enter into this Agreement and to carry out and perform its obligations under the terms of this Agreement.

**5.03 Disclaimers.** Nothing in this Agreement shall be construed as (a) a warranty or representation by PDL as to the validity, enforceability or scope of any PDL Licensed Patents; (b) a requirement that PDL file any patent application, or to secure any patent or patent rights, or maintain any patent in force, or to provide copies of patent applications to GNE or its Affiliates or sublicensees, or to disclose any inventions described or claimed in such patent applications; or (c) a warranty or representation by PDL that any Licensed Product made, used, imported, sold or otherwise disposed of under the license granted in this Agreement is or will be free from infringement of patents, copyrights, trademarks, trade secrets or other rights of third parties. GNE acknowledges and agrees that any royalties or payments that may be due to third parties in order

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for GNE to make, have made, import, use, sell or otherwise dispose of Licensed Products shall be the sole responsibility of GNE.

**5.04 No Other Warranties.** EXCEPT AS SPECIFICALLY SET FORTH IN ARTICLE 5, PDL MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO PDL LICENSED PATENTS OR ANY CELL LINES, ANTIBODIES OR LICENSED PRODUCTS DEVELOPED BY GNE UNDER THE LICENSE SET FORTH IN THIS AGREEMENT AND PDL FURTHER MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF OR PRACTICE UNDER PDL LICENSED PATENTS OR ANY CELL LINES, ANTIBODIES, LICENSED PRODUCTS OR OTHER MATERIALS DEVELOPED BY GNE UNDER THE LICENSE SET FORTH IN THIS AGREEMENT WILL NOT INFRINGE ANY THIRD PARTY RIGHTS.

**5.05 Indemnification.** GNE shall at all times, during the term of this Agreement and thereafter, indemnify and hold harmless PDL and its Affiliates, sublicensees, directors, officers, agents and employees from any claim, proceeding, loss, expense, and liability of any kind whatsoever (including but not

limited to those resulting from death, personal injury, illness or property damage and including legal expenses and reasonable attorneys' fees) arising out of or resulting from (a) any claim of patent infringement (direct or contributory) or inducing patent infringement with respect to the activities of GNE or its Affiliates or sublicensees, and (b) the development, manufacture, holding, use, testing, advertisement, sale or other disposition by GNE, its Affiliates or sublicensees, or any distributor, customer or representative thereof or any one in privity therewith, of any Licensed Product; provided, however, that PDL shall promptly notify GNE of such claim, proceeding, loss, expense or liability and GNE, at GNE's cost, shall have sole control over the defense, including settlement of any claim or action, with full cooperation from PDL.

## 6. CONFIDENTIALITY

The provisions of Article 9 of the Master Agreement are incorporated by reference as if set forth in their entirety herein.

## 7. TERM AND TERMINATION

**7.01 Term.** Unless earlier terminated as provided in this Article 7, this Agreement shall come into force on the Effective Date and shall continue until the last to expire of the PDL Licensed Patents. Thereafter, this Agreement shall terminate and all licenses or sublicenses granted hereunder shall become fully-paid licenses.

### 7.02 Termination.

(a) This Agreement may be terminated on sixty (60) days prior written notice by GNE.

(b) If GNE shall at any time default in the payment of any royalty, or the making of any report hereunder, or shall commit any material breach of any covenant or agreement herein contained or shall make any false report, and shall fail to have initiated and actively pursued remedy of any such default or breach within thirty (30) days after receipt of written notice thereof by the other party, PDL may, at its option, cancel this Agreement and revoke any rights and licenses herein granted

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and directly affected by the default or breach by notice in writing to such effect, but such act shall not prejudice PDL's rights to recover any royalty or other sums due at the time of such cancellation, it being understood, however, that if within thirty (30) days after receipt of any such notice GNE shall have initiated and actively pursued remedy of its default, then the rights and licenses herein granted shall remain in force as if no breach or default had occurred on the part of GNE, unless such breach or default is not in fact remedied within a reasonable period of time. If GNE disputes the existence of a default or material breach or making a false report or the failure to pursue a remedy or to remedy the default or breach, the provisions for resolution of a default shall be limited to those set forth in Section 11.6 of the Master Agreement.

(c) This Agreement may be terminated by either party upon the occurrence of any of the following which is not stayed or vacated within sixty (60) days of such occurrence: (i) petition in bankruptcy filed by or against the other party; (ii) adjudication of the other party as bankrupt or insolvent; (iii) appointment of a liquidator, receiver or trustee for all or a substantial part of the other party's property; or (iv) an assignment for the benefit of creditors of the other party.

(d) In the event that GNE: (i) breaches its obligations under Sections 2.3 or 2.4 of the Settlement Agreement and (ii) fails to cure such breach(es) as provided under Section 4.2 of the Settlement Agreement, then PDL, at its sole discretion, may invoke its rights under Article 4 of the Settlement Agreement.

**7.03 No Waiver.** The right of either party to terminate this Agreement as provided herein shall not be affected in any way by its waiver of any previous failure to perform hereunder or by its failure to take action with respect thereto.

**7.04 Survival.** Termination for any reason hereunder shall not affect any accrued rights or obligations of the parties arising in any manner under this Agreement as of the date of termination. In any event, the rights and obligations, including without limitation any accrued payment obligations, under Articles 3, 5 and 6 shall survive any termination of this Agreement.

## 8. MISCELLANEOUS

**8.01 Assignment.** This Agreement may not be assigned by either party without the prior written consent of the other, except that either may assign this Agreement without consent to a party which acquires all or substantially all of that portion of the business to which this Agreement pertains, whether by merger, sale of assets or otherwise. A merger or consolidation shall be deemed to constitute an assignment.

**8.02 Disputes.** The provisions of Section 11.6 of the Master Agreement are incorporated by reference as if set forth in their entirety herein.

**8.03 Severability.** If any provision of this Agreement is declared invalid by a court of law resort or by any court, the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof which relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement, in all other respects and all other jurisdictions, will remain in force; provided, however, that if the provision so invalidated is essential to the Agreement as a whole, then the parties shall negotiate in good faith to amend the terms hereof as

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nearly as practical to carry out the original interest of the parties, and, failing such amendment, either party may submit the matter to a court of competent jurisdiction for resolution.

**8.04 Notices.** Any notice or report required or permitted to be given under this Agreement shall be in writing and shall be sent by expedited delivery or telecopied and confirmed by mailing as follows (or to such other address as may be specified in writing) and shall be effective three (3) days after such delivery:

If to PDL: Protein Design Labs, Inc.  
34801 Campus Drive  
Fremont, CA. 94555  
Attention: General Counsel

Facsimile number: (510) 574-1500

If to GNE: Genentech, Inc.  
1 DNA Way  
South San Francisco, California USA 94080  
Attn: Corporate Secretary

Facsimile number: (650) 225-8654

**8.05 Choice of Law.** The validity, performance, construction, and effect of this Agreement shall be governed by the laws of the State of California which are applicable to contracts between California residents to be performed wholly within California.

**8.06 Waiver.** None of the terms, covenants and conditions of this Agreement can be waived except by the written consent of the party waiving compliance.

**8.07 Force Majeure.** Neither party shall be responsible to the other for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof provided that such delay or non-performance is occasioned by a cause beyond the reasonable - control and without fault or negligence of such party, including, but not limited to earthquake, fire, flood, explosion, discontinuity in the supply of power, court order or governmental interference, act of God, strike or other labor trouble and provided that such party will inform the other party as soon as is reasonably practicable and that it will entirely perform its obligations immediately after the relevant cause has ceased its effect.

**8.08 Headings.** The captions used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits, or limitations.

**8.09 Entire Agreement.** This Agreement and the Master Agreement constitute the entire Agreement between the parties hereto with respect to the Antigen and supersede all previous Agreements, whether written or oral. In the event of any conflict between the terms of this Agreement and the Master Agreement with respect to the subject matter herein, the terms of this Agreement shall govern. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both parties.

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**8.10 Counterparts.** This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date first above written.

By: /s/ Douglas O. Ebersole  
Douglas O. Ebersole  
SVP, Legal & Corporate Development

By: /s/ Stephen Juelsgaard  
Stephen Juelsgaard  
EVP & General Counsel

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## Exhibit A

### PDL Licensed Patents

The following are patents and patent applications (also known as the "Queen et al. patents") issued and filed in certain countries in the world and licensed as part of the PDL Patent Rights under the Agreement. (As of: September 23, 2003)

1. The following issued U.S. patents and pending U.S. patent applications:

Patent No. 5,585,089, "Humanized Immunoglobulins," issued December 17, 1996.

Patent No. 5,693,761, "Polynucleotides Encoding Improved Humanized Immunoglobulins," issued December 2, 1997.

Patent No. 5,693,762, "Humanized Immunoglobulins," issued December 2, 1997.

Patent No. 6,180,370 "Humanized Immunoglobulins and Method of Making the Same", issued January 30, 2001.

[...]

2. The following patents and patent applications outside the U.S.:

Issue Date	Patent No.	Country	Title*	
Issued	9/29/00	AR 254487 V1	Argentina	"Novel Immunoglobulins,



				Their Production and Use”
Issued	7/12/94	647383	Australia	“
Issued	1/7/97	671949	Australia	“
Issued	1/24/96	AT 0451216	Austria	“
Issued	1/24/96	0451216	Belgium	“
Issued	8/25/99	0682040	Belgium	“
Issued	1/14/03	1101125-4	Brazil	“
Issued	10/27/97	61095	Bulgaria	“
Issued	8/13/02	2328851	Canada	“
Issued	8/20/02	2006865	Canada	“
Issued	4/11/00	40279	Chile	“
Issued	7/21/00	58770	China	“
Issued	11/4/99	P920500A	Croatia	“
Issued	12/02/02	174317	Denmark	“
Issued	1/24/96	0451216B1	Europe(1)	“
Issued	8/25/99	0682040 B1	Europe(1)	“
Issued	3/28/02	108797	Finland	“
Issued	1/24/96	FR0451216	France	“

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Issued	8/25/99	FR0682040	France	“
Issued	1/24/96	DE 68925536.5	Germany	“
Issued	8/25/99	DE 68929061.6	Germany	“
Issued	1/24/96	DD 296 964	East Germany	“
Issued	1/24/96	GB 0451216	Great Britain	“
Issued	8/25/99	GB 0682040	Great Britain	“
Issued	1/5/93	1001050	Greece	“
Regist.	7/14/00	0682040	Hong Kong	“
Issued	3/22/96	211174	Hungary	“
Issued	2/3/03	82755	Ireland	“
Issued	1/24/96	IT 0451216	Italy	“
Issued	8/25/99	IT 0682040	Italy	“
Issued	9/18/98	2828340	Japan(2)	“
Issued	1/24/96	LU 0451216	Luxembourg	“
Issued	8/25/99	LU 0682040	Luxembourg	“
Issued	2/18/92	92.2146	Monaco	“
Issued	1/24/96	NL 0451216	Netherlands	“
Issued	8/25/99	NL 0682040	Netherlands	“
Issued	10/20/97	231984	New Zealand	“
Issued	6/8/00	314793	New Zealand	“
Issued	7/9/01	19912385	Norway(3)	“
Issued	12/26/91	132068	Pakistan	“
Issued	5/17/96	29729	Philippines	“
Issued	10/20/95	92758	Portugal	“
Issued	2/10/99	2126046	Russia	“
Issued	1/24/96	SG 0451216	Singapore	“
Issued	5/22/01	78258	Singapore	“
Issued	2/28/99	8912489	Slovenia	“
Issued	10/31/90	89/9956	South Africa	“
Issued	11/23/98	178385	South Korea	“
Issued	1/24/96	2081974 T3	Spain	“
Issued	8/25/99	0682040	Spain	“
Issued	1/24/96	SE 0451216	Sweden	“
Issued	8/25/99	SE 0682040	Sweden	“
Issued	1/24/96	CH 0451216	Switzerland	“
Issued	8/25/99	CH 0682040	Switzerland	“
Issued	12/2/91	50034	Taiwan	“
Issued	5/19/93	13349	Uruguay	“
Issued	2/9/96	56455	Venezuela	“

Country

Application No.

Title\*

[...]

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\* Exact titles may differ in different countries.

(1) and corresponding European national patents issued therefrom.

(2) registration date

(3) this is the application number; have not received patent yet.

[...] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Protein Design Labs, Inc.

Retiree Health Care Plan

Effective June 1, 2003

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### SECTION I - ESTABLISHMENT AND PURPOSE

#### 1.1 Establishment and Purpose

Protein Design Labs, Inc. (PDL), hereby establishes the Protein Design Labs, Inc. Retiree Health Care Plan (Plan) for certain eligible former employees of PDL and their eligible dependents. It is the intention of PDL that this Plan qualify as an accident and health plan within the meaning of Section 105 of the Internal Revenue Code (Code) and, to the extent the benefits provided under the Plan are not discriminatory, that they be eligible for exclusion from gross income under the Code.

#### 1.2 Exclusive Purpose

The exclusive purpose of this Plan is to provide health-related benefits described herein for the eligible former employees of PDL and their eligible family members. No expenses payable under this Plan will be payable under any other benefit plan of PDL.

#### 1.3 Effective Date

The original effective date of the Plan is June 1, 2003

#### 1.4 Plan Year

The Plan Year is December 1 through November 30 of the following calendar year.

### SECTION II - ELIGIBILITY

#### 2.1 Retiree Eligibility

All officers with at least ten full years of service and who were eligible to participate as employees in the PDL sponsored health plans made available to the active employees of PDL, who elect to retire under the terms of the then current PDL retirement requirements, shall become participants in the plan on the later of the Effective Date of the Plan or, upon their date of retirement.

#### 2.2 Eligible Dependents

For purposes of this Plan, eligible dependents shall include only those persons who meet the PDL sponsored health plan definition of dependents for purposes of the plan in which the employee participated on the day before his/her date of retirement.

#### 2.3 Contribution Requirements

In the event that PDL requires contributions toward the cost of this Plan, coverage under this plan shall not take effect for persons for whom contributions are required, until such time as the contribution requirements are met. Contributions, if any, are described in Appendix A of this Plan.

#### 2.4 Cessation of Participation

Eligibility under this Plan shall terminate upon the earliest of:

- a) the retiree meets the age requirements for benefits under Title XVIII of Social Security Act (commonly known as Medicare);
- b) the date the retiree dies, except as provided for under section 2.5 of this Plan;
- c) the date the retiree becomes covered under another group health plan;
- d) the date required contributions cease to be paid; and,
- e) the date the spouse or dependent of the retiree ceases to meet the eligibility requirements under the PDL Health Plan.

#### 2.5 Survivor Benefits

In the event the retiree dies prior to meeting the age requirements for benefits under Medicare, dependents covered under this Plan on the retiree's date of death shall remain eligible for extended benefits under this Plan under the same terms and conditions as applied on the date of the retiree's death. In the event that PDL changes the terms and conditions of this Plan, such changes shall apply to surviving eligible dependents.

#### 2.6 Newly Acquired Dependents

In the event the retiree acquires dependents while covered under this Plan, and said dependents meet the eligibility requirements specified in the PDL Health Plan, these newly acquired dependents shall become eligible to participate subject to the provisions of Section 2.7 of this Plan. Dependents (including spouses) acquired by a surviving spouse shall not be eligible to participate in this Plan.

## **2.7 Special Enrollment**

Subject to the special open enrollment periods of Section 9801 (f) of the Code, a covered retiree who acquires a dependent as a result of marriage, birth, adoption or placement for adoption, may be able to enroll dependents, provided that the retiree requests enrollment within 30 days after the marriage, birth, adoption, or placement for adoption. If the retiree fails to complete the

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enrollment process on a timely basis, the dependents may be required to wait until the group's next open enrollment to obtain coverage the dependents also may be subject to additional limitations on the coverage available at that time.

## **2.8 Qualified Medical Child Support Orders**

This Plan will also provide benefits as required by any qualified medical child support order, as defined in ERISA Section 609(a), and provide benefits to dependent children placed with participants or beneficiaries for adoption under the same terms and conditions as apply in the case of dependent children who are natural children of participants or beneficiaries, in accordance with ERISA Section 609(c). The Plan will provide a copy of its written procedures to plan participants upon request.

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## **SECTION III - BENEFITS**

### **3.1 Benefits Provided**

A participant, who meets the eligibility requirements of Section 2 of this Plan, shall be eligible to participate in the PDL retiree Health Plan. The Benefits under this Plan shall be identical to those provided under the health plans available to the eligible active employees of PDL.

### **3.2 Changes in Benefits**

In the event that PDL changes the benefits under its health plans, all such changes in benefits shall apply to this Plan as of the effective date of the changes to the health plans available to the eligible active employees of PDL.

### **3.3 Health Plan Defined**

For purposes of this Plan, the term health plan shall include the PDL medical and dental plans available to the eligible active employees of PDL.

### **3.4 Amendment and Termination**

In the event that PDL amends or terminates this Plan, this Plan will reimburse participants for any benefits payable for expenses incurred prior to the date of such amendment, modification or termination.

### **3.5 Newborns' and Mothers' Health Protection Act of 1996**

Group health plans and health insurance issuers generally may not, under federal law, restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case plans and issuers may not, under Federal law, require that a provider obtain authorization from the plan or the issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours).

### **3.6 The Federal "Women's Health and Cancer Rights Act of 1988" requires coverage of treatment related to mastectomy.**

If a participant is eligible for mastectomy benefits under this coverage and elects breast reconstruction in connection with such mastectomy, the participant is also covered for the following:

1. Reconstruction of the breast on which mastectomy has been performed;
2. Surgery and reconstruction on the other breast to produce a symmetrical appearance;
3. Prostheses; and,
4. Treatment for physical complications of all stages of mastectomy, including lymphedemas.

Coverage for reconstructive breast surgery may not be denied or reduced on the grounds that it is cosmetic in nature or that it otherwise does not meet the coverage definition of "medically necessary". Benefits will be provided on the same basis as for any other illness or injury under the relevant health plan.

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## **SECTION IV - ADMINISTRATION OF THE PLAN**

#### 4.1 Administration of the Plan

PDL is the Plan Sponsor and Plan Administrator as defined by ERISA.

PDL shall have the duty and authority to interpret and construe the Plan with regard to all questions of eligibility, the status and rights of any person under the Plan, and the manner, time, and amount of payment of any benefits under the Plan. Each Employee shall, from time to time, upon request of PDL, furnish to PDL such data and information as PDL shall require in the performance of its duties under the Plan.

PDL may adopt such rules and procedures, as it deems desirable for the administration of the Plan, provided that any such rules and procedures shall be consistent with provisions of the Plan and ERISA.

PDL shall discharge its duties with respect to the Plan (i) solely in the interest of persons eligible to receive benefits under the Plan, (ii) for the exclusive purpose of providing benefits to persons eligible to receive benefits under the Plan and of defraying reasonable expenses of administering the Plan and (iii) with the care, skill, prudence and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character with like aims.

#### 4.2 Named Fiduciary

Pursuant to ERISA Section 402 (a) (1), PDL is named fiduciary of the Protein Design Labs, Inc. Retiree Health Plan.

#### 4.3 Appointment of the Plan Administrator

PDL shall designate the Plan Administrator who shall administer PDL's Plan. Such Plan Administrator may consist of an individual, a committee of two or more individuals, whether or not, in either such case, the individual or any of such individuals are Employees of PDL, a consulting firm or other independent agent, or PDL itself. The Plan Administrator shall be charged with the full power and the responsibility for administering the Plan in all its details. If no Plan Administrator has been appointed by PDL, or if the person designated as Plan Administrator by PDL is not available to serve as such for any reason, PDL shall be deemed to be the Plan Administrator. The Plan Administrator may be removed by PDL, or may resign by giving notice in writing to PDL, and in the event of the removal, resignation, death or termination of service by the Plan Administrator, PDL shall, as soon as practicable, appoint a successor Plan Administrator, such successor thereafter to have all of the rights, privileges, duties and obligations of the predecessor Plan Administrator.

#### 4.4 Powers and Responsibilities

- (a) **Administration of the Plan** The Plan Administrator shall have all powers necessary to administer this Plan, including the power to construe and interpret the Plan documents; to decide all questions relating to an Employee's eligibility to participate in the Plan; to determine the amount, manner, and timing of any payment of benefits or change in accordance with Section 5 of the Plan; and to appoint or employ advisors, including legal counsel, to render advice with respect to any of the Plan Administrator's responsibilities under the Plan. Any construction, interpretation, or application of the Plan by the Plan Administrator shall be final, conclusive and binding. All actions by the Plan Administrator shall be taken pursuant to uniform standards applied to all persons similarly situated. The Plan Administrator shall have no power to add to, subtract from or modify any of the

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terms of the Plan, or to add to any benefits provided by the Plan, or to waive or fail to apply any requirements of eligibility for a benefit under the Plan.

- (b) **Records and Reports** The Plan Administrator shall be responsible for maintaining sufficient records to reflect the compensation of each Participant for purposes of determining the amount of compensation of each Participant under the Plan. The Plan Administrator shall be responsible for submitting all required reports and notifications relating to the Plan to Participants or their Beneficiaries, the Internal Revenue Service and the Department of Labor.
- (c) **Rules and Decisions** The Plan Administrator may adopt such rules as it deems necessary, desirable or appropriate in the administration of the Plan. All rules and decisions of the Plan Administrator shall be applied uniformly and consistently to all Employees and Participants in similar circumstances. When making a determination or calculation, the Plan Administrator may rely upon all such information so finished, including the Participant's, former Participant's or Beneficiary's current mailing address.

#### 4.5 Allocation of Duties and Responsibilities

The Plan Administrator may by written or instrument designate persons other than the Plan Administrator to carry out any of its duties or responsibilities under the Plan. Any such duties or responsibilities thus allocated must be described in the written instrument. If a person other than an Employee of (PDL) is so designated, such person must acknowledge acceptance of the allocated duties and responsibilities in writing. All such instruments shall be attached to, and made part of the Plan.

#### 4.6 Delegation of Authority

PDL also hereby appoints each group insurance policy issuer (issuer) listed in Appendix A as a named fiduciary as defined by ERISA Section 402 (a)(1), with such powers as may be necessary to determine the benefits payable under the insurance policies and resolve all questions pertaining to the applicability of the benefit provisions of the insurance policies.

PDL hereby intends that each Issuer shall be deemed to have complied with the requirements of ERISA Act Section 503 (claims procedure) in its exercise of its authority unless it has abused its discretion hereunder by acting arbitrarily and capriciously.

#### 4.7 Expenses

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## SECTION V – HEALTH CLAIM PROCEDURES

The procedures outlined below must be followed by Covered Persons (“claimants”) to obtain payment of health benefits under this Plan.

### 5.1 Health Claims

All claims and questions regarding health claims should be directed to the Contract Administrator. The Plan Administrator shall have final authority for adjudicating all claims and a full review of the decision on such claims in accordance with the following provisions and with the Employee Retirement Income Security Act of 1974, as amended (“ERISA”). The Plan Administrator has delegated the authority to the Contract Administrator subject to the Plan Administrator’s right to make all final decisions to process claims in accordance with the Plan Document and Summary Plan Description.

Each claimant claiming benefits under the Plan shall be responsible for supplying, at such times and in such manner as the Plan Administrator in its sole discretion may require, written proof that the expenses were incurred or that the benefit is covered under the Plan. If the Plan Administrator in its sole discretion shall determine that the claimant has not incurred a covered expense or that the benefit is not covered under the Plan, or if the claimant has failed to furnish such proof as is requested, no benefits shall be payable under the Plan.

Under the Plan, there are four types of claims: Urgent Pre-service, Non-urgent pre-service, Concurrent Care and Post-service.

#### Pre-service Claims:

A “Pre-service Claim” is a claim for a benefit under the Plan where the Plan conditions receipt of the benefit, in whole or in part, on approval of the benefit in advance of obtaining medical care.

A “Pre-service Urgent Care Claim” is any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the claimant or the claimant’s ability to regain maximum function, or, in the opinion of a physician with knowledge of the claimant’s medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

It is important to remember that, if a claimant needs medical care for a condition which could seriously jeopardize his life, there is no need to contact the Plan for prior approval. The claimant should obtain such care without delay.

Further, if the Plan does not require the claimant to obtain approval of a medical service prior to getting treatment, then there is no “Pre-service Claim.” The claimant simply follows the Plan’s procedures with respect to any notice which may be required after receipt of treatment, and files the claim as a Post-service Claim.

#### Concurrent Claims:

A “Concurrent Claim” arises when the Plan has approved an on-going course of treatment to be provided over a period of time or number of treatments, and either (a) the Plan determines that the course of treatment should be reduced or terminated, or (b) the claimant requests extension of the course of treatment beyond that which the Plan has approved.

If the Plan does not require the claimant to obtain approval of a medical service prior to getting treatment, then there is no need to contact the Plan Administrator to request an extension of a

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course of treatment. The claimant simply follows the Plan’s procedures with respect to any notice which may be required after receipt of treatment, and files the claim as a Post-service Claim.

#### Post-service Claims:

A “Post-service Claim” is a claim for a benefit under the Plan after the services have been rendered.

### 5.2 When Health Claims Must Be Filed

Health claims must be filed with the Contract Administrator within 90 days of the date charges for the service were incurred. Benefits are based upon the Plan’s provisions at the time the charges were incurred. Charges are considered incurred when treatment or care is given or supplies are provided. **Claims filed later than that date shall be denied, unless it is shown that it was not reasonably possible to file within 90 days, but in no event later than twelve (12 months from the date on which covered charges were incurred).**

A Pre-service Claim (including a Concurrent Claim that also is a Pre-service Claim) is considered to be filed when the request for approval of treatment or services is made and received by the Third Party Administrator in accordance with the Plan’s procedures. However, a Post-service Claim is considered to be filed when the following information is received by the Contract Administrator, together with a Form HCFA or Form UB92:

- a. The date of service;
- b. The name, address, telephone number and tax identification number of the provider of the services or supplies;
- c. The place where the services were rendered;
- d. The diagnosis and procedure codes;
- e. The amount of charges;
- f. The name of the Plan;
- g. The name of the covered employee; and
- h. The name of the patient.

Upon receipt of this information, the claim will be deemed to be filed with the Plan. The Contract Administrator will determine if enough information has been submitted to adjudicate the claim. If not, the Contract Administrator may request more information. The Contract Administrator must receive the additional information within 45 days (48 hours in the case of Pre-service Urgent Care Claims) from receipt by the claimant of the request for additional information. **Failure to do so may result in claims being declined or benefits reduced.**

### 5.3 Timing of Claim Decisions

The Plan Administrator shall notify the claimant, in accordance with the provisions set forth below, of a denial (and, in the case of Pre-service Claims and Concurrent Claims, of decisions that a claim is payable in full) within the following timeframes:

#### Pre-service Urgent Care Claims:

- a. If the claimant has provided all of the necessary information, as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim.
- b. If the claimant has not provided all of the information needed to process the claim, then the claimant will be notified as to what specific information is needed as soon as possible, but not later than 24 hours after receipt of the claim. The claimant will be notified of a determination of benefits as soon as possible, but not later than 48 hours, taking into account the medical exigencies, after the earliest of (i) the Plan's receipt of the specified

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information, or (ii) the end of the period afforded the claimant to provide the information.

#### Pre-service Non-urgent Care Claims:

- a. If the claimant has provided all of the information needed to process the claim, in a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim, unless an extension has been requested, then prior to the end of the 15-day extension period.
- b. If the claimant has not provided all of the information needed to process the claim, then the claimant will be notified as to what specific information is needed as soon as possible, but not later than 5 days after receipt of the claim. The claimant will be notified of a determination of benefits in a reasonable period of time appropriate to the medical circumstances, either prior to the end of the extension period (if additional information was requested during the initial processing period), or by the date agreed to by the Plan Administrator and the claimant (if additional information was requested during the extension period).

#### Concurrent Claims:

- a. **Plan Notice of Reduction or Termination.** If the Plan Administrator is notifying the claimant of a reduction or termination of a course of treatment (other than by Plan amendment or termination), before the end of such period of time or number of treatments. The claimant will be notified sufficiently in advance of the reduction or termination to allow the claimant to appeal and obtain a determination on review of that adverse benefit determination before the benefit is reduced or terminated.
- b. **Request by Claimant Involving Urgent Care.** If the Plan Administrator receives a request from a claimant to extend the course of treatment beyond the period of time or number of treatments that is a claim involving Urgent Care, as soon as possible, taking into account the medical exigencies, but not later than 24 hours after receipt of the claim, as long as the claimant makes the request at least 24 hours prior to the expiration of the prescribed period of time or number of treatments. If the claimant submits the request with less than 24 hours prior to the expiration of the prescribed period of time or number of treatments, the request will be treated as a claim involving Urgent Care and decided within the Urgent Care timeframe.
- c. **Request by Claimant Involving Non-urgent Care.** If the Plan Administrator receives a request from the claimant to extend the course of treatment beyond the period of time or number of treatments that is a claim not involving Urgent Care, the request will be treated as a new benefit claim and decided within the timeframe appropriate to the type of claim (either as a Pre-service Non-urgent Claim or a Post-service Claim).

#### Post-service Claims:

- a. If the claimant has provided all of the information needed to process the claim, in a reasonable period of time, but not later than 30 days after receipt of the claim, unless an extension has been requested, then prior to the end of the 15-day extension period.
- b. If the claimant has not provided all of the information needed to process the claim and additional information is requested during the initial processing period, then the claimant will be notified of a determination of benefits prior to the end of the extension period, unless additional information is requested during the extension period, then the claimant will be notified of the determination by a date agreed to by the Plan Administrator and the claimant.

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### **Extensions – Pre-service Urgent Care Claims.**

No extensions are available in connection with Pre-service Urgent Care Claims.

### **Extensions – Pre-service Non-urgent Care Claims.**

This period may be extended by the Plan for up to 15 days, provided that the Plan Administrator both determines that such an extension is necessary due to matters beyond the control of the Plan and notifies the claimant, prior to the expiration of the initial 15-day processing period, of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision.

### **Extensions – Post-service Claims.**

This period may be extended by the Plan for up to 15 days, provided that the Plan Administrator both determines that such an extension is necessary due to matters beyond the control of the Plan and notifies the claimant, prior to the expiration of the initial 30-day processing period, of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision.

### **Calculating Time Periods.**

The period of time within which a benefit determination is required to be made shall begin at the time a claim is deemed to be filed in accordance with the procedures of the Plan.

## **5.4 Claims Appeal Procedure**

### **Nature of Denial**

The notice of a denial of a claim shall be written in a manner calculated to be understood by you and shall set forth:

- a. The specific reason for the denial;
- b. Specific references to the pertinent Plan provisions on which the denial is based;
- c. A description of any additional material or information necessary for the claimant to perfect the claim and an explanation as to why such information is necessary; and,
- d. An explanation of the Plan's claims procedures.

## **5.5 Timing of an Appeal**

### **Pre-Service Claims: Special Rule**

For Pre-service Urgent Care Claims, if the claimant chooses to orally appeal, claimant may telephone the Senior Manager of Human Resources at 510-574-1400. To file an appeal in writing, the claimant's appeal must be addressed as follows and faxed to the following number: 510-574-1447.

### **All Other Claims**

Within 180 days after the receipt of the above material, the claimant shall have a reasonable opportunity to appeal the claim denial to the Plan Administrator through the Contract Administrator for a full and fair review. The claimant or his duly authorized representative may:

- a. Request a review upon written notice to the Contract Administrator;
- b. Review pertinent documents; and,
- c. Submit issues and comments in writing.

## **5.6 Timing of Notification of Benefit Determination on Review**

The Plan Administrator shall notify the claimant of the Plan's benefit determination on review within the following timeframes:

**Pre-service Urgent Care Claims:** As soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the appeal.

**Pre-service Non-urgent Care Claims:** Within a reasonable period of time appropriate to the medical circumstances, but not later than 30 days after receipt of the appeal.

**Concurrent Claims:** The response will be made in the appropriate time period based upon the type of claim – Pre-service Urgent, Pre-service Non-urgent or Post-service.

**Post-service Claims:** Within a reasonable period of time, but not later than 60 days after receipt of the appeal.

**Calculating Time Periods.** The period of time within which the Plan's determination is required to be made shall begin at the time an appeal is filed in accordance with the procedures of this Plan, without regard to whether all information necessary to make the determination accompanies the filing.

The decision of the Plan Administrator through the Contract Administrator, shall be written and shall include specific reasons for the decision, written in a manner calculated to be understood by the claimant, with specific references to the pertinent Plan provisions on which the decision is

based. Should you receive an adverse determination of the appeal, you have the right to file a second appeal. The second appeal must be filed no later than 30 days from the date indicated on the response letter to the first appeal. The timing of response to the second appeal shall be made in accordance with the same time guidelines as those outlined for the first appeal.

## 5.7 Requirements for Medicaid

To the extent required by Section 609 of ERISA with respect to group health plans, effective August 10, 1993, payment of benefits with respect to a Participant will be made in accordance with any assignment of rights made by or on behalf of such Participant as required by a state plan of medical assistance approved under Title XIX of the Social Security Act pursuant to Section 1912(a)(1)(A) of such Act (as in effect on the date of enactment of the Omnibus Budget Reconciliation Act of 1993). In enrolling a Participant or in determining or making any payments for benefits for benefits to or on behalf of the Participant, the fact that such Participant is eligible for or is provided medical assistance under a state plan for medical assistance under Title XIX of the Social Security Act will not be taken into account for purposes of this Plan. To the extent that payment has been made under a state plan for medical assistance approved under Title XIX of the Social Security Act in any case in which the Plan, after applying the Plan's claims filing deadlines and other general procedures, has a legal liability to make payments for items or services constituting such assistance, payment for benefits under the Plan will be made in accordance with any state law which provides that the state has acquired the rights of the Participant to such payment for such items or services.

## 5.8 Privacy of Information

In the administration of this Retiree Health Care Plan, Protein Design Labs, Inc. may be required to use or disclose protected information for purposes of paying or causing to be paid benefits under this Plan. PDL has established the following policy regarding the use and disclosure of protected information. PDL hereby agrees to:

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- Not use or disclose information other than as permitted or required by the plan document or by law;
- Ensure that any agents to whom it provides protected information agrees to the same restrictions and conditions that apply to the plan sponsor;
- Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;
- Report to the group health plan any use or disclosure inconsistent with plan provisions;
- Make protected information available as required under other privacy rule provisions;
- Make internal practices and records regarding protected information available to the HHS Secretary; and,
- Where feasible, return or destroy all protected information received from the group health plan when no longer needed for the purpose for which disclosure was made.

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## SECTION VI - GENERAL PROVISIONS

### 6.1 Nonguarantee of Employment

Nothing contained in This Plan shall be construed as a contract of employment between PDL and any Employee, or as a right of any Employee to be continued in the employment of PDL, or as a limitation of the right of PDL to discharge any of its Employees, with or without cause.

### 6.2 Mailing Notices

Notices, accountings and reports required to be given by the Plan Administrator may be given by the Plan Administrator by personal delivery or by mail addressed to the party involved at the last address of such party recorded on the general address files of the plan Administrator. If given by mail, the date of mailing shall be deemed to be the date as of which the same was given or furnished to the addressee. Any notice required under the plan may be waived in writing by the person entitled to such notice.

### 6.3 Submitting Notices

All notices, designations and elections of Participants shall be submitted to the Plan Administrator on forms and to the address specified by the Plan Administrator.

### 6.4 Non-Assignability

It is a condition of the Plan, and all rights of each person eligible to receive benefits under the Plan shall be subject thereto, that no right or interest of any such person in the Plan shall be assignable or transferable in whole or in part, either directly or by operation of law or otherwise, including, but not by way of limitation, exclusion, levy, garnishment, attachment, pledge, or bankruptcy, but excluding devolution by death or mental incompetence, and no right or interest of any such person in the Plan shall be liable from, or subject to, any obligation or liability of such person, including claims for alimony or the support of any spouse.

### 6.5 No Guarantee of Tax Consequences

Neither the Administrator nor (PDL) makes any commitment or guarantee that any amounts paid to or for the benefit of a Participant under the Plan will be excludible from the Participant's gross income for federal or state tax nor that any other favorable tax treatment will apply to or be available to any Participant with respect to such amounts. It shall be the obligation of each Participant to determine whether each payment under this Plan is

excludible from the Participant's gross income for federal and state tax purposes, and to notify the Administrator if the Participant has reason to believe that any such payment is not so excludible.

**6.6 COBRA Applicability**

Under certain circumstances, this Plan may be subject to the continuation of health care provisions of Section 4980B of the Code as amended.

**6.7 Governing Law**

The Plan is intended to constitute an accident and health plan with the meaning of Section 105 of the Code. To the extent not preempted by ERISA, this Plan shall be construed in accordance with the Code and the laws of the State of California.

**6.8 Gender and Number**

Whenever used in the Plan, words in the masculine gender shall include masculine or feminine gender, and unless the context otherwise requires, word in the singular shall include the plural, and words in the plural shall include the singular.

**6.9 Official Document**

This contains all of the operative provisions of this Plan. Any conflict between the provisions of this document and any other document purporting to explain the rights, benefits, or obligations of the parties hereunder shall be resolved in favor of This Plan document. In the event that a tribunal of competent jurisdiction shall determine in a final judgment or decree that one or more of the provisions of this Plan is invalid due to the provisions of applicable law, this Plan shall be interpreted as if the invalid language had been stricken from its provisions and the remainder of the Plan document continued in full force and effect.

**6.10 Amendment or Modification**

The Plan may at any time and from time to time be amended or modified by written instrument duly adopted by PDL. Other provisions of this Plan notwithstanding, this Plan may be amended or modified only with regard to the eligibility requirements contained in Section II, paragraphs 2.1 through 2.8 of this Plan document or in such other manner as required by law to maintain the status of the Plan under the Internal Revenue Code or such other applicable federal law. Any such amendment, or modification shall become effective on such date as PDL shall determine. No such amendment or modification, shall deprive any Participant of any benefits payable for expenses incurred prior to the date of such amendment or modification.

**6.11 Plan Termination**

Protein Design Labs, Inc. and any successor to PDL may terminate this Plan at any time in the future for any reason, but only with regard to employees who are not Participants in the Plan at the time of its termination. In the event of Plan termination, the plan will remain in effect and subject to modification until such time as all participants in the Plan at the time of its termination have ceased participation pursuant to the provisions of Section 2.4 of this Plan.

IN WITNESS WHEREOF, the duly authorized representative of PDL has executed this Plan this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, on behalf of Protein Design Labs, Inc. to evidence the adoption of the Plan as set forth herein.

By: \_\_\_\_\_

Title: \_\_\_\_\_

**APPENDIX A**

**Eligibility**

It is agreed that any termination of the employment relationship between Dr. Laurence Korn and PDL, other than for "Cause", as such term is defined in Section 7(a) of that certain Special Compensation and Continued Employment Agreement dated May 1, 2002 by and between PDL and Dr. Korn, or as a result of Dr. Korn's death, shall be deemed a retirement under the plan.

**APPENDIX B**

**Protein Design Labs, Inc., Retiree Health Care Plan**

**1. Effective Date**

This Plan shall take effect on June 1, 2003.

**2. Benefits**

The applicable benefits and coverage options provided under this Plan are set forth in the Summary Description for each of PDL's health and dental plan options available to the active employees of PDL. The availability of coverage options will be determined by PDL from time to time. A Participant who elects coverage under an applicable plan option will receive the benefits provided by that plan.

**3. Source of Benefits**

Benefits under any health plan whether insured or self insured will be provided and paid solely by the Policy Issuer and pursuant to the terms the insurance policy or service contract. PDL neither guarantees nor has any responsibility for the quality of the health care or services provided or arranged by a Policy Issuer, nor the level of benefits provided under any insurance policy or service contract.

**4. Policy Issuers**

<u>Issuers</u>	<u>Policy Numbers</u>	<u>Coverage</u>
California Physician's Service	NH 0017	Medical Care (HMO)
California Physician's Service	086455	Medical Care (PPO)
Delta Dental Plan of California	7396	Dental Care
Kaiser Permanente	38513	Medical Care

**5. Monthly Contributions**

	<u>Retiree</u>	<u>Dependents</u>
Retiree Health Plan	none	25% of premium for dependents

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**EXHIBIT 23.1**

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

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-36708, 333-108701), and in the related prospectuses, and on Form S-8 (Nos. 333-44762, 333-87957, 33-65224, 33-50116, 33-50114, 33-96318, 333-68314 and 333-104170), pertaining to the 1993 Employee Stock Purchase Plan, Outside Directors Stock Option Plan, 1991 Stock Option Plan, 1999 Nonstatutory Stock Option Plan, 1999 Stock Option Plan, and 2002 Outside Directors Stock Option Plan of Protein Design Labs, Inc. of our report dated February 2, 2004 with respect to the consolidated financial statements of Protein Design Labs, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ ERNST & YOUNG LLP

Palo Alto, California

March 5, 2004

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[CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS](#)

**CERTIFICATIONS**

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 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2004

/s/ MARK MCDADE

Mark McDade  
Chief Executive Officer

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[EXHIBIT 31.1](#)

[CERTIFICATIONS](#)

**CERTIFICATIONS**

I, Glen Sato, certify that:

1. I have reviewed this annual report on Form 10-K of Protein Design Labs, Inc.;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2004

/s/ GLEN SATO

Glen Sato  
*Chief Financial Officer*

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[EXHIBIT 31.2](#)

[CERTIFICATIONS](#)

**CERTIFICATION**

Mark McDade, Chief Executive Officer and Glen Sato, Chief Financial Officer of Protein Design Labs, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- (1) the Annual Report on Form 10-K for the fiscal year ended December 31, 2003 of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

A signed original of this written statement required by Section 906 has been provided to the Securities and Exchange Commission or its staff upon request.

Dated: March 5, 2004

By:

/s/ MARK MCDADE

\_\_\_\_\_  
Mark McDade  
*Chief Executive Officer*

/s/ GLEN SATO

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Glen Sato  
*Chief Financial Officer*

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[EXHIBIT 32.1](#)

[CERTIFICATION](#)