UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004**

OR

o **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	**94-3023969**
(State or other jurisdiction of incorporation or organization)	(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 o

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 o

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, 2004, as reported on the NASDAQ National Market System, was approximately $1,754,800,000.

As of February 28, 2005, the registrant had outstanding 96,070,471 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PART I

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, including the proposed acquisition of ESP Pharma Holding Company, Inc. and the proposed acquisition of certain rights to the Retavase ® product, 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 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, the PDL logo and *Nuvion* are registered U.S. trademarks, and *HuZAF* and *Zamyl* are trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche. *Cardene* IV, IV *Busulfex*, *Tenex*, *Sectral*, and *Ismo* are registered trademarks of ESP Pharma, Inc. *Retavase* is a registered U.S. trademark of Centocor, Inc. 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, 2004, a total of eight marketed products were licensed under our humanization patents, and of these, seven generated royalties to us. We are aware of more than 40 humanized antibodies in clinical stage development worldwide by various pharmaceutical and biotechnology companies, of which a large number may be covered under our patent agreements. 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 launch our first PDL-developed proprietary antibody product into the North American market by the end of 2007.

We license our patents covering numerous humanized antibodies in return for license fees, annual maintenance payments and royalties on product sales. Eight of the nine humanized antibodies currently approved by the U.S. Food and Drug Administration (FDA) are licensed under our patents and seven of these licensed products generated royalties to PDL that were recognized in 2004: Genentech Inc.'s Herceptin®, Xolair®; Raptiva® and Avastin™; MedImmune, Inc.'s Synagis®; Wyeth Pharmaceuticals' Mylotarg®; and Hoffmann-La Roche's Zenapax®. Combined annual worldwide sales of these products exceeded $2.9 billion in 2004. For 2004, we received approximately $83.8 million in product royalties. Additionally, Elan Corporation, plc entered into a license under our patents for the Tysabri® antibody product, which was approved by the FDA in late November 2004 and was marketed until the end of February 2005, when Tysabri was voluntarily withdrawn from the market by Elan and Biogen-Idec and is currently pending review for further clinical trial use as well as marketing and commercial sale.

In January 2005, we announced the acquisition of ESP Pharma, and approximately one week later ESP Pharma announced the acquisition of commercialization rights to Retavase from Centocor. By adding such marketed products through ESP Pharma's sales and distribution capabilities to our antibody development and humanization technology platform, these ESP acquisitions should establish PDL as a fully integrated, commercial biopharmaceutical company with proprietary marketed products, a growing and diverse high-margin operating revenue base and a broad, proprietary pipeline. The transaction is expected to close late in the first or early in the second quarter of 2005. Assuming the closing of the acquisition by this anticipated date, we believe that we will achieve positive cash flow from operations on a quarterly basis, beginning in the second half of 2006 based upon revenues consisting of royalties, license and other income and product sales.

RECENT DEVELOPMENTS

AGREEMENT TO ACQUIRE ESP PHARMA AND RETAVASE®

In January 2005, we entered into a definitive agreement with ESP Pharma, a privately held, hospital-focused pharmaceutical company, under which PDL will acquire ESP Pharma for $300 million in cash and approximately $175 million in PDL common stock, or an aggregate value of approximately $475 million. Subject to regulatory approvals, this acquisition is expected to close late in the first or early in the second quarter of 2005.

On February 1, 2005, PDL and ESP Pharma agreed to increase the purchase price by $25 million in cash in connection with ESP Pharma's agreement to acquire Retavase from Centocor for $110 million plus up to $45 million in certain milestones. The ESP Pharma-Retavase acquisition is expected to close by the end of March 2005.

ESP Pharma has a hospital-focused sales force committed to the acute-care setting. ESP Pharma has grown its sales force from 22 as of September 2002 to 66 field representatives as of January 2005 and intends to employ at least 85 representatives by the end of 2005. If the Retavase acquisition is completed, ESP Pharma intends to further expand its sale force to more than 100 representatives. The existing sales team allows ESP Pharma to market to approximately 800 hospitals in the United States. In the hospitals, the ESP Pharma sales force focuses on the cardiac, neurological and intensive care unit, or ICU, sections.

ESP Pharma has actively pursued a strategy for identifying, acquiring and maximizing the revenue potential of approved and late-stage development specialty therapeutics. ESP Pharma began operations in May 2002 when it acquired the U.S. rights to four cardiovascular products from Wyeth Pharmaceuticals (Wyeth): Cardene® IV, Sectral®, Tenex® and Ismo®. ESP Pharma acquired worldwide rights to IV Busalfex from Orphan Medical, Inc. in June 2003. ESP Pharma's sales force focuses its efforts on Cardene IV and IV Busulfex®:

- ***Cardene IV.*** Cardene IV is the only branded, U.S.-approved dihydropyridine class calcium channel blocker delivered intravenously that is indicated for short-term treatment of hypertension when oral therapy is not feasible or desirable. The product is patent protected through November 2009. This patent covers a process for producing the pharmaceutical composition as well as the pharmaceutical composition, being used in injectable form.

  Many surgical patients develop hypertension during or following surgery. Patients receive Cardene IV to reduce high blood pressure during or after surgery. Competing products also reduce blood pressure, but are either not as effective in stabilizing blood pressure predictably, are only available orally, or are more toxic than Cardene IV. The primary driver in future growth of Cardene IV will be the effective marketing to approximately 800 currently targeted hospitals in the United States plus potential new specialty dosing formulations and indications.

- Cardene IV is currently manufactured by Baxter Healthcare under a long-term toll manufacturing agreement. Nicardipine, the active pharmaceutical ingredient (API) for Cardene IV, is purchased from Roche Palo Alto, LLC (formerly Syntex Pharmaceuticals, a subsidiary of Roche Pharmaceuticals) under a Sublicense and Supply Agreement.

- ***IV Busulfex.*** IV Busulfex, an IV formulation of busulfan, is a chemotherapeutic agent used as part of a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. IV Busulfex provides antitumor effect to eradicate residual malignancy, ablation of the bone marrow to make space for the new source of stem cells and to provide immunosuppression to prevent graft rejection. Its U.S. patent expires in 2015. IV Busulfex competes with other unapproved conditioning regimens including oral busulfan tablets, which are cumbersome in their dosing and have a more variable or slower onset of action compared to IV Busulfex.

  For the year ended December 31, 2004, approximately 82% of sales were in the United States and Canada. ESP Pharma launched IV Busulfex in Europe in the fourth quarter of 2003 through its marketing partner, Pierre Fabre. In Japan and the remainder of Asia, IV Busulfex is in the approval process and is expected to be launched via Kirin Pharmaceuticals in early 2005.

- ***Retavase.*** ESP Pharma and PDL have amended the definitive merger agreement to increase the purchase price by $25 million in connection with ESP Pharma's agreement to acquire from Centocor certain rights to Retavase. Retavase is indicated for use in the management of heart attacks (acute myocardial infarction, or AMI) in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. The acquisition price for the product from Centocor is $110 million, representing approximately two times net 2004 product sales. Milestone payments of up to $45 million will be paid to Centocor if additional conditions relating to ongoing clinical trials and manufacturing arrangements are satisfied. ESP Pharma's agreement to acquire Retavase includes U.S. and Canadian distribution, manufacturing and marketing rights, all relevant intellectual property and approximately two years supply of inventory plus certain manufacturing equipment.

Off-Patent Brands

In May 2002, along with the acquisition of Cardene IV, ESP Pharma acquired three off-patent branded orally delivered drugs: Tenex, Sectral and Ismo. These have a 90% substitution rate, which means for every 10 prescriptions written for the brand, nine are filled with generics. However, 38 states have "Dispense as Written" laws which preclude pharmacists from substituting generics for brands if the prescribing doctor specifies a brand name. Average prices for these three products are approximately 6 to 7 times greater than their generic competitors. A summary description of these products and their approved indications is as follows:

- Tenex is a centrally-acting alpha-blocking agent for use in the treatment of hypertension.

- Sectral is a cardioselective beta-blocker for the treatment of hypertension and ventricular arrhythmia.

- Ismo is a long-acting nitrate for the treatment of angina pectoris due to coronary artery disease.

PDL expects that unit volumes and overall sales of these off-patent brands will continue to decline.

Declomycin. Declomycin is an antibiotic that was approved in the late 1970s and, since the late 1990s, has been indicated for treatment of Rocky Mountain spotted fever, certain types of pneumonia, anthrax, and other bacterial based infections; however, it also suppresses a hormone that prevents urination. Currently, lithium is the only other drug that has shown efficacy in treating this, but has numerous side effects severely limiting its use. During the second quarter of 2004, Impax Laboratories, Inc.'s (Impax) Abbreviated New Drug Application, or ANDA, to manufacture and distribute a generic form of declomycin was approved by the FDA. Impax began selling this generic product in the third quarter of 2004. ESP Pharma also is aware that Barr Laboratories has submitted an ANDA also to begin manufacturing and distributing another generic form of declomycin.

As part of ESP Pharma's strategic response, an agreement was finalized in June 2004 with Stiefel Laboratories, Inc. to sell a generic version of declomycin through its Glades Pharmaceutical division (Glades). As part of the arrangement, ESP Pharma will realize profit in the sale of brand product to this authorized generic distributor (AGD), plus share in the gross profit of generic Demeclocycline sold through Glades' distribution channel. In September 2004, Glades ordered declomycin from ESP Pharma under this arrangement. Nevertheless, PDL expects overall sales of declomycin to decline.

ESP Pharma's Operations

Customers. ESP Pharma's products are sold through wholesale distributors to roughly 800 hospitals in the United States. Currently, ESP Pharma's sales force consists of 8 sales managers and 66 representatives in the field.

Facilities. ESP Pharma maintains leased offices consisting of approximately 23,000 square feet for administrative and sales purposes in Edison, New Jersey. Specialty Pharmaceutical Services (formerly Cord), a subsidiary of Cardinal Health (Specialty Pharmaceutical), handles a number of tasks for ESP Pharma

including: warehousing, distribution, receiving orders from customers, invoicing and collection of receivables. All ESP Pharma product inventory is shipped directly from Specialty Pharmaceutical's third-party warehouse located in Tennessee.

ESP Pharma's Clinical-stage Pipeline

Although the ESP acquisition is not expected to close until late March 2005, ESP holds U.S. and certain other territory license rights to certain compounds in later stage clinical development. These products include two products that are new formulation versions of off-patent agents approved in the U.S, and two in-licensed products in Phase II and Phase III respectively. These latter agents are under development for congestive heart failure and hepatorenal syndrome respectively. Following the close of the ESP transaction by PDL, we intend to provide additional detailed information as to PDL's future development plans for these programs. Certain of these programs may in fact be either terminated or out-licensed.

PDL PRODUCTS IN CLINICAL STAGE DEVELOPMENT

We currently have four antibodies in clinical development for various disease indications, with a near-term emphasis on autoimmune and inflammatory diseases and cancer, specifically inflammatory bowel disease, asthma and solid tumors.

The following table summarizes the potential therapeutic applications and development status for our antibody-based 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
Nuvion (visilizumab, anti-CD3)	Intravenous steroid-refractory ulcerative colitis	Phase I / II
Zenapax (daclizumab, anti-IL-2 receptor)	Prevention of acute kidney transplant rejection	Marketed/Roche
	Asthma	Phase II
M200 (volociximab, anti-α5β1 integrin)	Advanced solid tumors	Phase II
HuZAF (fontolizumab, anti-gamma-interferon)	Crohn's disease	Phase II

Nuvion (visilizumab, anti-CD3). *Nuvion* is in a Phase I/II clinical study in patients with intravenous steroid-refractory ulcerative colitis. 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 *Nuvion* in ulcerative colitis is still being characterized in ongoing studies, early research has demonstrated that *Nuvion* induces selective programmed cell death of activated, but not resting T cells *in vitro*, which may provide therapeutic benefit in ulcerative colitis.

Nuvion is being evaluated in patients with ulcerative colitis that is refractory to treatment with intravenous steroids. This refractory patient population has no approved medical alternatives and generally requires surgery. We have completed a 32-patient Phase I clinical trial in which patients received one intravenous injection of *Nuvion* on two consecutive days. The two dose cohorts tested were at 15 and 10 µg/kg. In the 15 µg/kg dose cohort, all 8 patients had achieved a response and 7 of the 8 patients had achieved a remission at day 30. At the 10 µg/kg dose level, 19 of 24 (79%) patients had responded and 8 (33%) patients had achieved a remission at day 30. The antibody has demonstrated an acceptable safety profile for these patients for whom there are no approved medical treatments.

Because we saw a strong signal of activity in the Phase I study, PDL initiated a Phase I/II trial of *Nuvion* in this patient population to more fully explore lower doses. In the Phase I dose-ranging portion of this Phase I/II study, we are exploring four dose levels, from 5 µg/kg to 12.5 µg/kg given intravenously on days 1 and 2 as a bolus injection. This study has enrolled patients with Epstein-Barr virus levels up to 5,000 copies/ml and has an exploratory provision for re-treatment of patients who have an initial response, but relapse within one year.

Interim findings from the Phase I portion of this study were presented at the United European Gastroenterology Week meeting in Prague in September 2004. We have now seen clinical responses at all dose levels tested to date.

In each of the studies reported to date, the most common adverse events have been associated with the cytokine release syndrome, which generally consists of flu-like symptoms and is typically characterized by fatigue, nausea, chills and headache. The symptoms were generally transient in nature, were seen less frequently following the second day of treatment and were typically resolved within 24 hours following the second treatment. In addition, *Nuvion* administration results in transient depletion of T-cells and frequently a corresponding transient rise in EBV titers. To date, there have not been obvious clinical signs or symptoms associated with these laboratory abnormalities in ulcerative colitis patients, although an increased rate of infection and/or lymphproliferative disease is a theoretical possibility. *Nuvion* administration also results in the generation of antibodies, including neutralizing antibodies in some patients. Rare allergic reactions have also been associated with *Nuvion* administration.

We plan to conduct a *Nuvion* end-of-Phase I meeting with the FDA late in the first quarter of 2005. We anticipate that the future registration pathway will be based on the Special Protocol Assessment process. If our March discussions with the FDA are successful, we expect to seek approval to initiate Phase III studies by the fourth quarter of 2005 in the intravenous steroid-refractory ulcerative colitis setting. We have received "Fast Track" status from the FDA for the investigation of *Nuvion* in patients with intravenous steroid-refractory ulcerative colitis, which is the first PDL program to receive such designation. The FDA grants fast track status under the Food and Drug Administration Modernization Act of 1997 to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address an unmet medical need. The fast track process includes the potential for more frequent meetings with the FDA to receive their input into the development plan, the option of be considered for the submission of a Biologic License Application (BLA) serially in sections rather than submitting all components simultaneously, and the potential to be considered for priority review and/or accelerated approval. The fast track designation does not guarantee that the *Nuvion* program will qualify for or be able to take advantage of the expedited review process and/or accelerated approval process and it does not increase the likelihood that *Nuvion* will receive regulatory approval.

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, Hoffmann-La Roche (Roche), sells daclizumab under the brand name 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 paid $80 million in cash for return of exclusive rights to daclizumab in indications other than transplantation. Under the terms of this arrangement, Roche has the right to put the transplant indications as early as 2005 upon six months prior written notice to us. If Roche does not exercise its put right, we have the right to acquire these transplant indications, which right is exercisable beginning in the second quarter of 2006 and effective no earlier than six months following the date of notice of the exercise but no later than July 1, 2007. 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 we exercise our option, 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 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.

In September 2004, we entered into an agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases. Under the terms of this agreement, we received a $17.5 million upfront payment and may receive up to $187.5 million in milestone payments for successful further development and commercialization of daclizumab. This agreement provides that Roche and PDL will globally co-develop daclizumab in asthma, equally share development expenses and co-promote the product in the United States. Outside the United States, PDL will receive royalties on net sales of the product in asthma and related respiratory diseases.

Daclizumab binds to the IL-2 receptor on immune system cells known as T cells. IL-2 is a cytokine, 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.

Positive results from a Phase II trial of daclizumab in moderate-to-severe persistent asthma were reported in March 2004 at the American Academy of Allergy, Asthma & Immunology meeting. This Phase II randomized, double blind, placebo controlled clinical trial treated 115 patients who suffer from chronic, persistent asthma and whose disease is not well controlled with high doses of inhaled corticosteroids. We reported that statistically significant treatment differences (p=0.05) were observed in treatment period one for the primary endpoint, which was the percent change in FEV_1 (Forced Expiratory Volume in one second) from baseline to 12 weeks, or day 84. Secondary clinical endpoints also supported these findings. Treatment with daclizumab was generally well tolerated. We expect that the next trial of daclizumab in asthma will be a single-dose, Phase I clinical trial in healthy volunteers, intended to gather additional experience with the PDL-manufactured subcutaneous formulation of daclizumab. This single-dose subcutaneous study should begin in the first quarter of 2005. This single-dose trial is expected to be followed by a multiple-dose Phase I study. We anticipate that a subsequent Phase IIb clinical trial in moderate-to-severe persistent asthma could begin in the first quarter of 2006.

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. A PDL-sponsored Phase II study of daclizumab in MS is expected to be initiated late in the first quarter or early in the second quarter of 2005.

We evaluated daclizumab in a Phase II clinical study in patients with moderate-to-severe ulcerative colitis. This randomized, placebo controlled Phase II clinical trial enrolled approximately 159 patients. In May 2004, we reported that daclizumab did not meet primary or secondary endpoints in the study, and that we do not plan further development of daclizumab in ulcerative colitis.

M200 (volociximab, anti-α5β1 integrin antibody). Our anti-α5β1 integrin chimeric antibody program, M200, is in Phase II 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 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 α5β1 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.

In September 2004, we presented interim clinical data from the Phase I study of M200. In the Phase I trial, 16 men and women between the ages of 29 and 81 (mean 58 years) with various solid tumor types refractory to standard therapy had been enrolled. Tumor types included colorectal, melanoma, hepatic, pancreatic and non-small cell lung cancers. The study data showed that adverse events were generally mild to moderate in intensity and included fatigue, nausea, constipation, headache, and anorexia. There were no severe or serious adverse events that were dose limiting or considered by investigators to be related to M200. In addition, 10 of 15 evaluable patients had stable disease as their best response, and five of six patients treated at the highest dose level reported, 10 mg/kg, achieved stable disease. Four patients with stable disease after 5 doses of M200 in the Phase I study continued treatment with M200 in a Phase I extension study. Three of these patients maintained stable disease for greater than 16 weeks over the two studies.

We have initiated a series of open-label, Phase II clinical trials which are planned to study M200 in the treatment of renal, melanoma, pancreatic, and non-small cell lung cancers. The renal cell carcinoma study initiated in January 2005 is a single-agent trial, while the studies in the other three malignancies will be combination studies with standard therapy.

HuZAF™ (fontolizumab, anti-gamma interferon). 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.

This humanized antibody has completed two Phase II studies in a total of approximately 329 patients with Crohn's disease, a form of inflammatory bowel disease. These two randomized, placebo controlled, double blind Phase II trials were designed to better define the activity of this antibody in Crohn's disease.

The first trial explored 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. In March 2004, we reported results of these two trials of HuZAF in Crohn's disease. The primary endpoint for both trials was the response to the initial intravenous dose. HuZAF did not meet the primary endpoint in either trial following administration of a single intravenous dose. We did, however, in subset analysis of C-Reactive Protein (CRP)-elevated patients, identify very strong signals of activity. Based on the recent success of our pipeline and the allocation of resources to higher priority programs, we currently are seeking to partner HuZAF before initiating additional development in Crohn's disease or other autoimmune indications, such as systemic lupus and rheumatoid arthritis. Current efforts with HuZAF are limited to completion of an ongoing Phase II chronic dosing study in moderate to severe Crohn's Disease patients.

PDL PRODUCTS IN PRECLINICAL STAGE DEVELOPMENT

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.

BUSINESS AND COMMERCIALIZATION STRATEGY

Our current business and commercialization strategy is to transition from a company dependent on licensing activities, development arrangements, humanization services and royalties as the primary sources of revenues to a commercial enterprise that derives the majority of its revenues from sales of its proprietary products. Key elements of our strategy include the following:

- *Fully-integrated commercial organization.* We believe that our current clinical development programs address areas of significant unmet medical need that could, at least in North America, effectively be serviced with a modest-sized sales force of between 80 to 125 representatives. If our programs are successful in later stage trials, and subsequently gain regulatory approval for therapeutic use in the United States and Canada, our goal is to create a North American hospital-focused sales and marketing operation related to our core therapeutic focus in inflammatory diseases by 2007. Prior to that time, we expect to develop a small PDL sales and marketing capability in transplantation in connection with the anticipated reversion of rights to manufacture and market Zenapax, and we believe such infrastructure would be complementary to our potential marketing needs as they relate to *Nuvion* for ulcerative colitis. In the event the ESP Pharma acquisition is completed, we believe the integration of this sales and marketing capability with ESP Pharma's in-line marketing and sales team will help to enable successful commercialization following the reversion of Zenapax transplant rights to PDL.

- *Development of proprietary drugs.* Our most advanced clinical-stage programs are *Nuvion* antibody product for potential treatment of intravenous steroid-refractory ulcerative colitis (IVSR-UC), and daclizumab for the potential treatment of moderate-to-severe asthma. Additionally, in 2003, we repurchased rights from Roche to market and manufacture daclizumab in indications other than transplantation, and we obtained an option to acquire rights to daclizumab in transplant indications, marketed as Zenapax, by no later than 2007. We believe that the market potential for daclizumab could be expanded beyond the current approved indication in renal transplantation through potential development of this already-marketed antibody in other autoimmune or inflammatory disease indications, such as asthma and multiple sclerosis (MS). In September 2004, we completed an agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases. Following the ESP Pharma acquisition, we plan to develop certain programs in-licensed by ESP Pharma.

- *Licensing arrangements.* 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. For example, we have partnered with Roche for the joint development and commercialization of daclizumab in asthma. We retain worldwide rights to each of the other products we are currently developing. We may receive upfront fees, milestone payments or other types of funding under these arrangements, in addition to possible royalties or other profit-sharing rights on any product sales by such marketing partners.

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. Eight of the nine humanized antibodies currently approved by the U.S. Food and Drug Administration (FDA) are licensed under our patents and seven of these licensed products generated royalties to PDL that were recognized in 2004: Genentech Inc.'s Herceptin®, Xolair®; Raptiva® and Avastin™; MedImmune, Inc.'s Synagis®; Wyeth Pharmaceuticals' Mylotarg®; and Hoffmann-La Roche's Zenapax®. Combined annual worldwide sales of these products exceeded $2.9 billion in 2004. In 2004, we received $83.8 million in product royalties. Additionally, Elan Corporation, plc entered into a license under our patents for the Tysabri® antibody product, which was approved by the FDA in late November 2004 and was marketed until the end of February 2005, when Tysabri was voluntarily withdrawn from the market by Elan and Biogen-Idec and is currently pending review for further clinical trial use as well as marketing and commercial sale. We recognize royalty revenues in the quarter reported to us by our licensees (i.e., generally one quarter following the quarter in which sales by our licensees occurred).

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.

Also, we recognize revenues related to our agreement with Hoffmann-La Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases, which includes an upfront fee, milestone payments and partial funding of our research and development costs in addition to royalties and profit-sharing on future product sales.

In addition, we are seeking to out-license marketing rights for other 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. Fifteen human, humanized or chimeric antibodies have already been approved for marketing by the FDA, of which eight 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 more than 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 45,000 square-foot manufacturing facility in Plymouth, Minnesota, which we have leased since 1992. We currently manufacture *Nuvion*, daclizumab, fontolizumab and other preclinical antibodies in that facility. We renovated this facility in 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 resumed manufacturing of antibodies in the first half of 2003. Based on our current capacity in our Brooklyn Park manufacturing facility, our current plans are to reduce or close operations in this facility in 2006.

We are validating a new commercial manufacturing facility in Brooklyn Park, Minnesota, approximately nine miles from our Plymouth location. Physical construction of our approximately 22,000-liter capacity manufacturing facility was completed in December 2004. We currently expect to be able to produce antibodies for clinical use from this facility by 2006 and for commercial sale in 2007. Antibodies currently in our clinical stage pipeline that may be made in this facility include *Nuvion*, fontolizumab, daclizumab and volociximab, the anti-α5β1 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, Genentech, Medarex, MedImmune, Merck KGaA, Millenium Pharmaceuticals, Morphotek, 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, MedImmune, Millennium Pharmaceuticals and Tanox. Under these agreements, licensees currently purchase a research license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of target antigens. Our patent rights agreements with Celltech, Genentech, Morphotek and Seattle Genetics 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.

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 2003 acquisition of Eos Biotechnology, Inc. We have initiated efforts to change over from ICOS supply to our own supply as soon as is reasonably practicable, subject to regulatory and physical constraints.

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 $7.9 million mortgage on these facilities. In addition, we lease approximately 100,000 square feet of adjacent research and development and general office space in Fremont, California. Our lease terms for these facilities will expire on December 31, 2006 and February 28, 2007.

In Plymouth, Minnesota, we lease a total of approximately 75,000 square feet of manufacturing, laboratory and office space in three separate buildings. The lease terms 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 have built a new commercial manufacturing plant on this property that is currently being validated. In January 2005, we entered into an agreement to purchase approximately 6 acres adjacent to our existing Brooklyn Park facility to permit further expansion of our existing site if we deem this necessary in the future.

- In Somerville, New Jersey, we lease approximately 6,000 square feet of general office space. The lease term will expire on October 31, 2005. We no longer occupy this facility and currently sublease a portion of the space.

- In Paris, France, we lease approximately 600 square feet of general office space. The lease term will expire on August 12, 2013.

- 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 no longer occupy this facility.

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 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 2014.

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). 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. We believe that such claims, if upheld by the Opposition Division, would cover the production of many humanized antibodies.

At an oral hearing in February 2005, the Opposition Division of the European Patent Office decided to revoke the claims in our second European antibody humanization patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We appealed the decision to the Technical Board of Appeal at the European Patent Office. The appeal suspends the legal effect of the decision of the Opposition Division during the appeal process, which is likely to take several years.

In regard to our Japanese humanization patent, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court decision upholding revocation of the patent by the Japanese Patent Office. The Japanese Supreme Court decision concludes the proceedings in the matter and the Japanese Patent Office decision to revoke our patent is final.

In October 2004, the Japanese Patent Office issued a patent to our first divisional humanization patent application. The Japanese Patent No. 3604058 claims a method of producing a humanized immunoglobulin specifically reactive with the human IL-2 receptor and the composition of matter directed to Zenapax (daclizumab).

There are two additional divisional patent applications pending before the Japanese Patent Office with respect to our humanization technology.

We intend to vigorously defend our patents 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 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.

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. Before we are able to manufacture commercial products in our new Brooklyn Park, Minn. facility, we must meet the FDA guidelines. We will need to manufacture Zenapax and demonstrate comparability with the material currently manufactured by Roche in order to manufacture and sell this product for ourselves. In addition, all of our products produced by a different manufacturing process will be subject to confirmation and testing that the material from our new site represents a similar product for further development and, ultimately, commercial sale.

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 Biologics License Application (BLA) for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA if applicable regulatory criteria are not satisfied. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which the pharmaceutical product may be marketed. Further, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA, the manufacturer continues to be subject to facility inspection and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holder.

COMPETITION

Potential competitors have developed and are developing 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.

Also, if we complete our pending acquisition of ESP Pharma, you should consider certain additional risks related to the business of ESP Pharma. Potential competitors of ESP Pharma in the U.S. and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. For example, we are aware that The Medicines Company has a product currently in Phase III development, Clevelox, which is an intravenous, short-acting calcium channel antagonist being developed in late-stage clinical trials for the short-term control of high blood pressure in the hospital setting. While we believe that Cardene IV has advantages over Clevelox, there can be no assurance that the ongoing or future clinical studies will not show superior benefits than those obtained with Cardene IV, or that The Medicines Company's sales and marketing efforts will not negatively impact Cardene IV.

In addition, ESP Pharma product sales face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of its products. ESP Pharma has several marketed products that are generic versions of brand-name products. Additionally, ESP Pharma has brand-name products that are subject to competition from generic products. ESP Pharma faces competition in its marketed products from brand-name pharmaceutical companies and from companies focused on generic pharmaceutical markets. In addition, competitors may succeed in developing products and technologies that are more effective or less costly than the ESP Pharma products, or that would render the ESP Pharma products obsolete or noncompetitive.

You should closely review the risk factors contained under the subheading "Risks Related to the ESP Business" for additional information regarding competitive factors and other risks relating specifically to the ESP Pharma business and products.

Other competitive factors affecting our business generally 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, 2004, we had 660 full-time employees. Of the total, 171 employees were engaged in research and process development, 113 in clinical and regulatory, 165 in manufacturing, 103 in general and administrative functions, and 108 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 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.

RISKS RELATED TO OUR BUSINESS

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

In general, our expenses have exceeded revenues. As of December 31, 2004, we had an accumulated deficit of approximately $273.5 million. We expect our expenses to increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain.

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;
- 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 and may require additional capital to fully execute our business strategy.

Increased leverage as a result of our sale of the 2005 Notes may harm our financial condition and results of operations.

At December 31, 2004, we would have had approximately $507.5 million of outstanding debt as adjusted for the offering of the 2.00% Convertible Senior Notes due February 15, 2012 in the aggregate principal amount of $250 million issued in February 2005 (the 2005 Notes). In addition to the 2005 Notes, approximately $250 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2003 (the 2003 Notes), and we have debt service obligations related thereto. The 2005 Notes do not restrict our future incurrence of indebtedness and we may incur additional indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

- we will have additional cash requirements in order to support the payment of interest on our outstanding indebtedness;
- increases in our outstanding indebtedness and leverage will increase our vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and
- depending on the levels of our outstanding debt, our ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes may be limited.

Our ability to make payments of principal and interest on our indebtedness depends upon our future performance, which will be subject to general economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control. If we are unable to generate sufficient cash flow from operations in the future to service our debt, we may be required, among other things:

- to seek additional financing in the debt or equity markets;
- to refinance or restructure all or a portion of our indebtedness, including the 2005 Notes or the 2003 Notes;
- to sell selected assets;
- to reduce or delay planned capital expenditures; or
- to reduce or delay planned operating expenditures, such as clinical trials.

Such measures might not be sufficient to enable us to service our debt. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms.

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

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

- the seasonality of sales of licensed products;
- the existence of competing products;
- the market launch of recently licensed products;
- the continued safety of approved 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, which product is marketed by MedImmune, Inc. (MedImmune). 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. For example, we expect to recognize expense for employee stock options beginning in the third quarter of 2005, and as a result, we will incur significantly higher losses. In addition, we hold a $30 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser’s financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new

accounting pronouncements or regulatory rulings could require us to report the change in the value of the Exelixis stock in our financial statements such that changes in the Exelixis stock price contribute to fluctuations of our operating results from quarter to quarter.

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 antibody 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 opponents are successful, our ability to collect royalties on European sales of antibodies humanized by others would depend on: (i) the scope and validity of our second European patent; and (ii) whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents, and if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to 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 in Europe 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.

At an oral hearing in February 2005, the Opposition Division of the European Patent Office decided to revoke the claims in our second European antibody humanization patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We plan to appeal the decision to the Technical Board of Appeal at the European Patent Office. The appeal will suspend the legal effect of the decision of the Opposition Division during the appeal process, which is likely to take several years.

We intend to vigorously defend the European patents 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 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.

In regard to our Japanese humanization patent, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court decision upholding revocation of the patent by the Japanese Patent Office. The Japanese Supreme Court decision concludes the proceedings in the matter and the Japanese Patent Office decision to revoke our patent is final.

In October 2004, the Japanese Patent Office issued a patent to our first divisional humanization patent application. This patent claims a method of producing a humanized antibody specifically reactive with the human IL-2 receptor and the composition of matter directed to Zenapax (daclizumab). Although we have additional divisional patent applications pending in Japan, there can be no assurance that any patents will issue from such divisional applications or that the scope of such patents, if any, would be sufficient to cover third party antibody products.

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, Inc. (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 our patents or result in a significant reduction in the scope of our issued patents.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings. 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. 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 in claim scope could reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope 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 we may not be able to market our products at all.

Celltech, for example, 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. At an oral hearing in January 2005, the Opposition Division decided to revoke this patent. Celltech has filed a notice of appeal. We cannot predict whether Celltech's appeal will be successful, 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 its 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. We recently negotiated an extension that has extended the term of the current agreement to December 2014. 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, 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.

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, 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.

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

We have not commercialized any antibody 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. Our antibody product candidates are in various stages of development and many are in an early development stage. If we are unsuccessful in our research efforts to identify and obtain rights to new targets and generate antibody product candidates that lead to the required regulatory approvals and the successful commercialization of products, our ability to develop new products could be harmed.

If we are unable to develop new products, our ability to grow may depend on our success in acquiring or licensing new porducts and integrating them successfully.

If we are unable to develop new products, we may depend on acquisitions of rights to products from others as our primary source of new products. Risks in acquiring new products include the following:

- we may not be able to locate new products that we find attractive and complementary to our business;
- the price to acquire or obtain a license for these products may be too costly to justify the acquisition;
- we may be unable to efficiently and economically integrate the research, development and commercialization of these products.

Clinical development is inherently uncertain and expensive, and costs may fluctuate unexpectedly.

Our development of current and future product candidates, either alone or in conjunction with collaborators, is subject to the risks of failure inherent in the development of new pharmaceutical products. Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products. Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended use in humans. We have incurred and will continue to incur substantial expense for, and we have devoted and expect to continue to devote a significant amount of time to, preclinical testing and clinical trials. Despite the time and expense incurred, there can be no assurance that our clinical trials will adequately demonstrate the safety and effectiveness of our product candidates.

Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or failures of our clinical trials as a result of many factors, all of which may increase the costs and expense associated with the trial, including:

- Changes in regulatory policy during the period of product development;
- Delays in obtaining regulatory approvals to commence a study;
- Delays in identifying and reach agreement on acceptable terms with prospective clinical trial sites;
- Delays in the enrollment of patients;
- Lack of efficacy during clinical trials; or
- Unforeseen safety issues.

Completion of clinical trials may take several years or more. The length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly according to the type, complexity, novelty and intended use of the product candidate and is difficult to predict. Further, we, the FDA, Investigational Review Boards or data safety monitoring boards may decide to temporarily suspend or permanently terminate 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. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to preclinical or clinical trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future. Despite the time and expense incurred, we cannot guarantee that we will successfully develop commercially viable products that will achieve FDA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

We are subject to extensive government regulation, which requires us to spend significant amounts of money, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize our products.

Our product candidates under development are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, research, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, quality control, adverse event reporting, advertising, promotions, sale and distribution of biopharmaceutical products. If we market our products abroad, they will also be subject to extensive regulation by foreign governments. Neither the FDA nor any other regulatory agency has approved any of our product candidates for sale in the United States or any foreign market. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain. 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 2004, we announced that daclizumab, our humanized antibody that binds to the interleukin-2 (IL-2) receptor, did not meet the primary endpoint in a Phase II clinical trial in patients with moderate-to-severe ulcerative colitis. As a result, we terminated further development of daclizumab in this indication.

Early 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. We may decide, or the FDA may require us, to make changes in our plans and protocols. Such changes may relate, for example, to changes in the standard of care for a particular disease indication, comparability of efficacy and toxicity of materials where a change in materials is proposed, or competitive developments foreclosing the availability of expedited approval procedures. We may be required to support proposed changes with additional preclinical or clinical testing, which could delay the expected time line for concluding clinical trials.

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, the daclizumab Phase II clinical trials in moderate-to-severe ulcerative colitis, which did not meet the primary endpoint in May 2004, were based on earlier Phase I physician-sponsored clinical trials that indicated safety and biological activity for a small number of patients in this indication.

Even when a drug candidate shows evidence of efficacy in a clinical trial, it may be impossible to further develop or receive regulatory approval for the drug if it causes an unacceptable incidence or severity of side effects, or further development may be slowed down by the need to find dosing regimens that do not cause such side effects.

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. The approval process takes many years, requires the expenditure of substantial resources, and may involve post-marketing surveillance and requirements for post-marketing studies. The approval of a product candidate may depend on the acceptability to the FDA of data from our clinical trials. Regulatory requirements are subject to frequent change. Delays in obtaining regulatory approvals may:

- adversely affect the successful commercialization of any drugs that we develop;
- impose costly procedures on us;
- diminish any competitive advantages that we may attain; and
- adversely affect our receipt of revenues or royalties.

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.

The "fast track" designation for development of *Nuvion* for the treatment of intravenous steroid-refractory ulcerative colitis may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood the *Nuvion* will receive regulatory approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA "fast track" designation for a particular indication. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although we have obtained a fast track designation from the FDA for Nuvion for the treatment of intravenous steroid-refractory ulcerative colitis, we may not experience a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that Nuvion will receive regulatory approval for the treatment of intravenous steroid-refractory ulcerative colitis.

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 clinical strategies that seek to advance potential products through clinical development as rapidly as possible. For example, our current projection for regulatory approval of *Nuvion* in the United States in 2007 depends upon regulatory approval to initiate Phase III studies in 2005. 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;
- 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 result in our being unable to successfully achieve our projected development timelines, or potentially even lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication. For example, our current expectations for registrational studies and regulatory approval for Nuvion are dependent on our ability to timely enroll a worldwide clinical program.

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 licensees or others. In February 2005, Biogen Idec, Inc. and Elan Corp. announced that they had voluntarily suspended supplying, marketing and sale of Tysabri, a drug approved to treat multiple sclerosis and which is licensed under our humanization patents. Financial analyst and investor expectations, as well as our own financial plans beginning in 2005, included potential royalties from the sale of Tysabri. There can be no assurance that Tysabri will be returned to the market, the timing of such return, if ever, or that even if subsequently marketed and sold, the product will result in our receiving any significant royalties from the sales of Tysabri.

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

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

We do not currently have the ability to independently conduct pre-clinical and clinical trials for any of our product candidates, and we must rely on third parties, such as medical institutions and clinical investigators, including physician sponsors, to conduct our clinical trials, including recruiting and enrolling patients in the trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed or may not be able to obtain regulatory approval for or commercialize our product candidates. If any of the third parties upon whom we rely to conduct our preclinical or clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, and need to be replaced, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by medical institutions and clinical investigators, including physician sponsors, is compromised due to their failure to adhere to applicable laws, our clinical protocols or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize any of our product candidates. If our relationships with any of these organizations or individuals terminates, we believe that we would be able to enter into arrangements with alternative third parties. However, replacing any of these third parties could delay our clinical trials and could jeopardize our ability to obtain regulatory approvals and commercialize our product candidates on a timely basis, if at all.

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

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

- the commitment of each partner's management to the continued development of the licensed products or technology;
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts; and
- the relative advantages of alternative products or technology being marketed or developed by each partner or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

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

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

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with partners. To market products directly, we must 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 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, especially in the event the ESP transaction does not close as scheduled. 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 attract additional and retain qualified clinical, manufacturing, scientific and management personnel. If we are unsuccessful in attracting and retaining qualified personnel, our business could be impaired.

Our own ability to manufacture our products on a commercial scale is uncertain, which may make it more difficult to sell our products.

The manufacture of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. We will need to manufacture such antibody therapeutic products in a facility and by an appropriately validated process that comply with FDA, European, and other regulations. Our manufacturing operations will be subject to ongoing, periodic unannounced inspection by the FDA and state agencies to ensure compliance with good manufacturing practices. If we are unable to manufacture product or product candidates in accordance with FDA and European good manufacturing practices, we may not be able to obtain regulatory approval for our products.

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 also 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 manufacturing capabilities. Our current plans are to validate and use our new manufacturing plant in Brooklyn Park, Minnesota in order to manufacture initial commercial supplies of Nuvion and daclizumab. 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 manufacturing plant. We may encounter problems with the following:

- production yields;
- quality control and assurance;
- availability of qualified personnel;
- availability of raw materials;
- adequate training of new and existing personnel;

- on-going compliance with our standard operating procedures;
- on-going compliance with FDA regulations;
- production costs; and
- development of advanced manufacturing techniques and process controls.

Failure to successfully operate our manufacturing plant, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis could delay commercialization of our products.

In addition, as we implement validation of our Brooklyn Park, Minnesota manufacturing facility, we are implementing an enterprise resource management software platform to support our operations, including our new manufacturing facility. These efforts will involve substantial costs and resource commitments. Any construction, validation, 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.

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

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 form the drug material previously produced. Changing the manufacturing site is considered to be a change in the manufacturing process, therefore moving production to our Brooklyn Park manufacturing facility from our Plymouth facility or from third parties will entail manufacturing changes. Further, any significant manufacturing changes for the production of our product candidates could result in delays in development or regulatory approval or in the reduction or interruption of commercial sales of our product candidates. Our inability to maintain our manufacturing operations in compliance with applicable regulations within our planned time and cost parameters could materially harm our business, financial condition and results of operations.

With respect to our M200 antibody product, ICOS Corporation (ICOS) has manufactured all of the drug material contemplated for use in our planned Phase II clinical studies. We plan to assume responsibility for manufacturing M200 for use in Phase III clinical studies and commercial supply, if required. We will need to show that the M200 drug material we produce will be sufficiently similar to the ICOS-produced drug material to use in future clinical studies in order to avoid delays in development or regulatory approval for this antibody product.

Additionally, when we assume responsibility for manufacturing Zenapax, we may 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 our material and 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. Our ability to successfully market and develop Zenapax, in particular in transplantation, depends upon our success in manufacturing Zenapax at commercial scale. 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 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 older material and the newer material after making manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

Our 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, are developing, 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. As a result of Novartis' relationship with Roche, Roche may not devote significant resources to the marketing and sales of Zenapax, which could harm our business.

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.

Even if marketing approval from the FDA is received, the FDA may impose post-marketing requirements, such as:

- labeling and advertising requirements, restrictions or limitations, such as the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our product candidates;
- adverse event reporting;
- testing and surveillance to monitor our product candidates and their continued compliance with regulatory requirements; and
- inspection of products and manufacturing operations and, if any inspection reveals that the product or operation is not in compliance, prohibiting the sale of all products, suspending manufacturing or withdrawing market clearance.

The discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, may result in restrictions of the products, including withdrawal from manufacture. Additionally, certain material changes affecting an approved product such as manufacturing changes or additional labeling claims are subject to further FDA review and approval. The FDA may revisit and change its prior determination with regard to the safety or efficacy of our products and withdraw any required approvals after we obtain them. Even prior to any formal regulatory action requiring labeling changes or affecting manufacturing, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety and efficacy develop.

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 are required to comply with the applicable FDA current good manufacturing practice (cGMP) regulations and other regulatory requirements. Good manufacturing practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities, including our facility, must pass an inspection by the FDA before initiating commercial manufacturing of any product. Pharmaceutical product manufacturing establishments are also subject to inspections by state 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. The FDA enforces post-marketing regulatory requirements, such as cGMP requirements, through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manufacturing operations.

In addition, during 2003 the FDA 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. In their regulation of advertising, the FDA, the Federal Trade Commission (FTC) and the Department of Health and Human Services (HHS) may investigate whether particular advertising or promotional practices are false, misleading or deceptive. These agencies may impose a wide array of sanctions on companies for such advertising practices. Additionally, physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of "off-label" use. Companies cannot promote FDA-approved pharmaceutical or biologic products for off-label uses. If our advertising or promotional activities fail to comply with applicable regulations or guidelines, we may be subject to warnings or enforcement action. In addition, if the ESP Pharma acquisition is completed, there may be a similar risk with respect to the products currently developed and marketed by ESP Pharma, including Cardene IV and IV Busulfex.

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. If we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including:

- delays;
- warning letters;
- fines;
- clinical holds;
- product recalls or seizures;
- changes to advertising;
- injunctions;
- refusal of the FDA to review pending market approval applications or supplements to approval applications;
- total or partial suspension of product manufacturing, distribution, marketing and sales;
- civil penalties;
- withdrawals of previously approved marketing applications; and

- criminal prosecutions.

If our products do not gain market acceptance among the medical community, our revenues would be adversely affected and might not be sufficient to support our operations.

Our product candidates may not gain market acceptance among physicians, patients, third-party payors and the medical community. We may not achieve market acceptance even if clinical trials demonstrate safety and efficacy, and the necessary regulatory and reimbursement approvals are obtained. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of our product candidates;
- their potential advantage over alternative treatment methods;
- reimbursement policies of government and third-party payors; and
- marketing and distribution support for our product candidates, including the efforts of our collaborators where they have marketing and distribution responsibilities.

Physicians will not recommend therapies using our products until such time as clinical data or other factors demonstrate the safety and efficacy of such procedures as compared to conventional drug and other treatments. Even if we establish the clinical safety and efficacy of therapies using our antibody product candidates, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our antibody products is effective for certain indications. Antibody products, including our product candidates as they would be used for certain disease indications, are typically administered by infusion or injection, which requires substantial cost and inconvenience to patients. Our product candidates, if successfully developed, will compete with a number of drugs and therapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payers and the medical community may not accept or utilize any product candidates that we or our customers develop. The failure of our products to achieve significant market acceptance would materially harm our business, financial condition and results of operations.

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. The FDA and other health care policies may change, and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. 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. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

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

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. For example, during the period from January 1, 2004 to February 28, 2005, our common stock closed as high as $27.14 per share and as low as $14.98 per share. 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:

- our financial results;
- developments or disputes as to patent or other proprietary rights;
- disappointing sales of approved products;
- approval or introduction of competing products and technologies;
- withdrawal from the market of an approved product from which we receive royalties;
- results of clinical trials;
- failures or unexpected delays in obtaining regulatory approvals or unfavorable FDA advisory panel recommendations;
- changes in reimbursement policies;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- disputes or disagreements with collaborative partners;
- developments in our relationships with customers;
- market reaction to announcements by other biotechnology or pharmaceutical companies, including market reaction to various announcements regarding products licensed under our technology;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- initiation, termination or modification of agreements with our collaborative partners;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

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

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

Future changes in financial accounting standards, including proposed changes in accounting for stock options, may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq 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.

If we are unable to favorably assess the effectiveness of internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment, our stock price could be adversely affected.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and beginning with this annual report on Form 10-K for the year ended December 31, 2004, our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal controls over financial reporting as of the end of 2004. The rules governing the standards that must be met for management to assess the effectiveness of our internal controls over financial reporting are new and complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal controls over financial reporting. This process has and may continue to result in increased expenses and the devotion of significant management resources. If we cannot continue to favorably assess the effectiveness of our internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment in the future, investor confidence and our stock price could be adversely affected.

We may not have the ability to raise the funds to repurchase the 2003 2.75% 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 2003 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 2003 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 2003 Notes, we could seek the consent of the lender to purchase the 2003 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 2003 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.

We may not have sufficient cash to purchase the 2005 Notes, if required, upon a fundamental change.

Holders of the 2005 Notes may require us to purchase all or any portion of your 2005 Notes upon a fundamental change, which generally is defined as the occurrence of any of the following: (1) our common stock is not traded on a national securities exchange or listed on The Nasdaq Stock Market; (2) any person acquires more than 50% of the total voting power of all shares of our capital stock; (3) certain mergers, consolidations, sales or transfers involving us occur; or (4) our board of directors does not consist of continuing directors. In certain situations, holders of the 2005 Notes will not have a repurchase right even if a fundamental change has occurred. In addition, we may not have sufficient cash funds to repurchase the 2005 Notes upon such a fundamental change. Although there are currently no restrictions on our ability to pay the purchase price, future debt agreements may prohibit us from repaying the purchase price. If we are prohibited from repurchasing the 2005 Notes, we could seek consent from our lenders at the time to repurchase the 2005 Notes. If we are unable to obtain their consent, we could attempt to refinance their debt. If we were unable to obtain a consent or refinance the debt, we would be prohibited from repurchasing the 2005 Notes upon a fundamental change. If we were unable to purchase the 2005 Notes upon a fundamental change, it would result in an event of default under the indenture. An event of default under the indenture could result in a further event of default under our other then-existing debt. In addition, the occurrence of the fundamental change may be an event of default under our other debt, which could have a significant adverse affect on our financial condition.

If any or all of our outstanding 2005 Notes are converted into shares of our common stock, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

Our 2003 Notes and 2005 Notes are convertible, at the option of the holder, into shares of our common stock at varying conversion prices. We have reserved shares of our authorized common stock for issuance upon conversion of our 2003 Notes and the 2005 Notes. If any or all of our 2003 Notes or the 2005 Notes are converted into shares of our common stock, our existing stockholders will experience immediate dilution and our common stock price may be subject to downward pressure. If any or all of our 2003 Notes or 2005 Notes are not converted into shares of our common stock before their respective maturity dates, we will have to pay the holders of such notes the full aggregate principal amount of the notes then outstanding. Any such payment would have a material adverse effect on our cash position.

RISKS RELATED TO THE ACQUISITION OF ESP PHARMA

The following risks may arise as a result of the completion of or failure to complete our pending acquisition of ESP Pharma.

Failure to complete the merger with ESP Pharma or the Retavase acquisition could harm our business and operations.

Our acquisition of ESP Pharma is subject to various closing conditions, including regulatory approval, the effectiveness of a registration statement for the resale of PDL common shares issued in the transaction and other customary approvals. Similarly, ESP Pharma's agreement with Centocor to acquire Retavase is subject to certain closing conditions. If any of these conditions are not met, our acquisition of either ESP Pharma or Retavase or both might not occur. If either of these transactions is not completed, we could suffer a number of consequences that could adversely affect our business, including:

- the price of our common stock may decline to the extent that the current market price of our common stock reflects a market assumption that these transactions will be completed;
- the diversion of management's attention from day-to-day business and the disruption to our employees as a result of efforts and uncertainties relating to these transactions may detract from our ability to grow our business; and
- costs related to these transactions must be paid even if these transactions are not completed.

PDL and ESP Pharma may not successfully integrate their businesses and may not realize the anticipated benefits of the merger.

If the acquisition of ESP Pharma is completed, achieving the benefits of the merger will depend in substantial part on the successful integration of the two companies' technologies, operations and personnel. Prior to the merger, PDL and ESP Pharma have operated independently, each with its own operations, corporate culture, locations, employees and systems. PDL and ESP Pharma now have to operate as a combined organization and begin utilizing common business, information and communication systems, operating procedures, financial controls and human resource practices, including benefits, training and professional development programs. PDL and ESP Pharma will face significant challenges in integrating their organizations and operations in a timely and efficient manner. Some of the challenges and difficulties involved in this integration include:

- demonstrating to the customers of PDL and ESP Pharma that the merger will not result in adverse changes in client service standards or business focus and helping customers conduct business successfully with the combined company;
- coordinating sales and marketing efforts to effectively communicate the capabilities of the combined company;
- coordinating and rationalizing commercialization and development activities to enhance introduction of new products and technologies;
- preserving important relationships of both PDL and ESP Pharma and resolving potential conflicts that may arise;
- management distraction from the business of the combined company;
- incompatibility of corporate cultures;
- costs and delays in implementing common systems and procedures;
- consolidating and rationalizing corporate, IT and administrative infrastructures;
- integrating and documenting processes and controls in conformance with the requirements of the Sarbanes-Oxley Act of 2002; and
- operating the combined company at multiple sites in the U.S.

Any one or all of these factors, many of which are outside of our control, may increase operating costs or lower anticipated financial performance. In addition, the combined company may lose distributors, suppliers, manufacturers and employees. Achieving anticipated synergies and the potential benefits underlying the two companies' reasons for the merger will depend on successful integration of the two companies.

In addition, the integration of PDL and ESP Pharma will be a complex, time consuming and expensive process and will require significant attention from management and other personnel, which may distract their attention from the day-to-day business of the combined company. The diversion of management's attention and any difficulties associated with integrating ESP Pharma into PDL could have a material adverse effect on the operating results of the combined company after the merger and the value of PDL shares, and could result in the combined company not achieving the anticipated benefits of the merger. It is not certain that PDL and ESP Pharma can be successfully integrated in a timely manner or at all or that any of the anticipated benefits will be realized. Failure to do so could have a material adverse effect on the business and operating results of the combined company.

The issuance of shares of PDL common stock in the merger will substantially reduce the percentage interests of holders of PDL common stock and securities convertible into PDL common stock, and the registered sale of these shares could decrease the market value of our common stock.

Upon completion of the merger, the shares of ESP Pharma preferred stock, common stock and options therefor will be converted into the right to receive up to $325 million in cash and up to approximately 9,855,000 shares of PDL common stock. Based on this estimated number of PDL shares to be issued in the acquisition of ESP Pharma, former ESP Pharma stockholders will own approximately 9% of the combined company's outstanding common stock following the completion of the merger. We have granted registration rights covering the PDL shares to be issued in the acquisition of ESP Pharma, which could result in the registered sale of a substantial number of shares of our common stock and which could lead to a decrease in the market price of our common stock. The issuance of these shares in connection with the merger will cause a significant reduction in the relative percentage interests in earnings, voting power, liquidation value and book and market value of all holders of common stock and securities convertible into common stock, including without limitation the 2003 Notes, the 2005 Notes and the PDL common stock issuable thereunder.

The market price of PDL common stock has historically been highly volatile and may continue to be so in the future. In addition to conditions that affect the market for stocks of biotechnology companies generally, factors such as new product announcements by PDL or its competitors, quarterly fluctuations in PDL's operating results and challenges associated with the integration of ESP Pharma's business may have a significant impact on the market price of PDL shares. These conditions could cause the price of PDL shares to fluctuate substantially over short periods.

Delays or problems with our integration of sales, marketing and distribution capabilities with the acquisition of ESP Pharma may hamper continued growth projections for products acquired in the merger.

We intend to continue to market and sell aggressively the products acquired as part of the ESP Pharma merger, including in particular Cardene IV, Retavase and IV Busulfex. In order to successfully achieve the planned results from the merger, we will need to transition existing relationships with distributors, third party vendors, manufacturers and customers of ESP Pharma. Although we plan to retain most of the hospital-focused sales force and related sales infrastructure, we have never sold, marketed or distributed products, and we may not be able to successfully integrate such capabilities from ESP Pharma necessary to continue to successfully promote the ESP products.

To be successful, the combined company must retain and motivate key employees, which will be more difficult in light of uncertainty regarding the merger, and failure to do so could seriously harm the combined company.

To be successful, the combined company must retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing and information technology support positions. Employees of PDL or ESP Pharma may experience uncertainty about their future role with the combined company until or after strategies with regard to the combined company are announced or executed. This potential uncertainty may adversely affect the combined company's ability to attract and retain key personnel. The combined company must also continue to motivate employees and keep them focused on the strategies and goals of the combined company, which may be particularly difficult due to the potential distractions of the merger or the loss of key employees due to such uncertainties.

If customers delay or defer purchasing decisions as a result of the merger, the operating results and prospects of the combined company could be adversely affected.

We cannot assure you that our customers will continue their current buying patterns; our customers may delay or defer purchasing decisions in response to the announcement of the proposed merger. Any such delay or deferral in purchasing decisions by such customers could have a material adverse effect on the business or operating results of PDL or ESP Pharma, regardless of whether the merger is ultimately completed.

As a result of the merger, the combined company will be a larger and more geographically diverse organization, and if the combined company's management is unable to manage the combined organization efficiently, its operating results will suffer.

Following the merger, the combined company will have approximately 800 full-time employees. As a result, the combined company will face challenges inherent in efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. The inability to manage successfully the geographically more diverse and substantially larger combined organization could have a material adverse effect on the operating results of the combined company after the merger and, as a result, on the market price of PDL's common stock.

Charges to earnings resulting from the merger may adversely affect the market value of PDL's common stock following the merger.

In accordance with U.S. generally accepted accounting principles, the combined company will account for the merger using the purchase method of accounting, which will result in charges to earnings that could have a material adverse effect on the market value of PDL's common stock following completion of the merger. Under the purchase method of accounting, the combined company will allocate the total estimated purchase price to ESP Pharma's

net tangible assets, amortizable intangible assets and in-process research and development based on their fair values as of the date of completion of the merger, and record the excess of the purchase price over those fair values as goodwill. The portion of the estimated purchase price allocated to in-process research and development will be expensed by the combined company in the quarter in which the merger is completed. The combined company will incur additional depreciation and amortization expense over the useful lives of certain of the net tangible and intangible assets acquired in connection with the merger. In addition, to the extent the value of goodwill becomes impaired, the combined company may be required to incur material charges relating to the impairment of goodwill. These depreciation, amortization, in-process research and development and potential impairment charges could have a material impact on the combined company's results of operations.

PDL expects to incur significant costs associated with the merger which could adversely affect future liquidity and operating results.

PDL estimates that it will incur transaction costs of approximately $5.3 million associated with the merger, which will be included as a part of the total purchase costs for accounting purposes. These amounts are estimates and could increase. In addition, we believe that the combined entity may incur charges to operations, in amounts that are not currently reasonably estimable, in the quarter in which the merger is completed or in subsequent quarters, to reflect costs associated with integrating the two companies. The combined company may incur additional material charges in subsequent quarters to reflect additional costs associated with the merger. These significant costs associated with the merger could adversely affect the future liquidity and operating results of the combined company.

RISKS RELATED TO THE BUSINESS OF ESP PHARMA

The following risks assume that we complete our pending acquisition of ESP Pharma and that ESP Pharma completes its acquisition of certain rights to Retavase®.

If Cardene IV sales do not continue to grow, our results of operations will suffer.

Cardene IV accounts for a significant portion of the operating income and growth in sales for ESP Pharma. Cardene IV faces a competitive marketplace with branded and generic intravenous anti-hypertensive products being marketed in the United States and it may be harder to continue to penetrate this market at the current rate of growth. While we expect to maintain and increase committed sales and marketing presence in order to ensure the continued growth of Cardene IV, there can be no assurance that we can continue the rapid growth rate that ESP Pharma has achieved. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for Cardene IV to continue its success, we will have to maintain and expand its position in the marketplace against these competitors' drugs.

Retavase is marketed in a declining market and if our planned sales and promotional efforts do not increase or at least maintain market acceptance, our results of operations will suffer.

Retavase is expected to account for a significant portion of our operating income and growth in cash flow from operations. Retavase is sold into the thrombolytic market that has recently been declining due to the more widespread use of stents and the introduction of gpIIb/IIIa inhibitor products. Moreover, Retavase competes for use in the management of acute myocardial infarction with TNKase™ and Activase from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we currently have available. While we believe our planned investment in additional sales and promotional efforts may increase the market acceptance of Retavase, there can be no assurance that we can increase the market share of Retavase, or that even if we are able to increase our market share, that the anti-thrombolytic market will not decline significantly regardless of our efforts. In addition, the product currently is marketed on behalf of Centocor by Scios, Inc. (Scios), a Johnson & Johnson company. We will require the cooperation of Centocor and Scios to successfully transfer the product to us and there can be no assurance that our sales and marketing efforts will be implemented in a timely manner or that we will be successful in achieving our projected sales levels.

We will be required to undertake the complex manufacturing of Retavase through use of a number of third parties, and the transition may result in delays in obtaining regulatory approval or marketing for Retavase.

As part of the acquisition of Retavase, we will be required to manufacture this product for sale and distribution no later than 2011. Retavase is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth Biotechnology and Roche. While ESP Pharma's agreement to purchase the rights to Retavase includes the acquisition of approximately 24 months of inventory, the manufacturing of this product for use as therapeutics in compliance with regulatory requirements will be complex, time-consuming and expensive. The eventual transfer of manufacturing could result in delays in regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

ESP Pharma relies on third party suppliers to provide for each of the products for sale. If we are unable to continue those manufacturing arrangements successfully or at a reasonable cost, our potential future results could suffer.

We have not manufactured any of the ESP Pharma products and are not familiar with the manufacturing process for these products. ESP Pharma has existing long-term agreements with various third parties to supply its products. If there are supply problems with the third party manufacturers for the ESP Pharma products, in particular Cardene IV, there may not be sufficient supplies of Cardene IV to meet commercial demand, in which case our future results could suffer.

In addition, reliance on a third-party manufacturer entails risks, including reliance on the third party for regulatory compliance and adhering to the FDA's current Good Manufacturing Practices, or cGMP requirements, the possible breach of the manufacturing agreement by the third party, and the possibility of termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient to us. Failure of the third party manufacturers or us to comply with applicable regulations, including FDA pre-or post-approval inspections and cGMP requirements, could result in sanctions being imposed on us. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operational restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Our profitability will depend in significant part upon ESP Pharma's continued successful operations.

ESP Pharma was founded in April 2002. While ESP Pharma was profitable in 2003 and 2004, it has a short operating history and there can be no assurance that it will continue to achieve profitable results as part of the combined companies. PDL has incurred losses since inception and expects to continue to incur losses until, at the earliest, 2008, the currently anticipated date in which PDL could complete its first full year of sales of its antibody products. In order for the combined companies to achieve a cash flow positive rate by 2007, ESP Pharma's products must continue to grow in accordance with the internal projections of the companies.

ESP Pharma revenues are substantially dependent on a limited number of wholesalers and distribution partners, and such revenues may fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners.

ESP Pharma sells its products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the year ended December 31, 2004, revenues from the sales of ESP Pharma products to its three largest U.S. wholesalers totaled approximately 87% of its net revenues. ESP Pharma's reliance on a small number of wholesalers and distribution partners could cause its revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners. In addition, as of December 31, 2004, these three U.S. wholesalers represented approximately 91% of ESP Pharma's outstanding accounts receivable. If any of these wholesalers or international partners fails to pay ESP Pharma on a timely basis or at all, ESP Pharma's financial position and results of operations could be materially adversely affected.

Failure to achieve revenue targets or raise additional funds in the future may require the combined company to delay, reduce the scope of or eliminate one or more of its planned activities.

The acquisition of ESP Pharma and certain rights to Retavase will require cash payments of approximately $435 million. While we believe we have sufficient funds for our anticipated operations, we will need to generate significantly greater revenues to achieve and then maintain profitability on an annual basis. The product development, including clinical trials, manufacturing and regulatory approvals of PDL's and ESP Pharma's product candidates currently in development, and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future funding requirements, which may be significantly greater than we expect, depend upon many factors, including:

- the extent to which Cardene IV is commercially successful;
- the extent to which Retavase sales can be maintained or increased from recent historical levels;
- the progress, level and timing of our research and development activities related to our clinical trials, in particular with respect to daclizumab, Nuvion and M200;
- the cost and outcomes of regulatory submissions and reviews;
- the continuation or termination of third party manufacturing or sales and marketing arrangements;
- the cost and effectiveness of our sales and marketing programs;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights;
- our ability to extend the patent protection of our currently marketed products; and
- the establishment of additional strategic or licensing arrangements with other companies, or acquisitions.

ESP Pharma faces substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

Our industry is highly competitive. Our success will depend on our ability to acquire and develop products and apply technology, and our ability to establish and maintain markets for PDL's and ESP Pharma's products. Potential competitors of PDL and ESP Pharma in the U.S. and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. For example, we are aware that The Medicines Company has a product currently in Phase III development, CleveloxÔ, which is an intravenous, short-acting calcium channel antagonist being developed in late-stage clinical trials for the short-term control of high blood pressure in the hospital setting. While we believe that Cardene IV has advantages over Clevelox, there can be no assurance that the ongoing or future clinical studies will not show superior benefits than those obtained with Cardene IV, or that The Medicines Company's sales and marketing efforts will not negatively impact Cardene IV.

In addition, ESP Pharma product sales face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of its products. ESP Pharma has several marketed products that are generic versions of brand-name products. Additionally, ESP Pharma has brand-name products that are subject to competition from generic products. ESP Pharma faces competition in its marketed products from brand-name pharmaceutical companies and from companies focused on generic pharmaceutical markets. In addition, competitors may succeed in developing products and technologies that are more effective or less costly than the ESP Pharma products, or that would render the ESP Pharma products obsolete or noncompetitive.

ESP Pharma's ability to generate future revenue from products will be affected by reimbursement and drug pricing.

Acceptable levels of reimbursement of drug treatments by government authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, ESP Pharma product candidates. We cannot be sure that reimbursement in the U.S. or elsewhere will be available for any products that we may develop or, if already available, will not be decreased in the future. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize ESP Pharma's products, and may not be able to obtain a satisfactory financial return on ESP Pharma's products.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the U.S. and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including products that ESP Pharma sells. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that are successfully developed by PDL or ESP Pharma and

approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on the ESP Pharma business.

A significant portion of ESP Pharma product sales result from off-patent products. If we are unable to maintain the cash flow returns from these products, our ability to achieve a cash flow positive position would be impacted.

For the year ended December 31, 2004, approximately 34% of the ESP Pharma net product sales resulted from the sale of the off-patent products Tenex, Sectral, Ismo and Declomycin. These products have accounted for a majority of the cash flow from operations of ESP Pharma. If sales of Cardene IV do not perform as planned and we are unable to maintain the cash flow returns from these off-patent products, our ability to achieve positive cash flow from operations by 2007 could be delayed.

We will spend considerable time and money complying with federal and state regulations and, if we are unable to fully comply with such regulations, we could face substantial penalties.

We may be subject, directly or through our customers, to extensive regulation by both the federal government, and the states and foreign countries in which we conduct our business. Laws that may directly or indirectly affect our ability to operate our business include, but are not limited, to the following:

- the federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- state law equivalents to the Anti-Kickback Law and False Claims Act, which may not be limited to government reimbursed items.

If our operations are found to be in violation of any of the laws described above or the other governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if the hospitals, physicians or other providers or entities with whom we do business are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management’s attention from the operation of our business and damage our reputation.

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, 2007 and December 31, 2006.

- In Plymouth, Minnesota, we lease approximately 75,000 square feet of manufacturing, laboratory and office space. Our lease terms will expire on February 28, 2009, subject to our option to extend the leases for an additional five-year term. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and have built a new commercial manufacturing plant on this property that is currently being validated. In January 2005, we entered into an agreement to purchase approximately 6 acres adjacent to our existing Brooklyn Park facility to permit further expansion of our existing site if we deem this necessary in the future.

- In Somerville, New Jersey, we lease approximately 6,000 square feet of general office space. Our lease term will expire on October 31, 2005. We no longer occupy this facility and currently sublease a portion of the space.

- In Paris, France, we lease approximately 600 square feet of general office space. Our lease term will expire on August 12, 2013.

- 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 no longer occupy this facility.

- 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 9 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.

At an oral hearing in February 2005, the Opposition Division of the European Patent Office decided to revoke the claims in our second European antibody humanization patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We plan to appeal the decision to the Technical Board of Appeal at the European Patent Office. The appeal will suspend the legal effect of the decision of the Opposition Division during the appeal process, which is likely to take several years.

We intend to vigorously defend the European patents 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 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.

In regard to our Japanese humanization patent, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court decision upholding revocation of the patent by the Japanese Patent Office. The Japanese Supreme Court decision concludes the proceedings in the matter and the Japanese Patent Office decision to revoke our patent is final.

In October 2004, the Japanese Patent Office issued a patent to our first divisional humanization patent application. This patent claims a method of producing a humanized antibody specifically reactive with the human IL-2 receptor and the composition of matter directed to Zenapax (daclizumab). We have two additional divisional patent applications pending before the Japanese Patent Office with respect to our humanization technology.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

	High	Low
2003		
First Quarter	$ 9.90	$ 6.98
Second Quarter	18.91	7.49
Third Quarter	15.77	10.81
Fourth Quarter	18.10	12.53
2004		
First Quarter	**$ 25.08**	**$ 17.37**
Second Quarter	**27.23**	**16.47**
Third Quarter	**20.51**	**15.02**
Fourth Quarter	**20.76**	**17.49**

Our common stock trades on the Nasdaq National Market under the symbol "PDLI." Prices indicated above are the high and low closing bid prices as reported by the Nasdaq National Market System for the periods indicated. We have never paid any cash dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future.

As of December 31, 2004, we had approximately 217 common stockholders of record. Because many of these shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders but we believe that there are in excess of 300 holders.

ITEM 6. SELECTED FINANCIAL DATA

CONSOLIDATED STATEMENTS OF OPERATIONS DATA:

	Years Ended December 31,				
(In thousands, except per share data)	**2004**	**2003**	**2002**	**2001**	**2000**
Revenues:					
Royalties	**$ 83,807**	**$ 52,704**	$ 40,421	$ 30,604	$ 19,189
License and other	**12,217**	**13,982**	5,952	13,796	21,220
Total revenues	**96,024**	**66,686**	46,373	44,400	40,409

Costs and expenses:					
Research and development	**122,563**	**82,732**	57,978	52,163	42,330
General and administrative	**31,806**	**27,613**	18,373	15,004	11,481
Acquired in-process research and development(1)	—	**85,993**	—	—	—
Total costs and expenses	**154,369**	**196,338**	76,351	67,167	53,811
Operating loss	**(58,345)**	**(129,652)**	(29,978)	(22,767)	(13,402)
Interest and other income, net(2)	**10,212**	**9,831**	25,978	35,135	22,647
Interest expense	**(5,028)**	**(9,770)**	(9,146)	(9,709)	(8,593)
Impairment loss on investment(3)	—	**(150)**	(1,366)	—	—
Income (loss) before income taxes	**(53,161)**	**(129,741)**	(14,512)	2,659	652
Provision for income taxes	**80**	**73**	42	12	5
Net income (loss)	**$ (53,241)**	**$ (129,814)**	$ (14,554)	$ 2,647	$ 647
Basic and diluted net income (loss) per share:	**$ (0.56)**	**$ (1.40)**	$ (0.16)	$ 0.03	$ 0.01
Shares used in computation of net income (loss) per share:					
Basic	**94,982**	**92,478**	88,865	87,624	80,904
Diluted	**94,982**	**92,478**	88,865	92,889	88,562

CONSOLIDATED BALANCE SHEET DATA:

	December 31,				
	2004	**2003**	**2002**	**2001**	**2000**
Cash, cash equivalents, marketable securities and restricted investments	**$ 397,080**	$ 504,993	$ 606,410	$ 650,315	$ 661,173
Working capital	**356,660**	467,248	599,215	641,896	651,641
Total assets	**713,732**	742,030	717,818	729,898	704,980
Long-term obligations, less current portion	**257,768**	258,627	158,426	158,892	159,324
Accumulated deficit	**(273,532)**	(220,291)	(90,477)	(75,923)	(78,570)
Total stockholders' equity	**412,510**	448,331	544,766	558,443	534,144

Certain reclassifications of previously reported amounts have been made to conform to the presentation in the Consolidated Statement of Operations and Consolidated Balance Sheets for the year ended December 31, 2003 and 2004.

(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 Note 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 15 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 7 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, including our pending acquisition of ESP Pharma and ESP Pharma's pending acquisition of certain rights to the Retavase product, 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. During the year ended December 31, 2004, we received royalties on seven marketed products, with approximately 84% of our royalty revenues derived from the Herceptin and Avastin antibody products marketed by Genentech and the Synagis antibody product marketed by MedImmune.

In September 2004, we entered into a Co-Development and Commercialization Agreement (the Collaboration Agreement) with Hoffmann-La Roche (Roche) for the joint development and commercialization of daclizumab (in transplantation, marketed as *Zenapax*®) for the treatment of asthma and other respiratory diseases. Under the terms of the Collaboration Agreement, we and Roche will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the United States. Outside the United States, we will receive royalties on net sales by Roche or its licensees of the product in asthma.

Under the terms of the Collaboration Agreement, we received a $17.5 million upfront payment from Roche in the third quarter of 2004, and we may receive up to $187.5 million in development and commercialization milestones in the future for successful further development of daclizumab. In addition, we receive partial reimbursement from Roche related to ongoing research and development efforts under the Collaboration Agreement. We determined that all of the elements under the Collaboration Agreement should be accounted for as a single unit of accounting under EITF 00-21. As such, and as we have continuing obligations under the Collaboration Agreement, we recorded the $17.5 million as deferred revenue and will recognize this amount over the approximately six years that research and development expenses are expected to be performed for Roche. During 2004, we recognized approximately $3.7 million in License and Other revenue related to the amortization of the upfront license fee and the reimbursement of certain research and development expenses.

In January 2005, we entered into a definitive agreement with ESP Pharma Holding Company, Inc. (ESP), a privately held, hospital-focused pharmaceutical company, under which PDL will acquire ESP for $300 million in cash and approximately $175 million in PDL common stock, or an aggregate value of approximately $475 million. In February 2005, this agreement was amended to reflect ESP's agreement to acquire from Centocor, Inc. (Centocor), a biopharmaceutical operating company of Johnson & Johnson, rights to manufacture, develop, market and distribute Retavase® (reteplase) in the United States and Canada, including an increase in the purchase price by $25 million in cash payable to the ESP stockholders at the closing of the ESP acquisition. The acquisition price to be paid to Centocor for the rights to Retavase is $110 million. Milestone payments of up to $45 million may be made if additional conditions relating to ongoing clinical trials and manufacturing arrangements are satisfied. In February 2005, we entered into a loan commitment agreement with ESP to ensure that the $110 million purchase price payable to Centocor would be available to complete the purchase of Retavase by ESP. No amount has been drawn under this commitment as of March 11, 2005.

The aggregate preliminary purchase price is expected to be approximately $503.0 million, including the cash to be paid to ESP stockholders of $325.0 million, the fair market value of PDL's common stock to be issued to ESP stockholders totaling approximately $172.5 million, and estimated direct transaction costs of approximately $5.3 million. In the event that there is a significant change in our stock price from the announcement of the acquisition to the closing date, we may be required to issue up to an additional 9.8 million shares of our common stock to ESP, which could increase the purchase price by an amount up to $19.2 million. We expect this transaction to close during late during the first quarter or early during the second quarter of 2005. We currently estimate between 80% and 85% of the aggregate purchase price will be allocated to capitalizable intangible assets and goodwill, with a smaller portion, or approximately 10%-15%, allocated to acquired in-process research and development expense.

By adding marketed products and sales and distribution capabilities to our antibody development and humanization technology platform, the ESP acquisition is intended to establish PDL as a fully integrated, commercial biopharmaceutical company with novel marketed products, a growing and diverse revenue base and a broad, proprietary pipeline. The transaction is expected to close late in the first or early in the second quarter of 2005. Assuming the closing of the acquisition by this anticipated date, we believe that we will achieve positive cash flow from operations on a quarterly basis beginning in the second half of 2006 based upon revenues consisting of royalties, license and other income and product sales.

In order to help fund the acquisition of ESP, in February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million (the 2005 Notes). The 2005 Notes are convertible into our common stock at a conversion price of $23.69 per share, subject to adjustment in certain events. Interest on the 2005 Notes is payable semiannually in arrears on February 15 and August 15 of each year. The 2005 Notes are unsecured and subordinated to all our existing and future indebtedness and may be redeemed at our option, in whole or in part, beginning on February 19, 2010 at par value.

Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of December 31, 2004, we had an accumulated deficit of approximately $273.5 million. Our expenses will continue to increase over the next several years because of the extensive resource commitments required to identify and develop antibody candidates to achieve regulatory approval and to market potential products for commercial success for any individual product. Also, 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 and manufacturing capabilities.

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 January 2005, we entered into an agreement to acquire ESP for an estimated purchase price of approximately $503 million. In the event that there is a significant change in our stock price from the announcement of the acquisition to the closing date, we may be required to issue additional shares to ESP, which could increase the purchase price by an amount up to $19.2 million. If the pending transaction closes, the integration of the two companies' product rights, technologies, operations and personnel will be a complex, time consuming and expensive process and will require significant attention from management and other personnel, which may distract their attention from the day-to-day business of the combined company. The diversion of management's attention and any difficulties associated with integrating ESP into our organization could have a material adverse effect on the operating results of the combined company after the merger and could result in the combined company not achieving the anticipated benefits of the merger.

In order to reach our goal to be cash flow positive on a quarterly basis beginning in 2006, we will have to continue to increase sales levels for the key ESP products from historical levels, in particular Cardene IV, Retavase and IV Busulfex. Accordingly, we will need to effectively transition existing relationships with distributors, third party vendors, manufacturers and customers of ESP. Although we plan to retain the hospital-focused sales force and related sales infrastructure, we have never sold, marketed or distributed products, and we may not be able to successfully integrate such capabilities from ESP necessary to continue to successfully promote the ESP products. In addition, the markets for Cardene IV and Retavase are highly competitive, and we will be marketing against pharmaceutical, biopharmaceutical and specialty pharmaceutical companies with substantially greater revenues and experience in marketing products than we have.

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 our proprietary products or maintain desired margins for products sold, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach a sustainable cash flow positive position and profitability are highly uncertain.

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

In addition, as of February 28, 2005 we have approximately $500 million in convertible debt outstanding, approximately $250 million of which are callable in each of 2008 and 2010. In order to be able to service our debt in the future, we will need to generate positive cash flows from our operations.

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 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, collaboration and humanization agreements that may contain multiple elements, such as upfront license fees, reimbursement of research and development expenses, milestones related to the achievement of particular stages in product development and royalties. 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 licensee 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. For example, as we did not establish fair value for all undelivered elements of the Roche Collaboration Agreement, including milestones and the reimbursement of research and development expenses, we are recognizing the $17.5 million upfront license fee that we received from Roche over the term of the Collaboration Agreement as services are provided.

In addition, we enter into nonmonetary transactions in connection with our patent licensing arrangements, and management must use estimates and judgments when considering the fair value of the technology rights acquired and the patent licenses granted under these arrangements. When available, the fair value of the nonmonetary transaction is based on vendor-specific objective evidence of fair value of each significant element of the patent license agreement. Otherwise, management uses other methods of estimating fair value, such as current pricing information within the Company. Therefore, the fair value of the technology right(s) acquired from the licensee is typically based on the fair value of the patent license and other consideration we exchange with the licensee.

Under our humanization agreements, the licensee typically pays an upfront fee for us to “humanize” an antibody. These upfront fees are recognized 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 on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, 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 value ascribed to each asset 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, 2004, 2003 and 2002

	Years Ended December 31,			Annual Percent Change	
(In thousands)	2004	2003	2002	2004 / 2003	2003 / 2002
Revenues					
Royalties	**$ 83,807**	$ 52,704	$ 40,421	**59%**	30%
License and other	**12,217**	13,982	5,952	**(13)%**	135%
Total Revenues	**$ 96,024**	$ 66,686	$ 46,373	**44%**	44%

Our total revenues increased in 2004 from 2003 due to higher royalties and license fees when compared to 2003. Total revenues increased in 2003 from 2002 due to higher royalties and license fees when compared to 2002. These revenue changes are further discussed below.

Royalties

Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth have been steadily increasing in 2004 and 2003. In 2004, the increase was primarily due to increased Herceptin sales reported by Genentech, higher Synagis sales reported by MedImmune, and the commercialization of Genentech's Avastin antibody product during the first quarter of 2004, for which we received royalty payments beginning in the second quarter of 2004. Royalty payments from MedImmune and Genentech accounted for 34% and 57%, respectively, of our royalty revenues during 2004. 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.

We expect that in 2005, based on the continued growth in product sales underlying our royalty revenues, we will continue to experience royalty revenue growth. We note that in February 2005, Biogen Idec, Inc. and Elan Corp. announced that they had voluntarily suspended supplying, marketing and selling Tysabri, which was approved to treat multiple sclerosis and which is licensed under our humanization patents. Financial analyst and investor expectations previously included potential royalties from the sale of Tysabri. There can be no assurance that Tysabri will be returned to the market, the timing of such return, if ever, or that even if subsequently marketed and sold, the product will result in our receiving any significant royalties from the sales of Tysabri. We also continue to expect quarterly fluctuations in royalty revenues due primarily to the seasonality of sales of Synagis.

License and Other Revenues

	Years Ended December 31,		
(in thousands)	2004	2003	2002
License and Other Revenues			
Patent rights and licensing	**$ 5,126**	$ 8,450	$ 3,650
Humanization and other	**7,091**	5,532	2,302
Total License and Other Revenues	**$ 12,217**	$ 13,982	$ 5,952

The decrease in license and other revenues in 2004 was primarily due to the timing of milestone achievement from our licensees and entering into fewer patent licensing agreements in 2004 as compared with 2003, partially offset by collaboration revenues of approximately $3.7 million from Roche pursuant to the Collaboration Agreement signed in the third quarter of 2004. In 2004, we entered into three patent licensing agreements, compared to six patent licensing agreements in 2003. In addition, in 2004, we recognized $0.5 million in milestone revenues, compared to $2.5 million in 2003.

The increase in license and other revenues in 2003 was primarily due to entering 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.

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. We also expect our license and other revenues to increase in 2005 due to a full year of revenue under our Roche Collaboration Agreement.

Costs and Expenses

	Years Ended December 31			Annual Percent Change	
(In thousands)	2004	2003	2002	2004 / 2003	2003 / 2002
Costs and Expenses					
Research and development	**$ 122,563**	$ 82,732	$ 57,978	**48%**	43%
General and administrative	**31,806**	27,613	18,373	**15%**	50%
Acquired in-process research and development	—	85,993	—	—	—

Total costs and expenses	**$ 154,369**	$ 196,338	$ 76,351	**(21)%**	157%

Research and Development Expenses

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 2004 was primarily due to an increase in personnel costs of approximately $16.1 million related to the hiring of additional employees to pursue our expanding research and development programs. Also contributing to the increase were contract manufacturing costs of $8.9 million, an increase in facility-related expenses of $7.5 million resulting from the expansion of our facilities in 2004, increased in-licensing of research and development technology of $3.9 million, increased outside services of $2.1 million related primarily to the validation, expansion and upgrade of our information systems infrastructure, and increased amortization of intangible assets of $1.4 million due to a full-year of amortization of assets acquired related to our acquisition of Eos Biotechnology and technology rights from Roche in 2003. These increases in costs were partially offset by lower direct clinical and preclinical studies' costs for our major research and development projects of approximately $2.0 million.

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 Biotechnology, Inc., 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.

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, including those to be obtained from the acquisition of ESP. 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, 2004	2003	2002
						(In thousands)	
Current Product Candidates							
Daclizumab	Asthma	Phase II	Roche	Completed	**$ 30,444**	$ 17,737	$ 7,778
HuZAF	Crohn's disease	Phase II	—	2005	**7,266**	22,888	14,047
Nuvion	Severe steroid-refractory ulcerative colitis	Phase I/II		2005	**21,407**	9,134	4,001
M200(1)	Solid tumors	Phase II	—	Unknown	**20,574**	3,528	—
Out-license Candidates(4)							
Anti-IL-4	Asthma	Phase IIa	GlaxoSmithKline	Completed(2)	**332**	1,123	2,791
Anti-IL-12	Autoimmune diseases	Phase I	—	Completed(3)	**—**	286	2,526
Remitogen			—		**233**	474	2,766
	Non-Hodgkin's B-Cell lymphoma	Phase II		Completed			
	Solid tumors	Phase I		Completed			
Zamyl	Acute myeloid leukemia	Phase III	—	Completed	**148**	327	3,981
Other(5)			—		**42,159**	27,235	20,088
	Total Research and Development Expenses				**$ 122,563**	$ 82,732	$ 57,978

(1) Product acquired from Eos in April 2003.

(2) Product was returned to GlaxoSmithKline.

(3) Target-related intellectual property outlicensed in December 2003.

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

(5) No single potential clinical 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 "If our research efforts are not successful, we may not be able to effectively develop new products," "Clinical development is inherently uncertain and expensive, and costs may fluctuate unexpectedly," "We are subject to extensive government regulation, which requires us to spend significant amounts of money, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize our products," "Our clinical trial strategy may increase the risk of clinical trial difficulties," "We may be unable to enroll sufficient patients in a timely manner in order to complete our clinical trials," "If our collaborations are not successful, we may not be able to effectively develop and market some of our products," "If we do

not attract and retain key employees, our business could be impaired," and "We may be unable to obtain or maintain regulatory approval for our products" sections of our Risk Factors.

Restructuring and Other Charges included in Research and Development Expenses

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials in June 2004, management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, in 2004 we incurred charges of approximately $305,000, including adjustments in the fourth quarter of 2004 related to the extension of a sublease of the facilities, included in research and development expenses in the Consolidated Statement of Operations. The restructuring charge included approximately $164,000 of severance-related amounts, $119,000 of committed cost for our New Jersey leased facility, primarily related to rent expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005, partially offset by expected proceeds from a short-term sublease entered into during October 2004. The workforce reductions were completed by June 30, 2004. We expect to pay the balance of the accrued facility-related costs of approximately $58,000 at December 31, 2004 through October 2005.

During 2004, we completed a physical inventory of substantially all of our laboratory equipment at our Fremont, California facilities. As a result, we recorded a charge to research and development expense in the Consolidated Statement of Operations of approximately $277,000, primarily in the second quarter of 2004 with minor adjustments in the fourth quarter of 2004, which represents the estimated amount of net book value of assets that are no longer in use.

General and Administrative Expenses

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 2004 was primarily related to increased personnel and recruiting costs of $1.4 million, increased facility-related costs of $1.0 million, costs related to compliance efforts surrounding Section 404 of the Sarbanes-Oxley Act of 2002 of approximately $0.9 million, and higher stock-based compensation expense associated with the continued vesting of certain stock options that had been granted to consultants and former employees of the Company of approximately $0.4 million. These increases were partially offset by lower legal costs related to our intellectual property, licensing and other contractual matters of $1.0 million.

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.

Assuming that the acquisition of ESP is completed, we would expect increases in our general and administrative expenses, in addition to sales and marketing expenses, related to the retention of ESP's sales force and supportive personnel.

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 and the status of these programs at December 31, 2004 follows:

Program	Description	Status of Development	Value Assigned (in thousands)
Anti-angiogenesis (M200, Anti-α5β1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including melanoma, pancreatic, non-small lung and renal cell cancers	Phase II clinical trials initiated in December 2004	$ 24,067
Ocular Neovascularization (F200, Anti-α5β1 Integrin Antibody)	Fab fragment of Anti-α5β1 Integrin Antibody for ocular indications, including age-related macular degeneration	No further development expected	$ 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

We recorded a charge to acquired in-process research and development totaling approximately $48.2 million in connection with the amendment to our collaboration agreement with Roche in October 2003, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell *Zenapax*® (daclizumab) in all disease indications other than transplantation. This amount relates to the rights to autoimmune indications for daclizumab that were then being developed and tested in clinical studies, specifically to treat asthma and ulcerative colitis. Significant changes to the acquired in-process research and development daclizumab projects since December 31, 2003 are as follows:

- In March 2004, we reported positive results from the initial clinical study of daclizumab in patients with chronic, persistent asthma whose disease is not well controlled with high doses of inhaled corticosteroids. We currently expect that the next trial of daclizumab to support development in asthma to be a single-dose, phase I study in healthy volunteers using PDL manufactured daclizumab administered subcutaneously. We expect this trial to begin enrollment in the first quarter of 2005. This single-dose trial is expected to be followed by a multiple-dose Phase I study. We anticipate that a subsequent Phase IIb clinical trial in moderate-to-severe persistent asthma could begin in the first quarter of 2006.

- In May 2004, we reported results from a Phase II clinical study of daclizumab in patients with moderate-to-severe ulcerative colitis. Daclizumab did not meet primary or secondary endpoints in the trial, and we do not intend to develop it further for this indication.

Assumptions Underlying In-Process Research and Development Charges

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	
(In thousands)	**2004**	**2003**	**2002**	**2004 / 2003**	**2003 / 2002**
Interest and Other Income, Interest Expense and Investment Impairment					
Interest and other income, net	**$ 10,212**	$ 9,831	$ 25,978	**4%**	(62)%
Interest expense	**(5,028)**	(9,770)	(9,146)	**(49)%**	7%
Impairment loss on investment	—	(150)	(1,366)	—	(89)%

In 2004, interest and other income, net included interest income of $9.7 million. In 2003, interest and other income, net consisted of interest income of $16.3 million, partially offset by early debt extinguishment charges of approximately $6.5 million. Interest income decreased by $6.6 million in 2004 when compared to 2003 primarily due to lower invested cash and marketable securities' balances, and to a lesser extent, declining interest rates on our marketable securities. Interest income decreased by $9.7 million in 2003 when compared to 2002 primarily due to declining interest rates on our marketable securities.

Interest expense in 2004, net of amounts capitalized, related to our 2.75% convertible notes issued in 2003, 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 2003, net of amounts capitalized, related to our 5.50% convertible subordinated notes that were redeemed in November 2003, our 2003 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 for 2004 decreased slightly compared 2003, due primarily to the redemption of our 5.50% convertible subordinated notes in November 2003 and increased capitalized interest during the year. Capitalized interest was $3.8 million and $2.2 million in 2004 and 2003, respectively, primarily in connection with the renovation of our existing manufacturing facilities and the development activities for our future manufacturing facilities.

Interest expense for 2003 increased slightly compared to the same period in 2002, due to increased interest expense resulting from the issuance of the 2003 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.

We expect that interest expense in 2005 will increase from the issuance of our 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250 million.

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. As of December 31, 2002, we estimated that the value of our investment in Signature had declined to $150,000 and that the impairment was other then 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 determined that our investment in Signature had become fully and permanently impaired. Accordingly, we recorded an impairment charge of $150,000 in March 2003 to write off the remaining book value of our investment.

Income Taxes

We have recorded a tax provision of approximately $80,000 for 2004 primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee, compared to $73,000 for 2003. We do not expect to record any tax provision for federal income taxes during 2005 based upon our projected U.S. tax loss for 2005.

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, 2004, we had cash and cash equivalents, marketable securities and restricted investments in the aggregate of $397.1 million, compared to $505.0 million at December 31, 2003.

Net cash used in our operating activities in 2004 was approximately $27.2 million compared with net cash used in operating activities of $23.6 million in 2003. In 2004, the change in cash used in operating activities as compared to the prior year related primarily to the funding of greater operating expenses partially offset by an increase in deferred revenue resulting from the Collaboration Agreement signed with Roche in September 2004. Net cash used in our operating activities in 2003 was approximately $23.6 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 and increases in other current assets and other assets resulting from the transaction costs associated with the issuance of our 2003 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.

In 2004, net cash used in our investing activities was $240.2 million, compared to cash used in investing activities in 2003 of $20.9 million. The change in 2004 was primarily the result of the timing of purchases of marketable securities, as well as the purchase of intangible assets with cash in 2003. The purchase of intangible assets in 2003 primarily 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. Purchases of property and equipment in 2004 and 2003 were primarily related to the development, construction and validation activities for our manufacturing facility in Brooklyn Park, Minnesota.

In 2003, net cash used in our investing activities was $20.9 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% $250 million convertible notes, as well as the purchase of intangible assets and increased purchases of property and equipment. Purchases of property and equipment in 2003 were primarily related to the development and construction activities for our manufacturing facility in Brooklyn Park, Minnesota. 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 financing activities in 2004 was $17.0 million compared to $98.5 million in 2003 and $3.8 million in 2002. Cash provided by financing activities in 2004 primarily related to the proceeds from the exercise of stock options. The increased levels in 2003 was primarily the result of proceeds totaling $250 million in 2003 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.

In February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million (2005 Notes). The 2005 Notes are convertible into our common stock at a conversion price of $23.69 per share, subject to adjustment in certain events. Interest on the Convertible Notes is payable semiannually in arrears on February 15 and August 15 of each year. The 2005 Notes are unsecured and subordinated to all our existing and future indebtedness and may be redeemed at our option, in whole or in part, beginning on February 19, 2010 at par value. We plan to use the proceeds from the 2005 Notes to help fund the acquisition of ESP Pharma (ESP) pursuant to an agreement signed in January 2005, as amended, as well as the purchase by ESP of the Retavase product (see Overview section above).

We estimate that our existing capital resources, including the cash proceeds from the 2005 Notes, will be sufficient to fund our current and future level of operations. 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; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; successful integration of acquired businesses, including the transition to PDL existing relationships with partners, distributors, third party vendors, manufacturers, and customers of acquired companies; 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 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 for the year ended December 31, 2003.

In July 2003, we issued 2.75% convertible subordinated notes due August 16, 2023 with a principal amount of $250.0 million (2003 Notes). The 2003 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 2003 Notes is payable semiannually in arrears on February 16 and August 16 of each year. The 2003 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 2003 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 2003 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 2003 Notes and the common stock issuable upon conversion of the notes.

We pledged a portfolio of U.S. government securities originally costing approximately $20.8 million as security for the 2003 Notes. These securities, and the earnings thereon, are sufficient to pay the first six scheduled interest payments due on the 2003 Notes. As of December 31, 2004, the portion of the $13.6 million balance related to payments to be made within one year, $6.9 million, is reflected on the Consolidated Balance Sheet within marketable securities, and the portion related to payments to be made thereafter, $6.7 million, is reflected on the balance sheet as long-term restricted investments.

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. During the funding period, which ended in June 2003, Exelixis performed certain genetic screens and other research activities intended to identify and validate targets for antibody therapeutics in oncology. We received an exclusive, worldwide license to develop antibodies against certain targets identified by Exelixis that are involved in cell growth, cell death and proliferation. Exelixis has the right to co-fund development of antibodies resulting from the collaboration. Therefore, we recognized the expense of research funding ratably over the periods for which it was performed. For antibody products we develop that Exelixis elects not to co-fund, we have agreed to make specified milestone payments and royalty payments on any product sales.

In 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 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, 2004, under these arrangements, the aggregate contractual costs totaled approximately $37.3 million, of which approximately $4.3 million is remaining to be paid in 2005. 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 in early 2005, 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 $42.1 million as of December 31, 2004, of which approximately $5.3 million and $1.7 million is remaining to be paid in 2005 and 2006, 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, 2004, the aggregate contractual costs totaled approximately $96.5 million, of which approximately $4.4 million remains to be paid in 2005. The facility construction is scheduled to be completed in early 2005.

In addition, as of December 31, 2004, we have made payments totaling $5.6 million to ICOS Corporation pursuant to a manufacturing agreement for the manufacture of supplies of clinical trial materials for one of our products. The aggregate amount of all committed future payments that we may make under that agreement is $1.8 million, payable in the first quarter of 2005.

Our contractual obligations under lease, debt, contract manufacturing, and construction agreements for the next five years and thereafter as of December 31, 2004 are as follows:

	Payments Due By Period				
(In thousands)	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
Contractual Obligations(1)					
Operating leases	$ 2,879	$ 3,980	$ 1,088	$ 330	$ 8,277
Long-term debt	1,583	2,382	2,278	5,505	11,748
Convertible notes	6,875	13,750	13,750	256,875	291,250
Contract manufacturing	1,800	—	—	—	1,800
Construction contracts	15,225	1,660	—	—	16,885
Total contractual cash obligations	$ 28,362	$ 21,772	$ 17,116	$ 262,710	$ 329,960

(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 December 2004, the FASB issued Statement No. 123 (revised 2004), “Share-Based Payment” (FAS 123R), which replaces FASB Statement No. 123, “Accounting for Stock-Based Compensation” (FAS 123) and supercedes APB Opinion No. 25, “Accounting for Stock Issued to Employees.” FAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under FAS 123, no longer will be an alternative to financial statement recognition. We are required to adopt FAS 123R on July 1, 2005. Under FAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive options,

prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are evaluating the requirements of FAS 123R and we expect that the adoption of FAS 123R will have a material impact on our consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting FAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under FAS 123.

Off-Balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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, 2004 levels, the fair value of the portfolio would decline by approximately $3.0 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, 2004, the aggregate fair values of our long-term debt and convertible subordinated notes were approximately $7.9 million and $319.3 million, respectively, based on available pricing information. 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 rates by year of expected maturity for our debt obligations. Our convertible notes may be converted to common stock prior to the maturity date.

Liabilties (000's)	2005	2006	2007	2008	2009	Thereafter	Total	Fair Value
Long-term debt, including current portion								
Fixed Rate	$ 544	$ 588	$ 635	$ 685	$ 741	$ 4,731	$ 7,924	$ 7,900*
Avg. Interest Rate	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	
Convertible subordinated notes								
Fixed Rate	$ —	$ —	$ —	$ —	$ —	$ 250,000	$ 250,000	$ 319,300*
Avg. Interest Rate	2.75%	2.75%	2.75%	2.75%	2.75%	2.75%	2.75%	

* 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

Consolidated Balance Sheets

(In thousands, except per share data)	December 31, 2004	2003
Assets		
Current assets:		
Cash and cash equivalents	**$ 91,395**	$ 341,768
Marketable securities, including $6.9 million and $7.4 million of restricted investments at December 31, 2004 and 2003, respectively	**298,969**	149,863
Prepaid and other current assets	**9,750**	10,689

Total current assets	**400,114**	502,320
Land, property and equipment, net	**238,077**	154,913
Intangible assets, net	**31,309**	32,311
Restricted investments	**6,716**	13,362
Other assets	**7,516**	9,124
Covertible note receivable	**30,000**	30,000
Total assets	**$ 713,732**	$ 742,030
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	**$ 4,921**	$ 3,644
Accrued compensation	**6,977**	5,940
Accrued clinical trial costs	**1,324**	1,759
Accrued interest	**2,593**	3,204
Other accrued liabilities	**9,327**	19,142
Deferred revenue	**17,389**	161
Current portion of notes payable	**379**	537
Capital lease obligations	**0**	183
Current portion of other long-term debt	**544**	502
Total current liabilities	**43,454**	35,072
Convertible subordinated notes	**249,998**	250,000
Notes payable	**89**	595
Other long-term debt	**7,380**	7,928
Other long-term liabilities	**301**	104
Total liabilities	**301,222**	293,699
Commitments and contingencies (Notes 2 and 16)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 10,000 shares authorized; no shares issued and outstanding	**—**	—
Common stock, par value $0.01 per share, 250,000 shares authorized; 95,857 and 93,886 issued and outstanding at December 31, 2004 and 2003, respectively	**959**	939
Additional paid-in capital	**686,302**	666,793
Accumulated deficit	**(273,532)**	(220,291)
Accumulated other comprehensive income (loss)	**(1,219)**	890
Total stockholders' equity	**412,510**	448,331
Total liabilities and stockholders' equity	**$ 713,732**	$ 742,030

See accompanying notes.

Consolidated Statements of Operations

(In thousands, except per share data)	Years ended December 31, 2004	2003	2002
Revenues:			
Royalties	**$ 83,807**	$ 52,704	$ 40,421
License and other	**12,217**	13,982	5,952
Total revenues	**96,024**	66,686	46,373
Costs and expenses:			
Research and development	**122,563**	82,732	57,978
General and administrative	**31,806**	27,613	18,373
Acquired in-process reasearch and development	**—**	85,993	—
Total costs and expenses	**154,369**	196,338	76,351
Operating loss	**(58,345)**	(129,652)	(29,978)
Interest and other income, net	**10,212**	9,831	25,978
Interest expense	**(5,028)**	(9,770)	(9,146)
Impairment loss on investment	**—**	(150)	(1,366)
Loss before income taxes	**(53,161)**	(129,741)	(14,512)
Provision for income taxes	**80**	73	42
Net loss	**$ (53,241)**	$ (129,814)	$ (14,554)
Basic and diluted net loss per share	**$ (0.56)**	$ (1.40)	$ (0.16)
Shares used in computation of basic and diluted net loss per share	**94,982**	92,478	88,865

See accompanying notes.

Consolidated Statements of Cash Flows

	Years Ended December 31,

(in thousands)	2004	2003	2002
Cash flows from operating activities:			
Net loss	**$ (53,241)**	$ (129,814)	$ (14,554)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	**—**	85,993	—
Depreciation and amortization	**11,361**	8,407	5,441
Amortization of convertible notes offering costs	**1,205**	1,147	721
Amortization of intangible assets	**2,502**	941	—
Stock-based compensation expense	**1,214**	276	—
Impairment loss on investment	**—**	150	1,366
Loss on early extinguishment of debt	**—**	6,538	—
Loss on disposal of fixed assets	**741**	455	—
Other non-cash research and development expenses	**3,000**	—	—
Non-cash license revenue	**(4,000)**	—	—
Changes in assets and liabilities:			
Interest receivable	**340**	2,975	3,904
Other current assets	**939**	(3,286)	(3,336)
Other assets	**405**	(8,941)	(643)
Accounts payable	**1,277**	1,064	379
Accrued liabilities	**(9,627)**	10,407	1,713
Deferred revenue	**16,728**	123	(62)
Total adjustments	**26,085**	106,249	9,483
Net cash used in operating activities	**(27,156)**	(23,565)	(5,071)
Cash flows from investing activities:			
Purchases of marketable securities	**(291,271)**	(110,049)	(79,954)
Maturities of marketable securities	**139,290**	278,000	283,500
Maturities (purchases) of restricted securities	**7,487**	(20,822)	—
Cash acquired in acquisition of Eos	**—**	2,453	—
Purchase of intangible assets	**—**	(80,000)	—
Purchase of land, property and equipment	**(95,683)**	(90,518)	(34,786)
Net cash provided by (used in) investing activities	**(240,177)**	(20,936)	168,760
Cash flows from financing activities:			
Proceeds from issuance of common stock	**18,313**	4,110	4,205
Proceeds from issuance of convertible notes	**—**	250,000	—
Extinguishment of long-term convertible debentures	**—**	(154,125)	—
Payments on other long-term obligations	**(1,353)**	(1,446)	(432)
Net cash provided by financing activities	**16,960**	98,539	3,773
Net increase (decrease) in cash and cash equivalents	**(250,373)**	54,038	167,462
Cash and cash equivalents at beginning of year	**341,768**	287,730	120,268
Cash and cash equivalents at end of year	**$ 91,395**	$ 341,768	$ 287,730
Supplemental Disclosure of Noncash Financing and Investing Activities			
Exchange of assets for third party preferred stock	**—**	—	$ 1,290
Cash Flow for Acquisition of Eos:			
Assembled workforce	**—**	$ 1,410	—
Other current assets acquired	**—**	691	—
Acquired in-process research and developemnt	**—**	37,834	—
Property and equipment acquired	**—**	2,274	—
Liabilities assumed	**—**	(5,848)	—
Acquisition and transaction costs incurred	**—**	(4,652)	—
Common stock issued	**—**	(34,162)	—
Supplemental Disclosure of Cash Flow Information			
Cash paid during the year for interest	**$ 8,220**	$ 10,736	$ 8,957

See accompanying notes.

Consolidated Statements of Stockholders' Equity

(In thousands, except shares of common stock data)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital
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
Issuance of common stock under employee benefit plans	**1,971,233**	**20**	**18,293**
Issuance of common stock options to consultants for services	**0**		**1,214**
Issuance of common stock upon conversion of convertible notes	**99**		**2**
Balance at December 31, 2004	**95,857,236**	**$ 959**	**$ 686,302**

	Accumulated	Accumulated	Total

	Deficit	Other Comnprehenbsive Income (Loss)	Stock Holders' Equity
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
Stock-based compensation expense			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
Issuance of common stock under employee benefit plans			**18,313**
Stock-based compensation expense			**1,214**
Issuance of common stock upon conversion of convertible notes			**2**
Comprehensive loss:			
Net loss	**(53,241)**		**(53,241)**
Change in unrealized gains and losses on securities		**(2,109)**	**(2,109)**
Total comprehensive loss			**(55,350)**
Balance at December 31, 2004	**$ (273,532)**	**$ (1,219)**	**$ 412,510**

See accompanying notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2004

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 our antibody humanization technology.

Principles of Consolidation

The consolidated financial statements include the accounts of Protein Design Labs, Inc. and its wholly-owned subsidiaries 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 revenues resulting from the licensing and use of our technology and from services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use as drugs, in drug development and production.

If we determine that any of our revenue arrangements contain separate elements pursuant to Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, payment is reasonably assured 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.

Revenues, and their respective treatment for financial reporting purposes, are as follows:

Royalties

Under some of our patent license agreements, we receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from our licensees approximately one quarter in arrears; that is, generally in 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 reported to us by our licensees (i.e., generally royalty revenue is recognized one quarter following the quarter in which sales by our licensees occurred).

License and Other

We include revenue recognized from upfront licensing and license maintenance fees, milestone payments and reimbursement of development costs in License and other revenues.

Upfront License 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. Generally there are three types of collaboration arrangements PDL enters into under which we provide access to our proprietary patent portfolio covering the humanization of antibodies.

- Under patent license agreements, the licensee typically obtains a non-exclusive license to one or more of 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. Consideration that we receive for patent license agreements is recognized upon execution and delivery of the patent license agreement and when payment is reasonably assured. Nonrefundable upfront licensing fees, including certain guaranteed, time-based payments that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue either (a) ratably over the development period if development risk is significant, or (b) ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.

- Under Patent Rights Agreements, the licensee purchases a research patent license in exchange for an upfront fee. In addition, the licensee has the right to obtain at a later date, 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. The licensee performs all of the research, 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; therefore, upon delivery of the patent rights agreement, the earnings process is complete. When a licensee exercises its right to obtain patent licenses to certain designated drug targets for commercial purposes, we recognize the related consideration as revenue upon the licensee's 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.

Milestones

We enter into patent license and humanization agreements that may contain milestone payments related to reaching particular stages in product development. We recognize revenues from milestones when we have no further obligation with respect to the activities under the agreement and when we have confirmed that the milestone has been achieved. Where we have continuing obligations in the form of development, manufacturing or other commercialization efforts, we recognize revenues from milestones either (a) ratably over the development period if development risk is significant, or (b) ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated. 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 generally 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 licensees to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the licensee's product.

- 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 licensed technology.

Reimbursement of Development Costs

Reimbursement of development costs from our collaborators is recognized as revenue as the related costs are incurred.

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients, the completion of portions of the clinical trial, or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual cost of services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the 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, payments related to work completed for us by third-party research organizations 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 years ended December 31, 2004 and 2002, interest and other income, net, primarily related to interest income of $9.7 million and $26.0 million, respectively, on our marketable securities. For the year ended December 31, 2003, the components of interest and other income, net, primarily included 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.

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. Our comprehensive loss for the years ended December 31, 2004, 2003 and 2002 is reflected in the Consolidated Statements of Stockholders' Equity.

Stock-Based Compensation

At December 31, 2004, we had six stock-based employee compensation plans, which are described more fully in Note 16. We account for our plans under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," (APB No. 25) and related Interpretations. During the year ended December 31, 2004, we recognized approximately $411,000 in stock-based compensation expense with respect to modifications to certain employee stock option awards. The tables below illustrate the effect on net loss and net loss per share if we had applied the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement No. 123, "Accounting for Stock-Based Compensation" (FAS 123), as amended by FASB Statement No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," to our stock-based employee compensation plans.

During the preparation of the notes to the consolidated condensed financial statements for the quarter ended June 30, 2004, we determined that the calculation of our pro forma net loss reported under FAS 123 for the years ended December 31, 2001, 2002 and 2003, as previously reported, was understated primarily as a result of our having inadvertently excluded the fair value of (and, therefore, the amortization expense related to) options granted during 1998 through 2001. In addition, we found that amortization expense was incorrectly calculated in 2001, 2002 and 2003 due primarily to inaccuracies in the computation of the weighted-average expected life used to calculate the fair value of stock options granted during 2000 through 2003. Accordingly, pro forma net loss reported under FAS 123 for the years ended December 31, 2002 and 2003, presented in the tables below, has been revised. These revisions had no effect on our previously reported consolidated results of operations or financial condition.

	Year Ended December 31		
(In thousands, except per share data)	**2004**	**2003 (revised)**	**2002 (revised)**
Net loss, as reported	**$ (53,241)**	$ (129,814)	(14,554)
Add: Total stock-based employee compensation expense included in net loss	**411**	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	**(19,594)**	(25,220)	(31,462)
Pro forma net loss	**$ (72,424)**	$ (155,034)	$ (46,016)
Basic and diluted net loss per share:			
As reported	**$ (0.56)**	$ (1.40)	$ (0.16)
Pro forma	**$ (0.76)**	$ (1.68)	$ (0.52)
Impact of revision on previously reported:			
Pro forma net loss		$ (5,965)	$ (19,620)
Basic and diluted net loss per share – pro forma		$ (0.06)	$ (0.22)

For the periods presented in the table below, 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:

	Year Ended December 31		
(In thousands, except per share data)	**2004**	**2003**	**2002**
Expected life, in years (revised, except 2004)	**2.4**	2.8	2.7
Risk-free interest rate	**2.6%**	2.9%	3.9%

Volatility	**64%**	72%	87%
Dividend yield	**0**	0	0

We account for stock options granted to non-employees at fair value using the Black-Scholes option-pricing model in accordance with EITF Issue No. 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 and stock options that are modified and continue to vest when an employee has a change in employment status 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. We recognized stock-based compensation expense related to stock options issued to non-employees of approximately $803,000, $276,000 and $0 for the years ended December 31, 2004, 2003 and 2002, respectively.

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 2004, 2003 and 2002 accounted for 51%, 40% and 38% of total revenues, and revenues from MedImmune in 2004, 2003 and 2002 accounted for 30%, 37% and 48% of total revenues, respectively. Revenues from Hoffmann-La Roche accounted for 11% of total revenues in 2004. No other revenue from any other source exceeded 10% of total revenues for all periods presented.

Capitalized Software

During the first quarter of 2004, we adopted Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use" (SOP 98-1). Pursuant to SOP 98-1, we recognize costs incurred in the preliminary planning phase of software development as expense as the costs are incurred. Software development costs incurred in the application development phase are capitalized and are included in property and equipment. Once the developed software is placed into service, these costs are amortized into expense over the estimated useful life of the software.

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

The U.S. dollar is the functional currency for our French subsidiary. All foreign currency gains and losses are included in interest and other income, net, in the accompanying Statements of Operations 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 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, the development and construction activities for our future manufacturing facility and the development costs underlying significant software development projects. 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 $8.8 million, $12.0 million and $9.6 million during the years ended December 31, 2004, 2003 and 2002, we capitalized interest of $3.8 million, $2.2 million and $0.5 million, respectively.

Intangible and Other Long-Lived Assets

Intangible assets consist of assembled workforce, purchased core technology, a reversion right to purchase certain technology from Roche and licensed research technology. In accordance with FASB Statement 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, core technology and licensed research technology assets on a straight-line basis over their estimated useful lives, 2, 10 and 5 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 development expenses in the Consolidated Statement of Operations. (See Note 10 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 December 2004, the FASB issued Statement No. 123 (revised 2004), "Share-Based Payment" (FAS 123R), which replaces FASB Statement No. 123, "Accounting for Stock-Based Compensation" (FAS 123) and supercedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." FAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under FAS 123, no longer will be an alternative to financial statement recognition. We are required to adopt FAS 123R on July 1, 2005. Under FAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive options, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are evaluating the requirements of FAS 123R and we expect that the adoption of FAS 123R will have a material impact on our consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting FAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under FAS 123.

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 were developing and testing in clinical studies, specifically to treat asthma and ulcerative colitis.

- In March 2004, we reported positive results from the initial clinical study of daclizumab in patients with chronic, persistent asthma whose disease is not well controlled with high doses of inhaled corticosteroids. We currently expect that the next trial of daclizumab to support development in asthma to be a single-dose, phase I study in healthy volunteers using PDL manufactured daclizumab administered subcutaneously. We expect this trial to begin enrollment in the first quarter of 2005. This single-dose trial is expected to be followed by a multiple-dose Phase I study. We anticipate that a subsequent Phase IIb clinical trial in moderate-to-severe persistent asthma could begin in the first quarter of 2006.

- In May 2004, we reported results from a Phase II clinical study of daclizumab in patients with moderate-to-severe ulcerative colitis. Daclizumab did not meet primary or secondary endpoints in the trial, and we do not intend to develop it further for this indication.

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.

In September 2004, we entered into a Co-Development and Commercialization Agreement (the Collaboration Agreement) with Roche for the joint development and commercialization of daclizumab (*Zenapax*®) for the treatment of asthma and other respiratory diseases. Under the terms of the Collaboration Agreement, we and Roche will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the United States. Outside the United States, we will receive royalties on net sales by Roche or its licensees of the product in asthma.

Under the terms of the Collaboration Agreement, we received a $17.5 million upfront payment from Roche in the third quarter of 2004, and we may receive up to $187.5 million in development and commercialization milestones in the future for successful further development of daclizumab. In addition, we receive partial reimbursement from Roche related to ongoing research and development efforts under the Collaboration Agreement. We determined that all of theconsider that all elements under the Collaboration Agreement should be accounted for as a single unit of accounting under EITF 00-21. As such, and as we have continuing obligations under the Collaboration Agreement, and as significant development risk remains we recorded the $17.5 million as deferred revenue and will recognize this amount over the approximately six years that research, development expenses are expected to be performed for Roche. During 2004, we recognized approximately $3.7 million in License and Other revenue related to the amortization of the upfront license fee and the reimbursement of certain research and development expenses.

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 (the 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 associated with our research funding ratably over the periods it was performed by Exelixis. We have 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. We continue to hold the Note, which is included in our Consolidated Balance Sheet. We accrue interest income on the Note, and during each of the years ended December 31, 2004, 2003 and 2002, we recognized approximately $1.7 million of interest income.

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.

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. In connection with this 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. We also obtained additional rights for non-exclusive, royalty-bearing licenses under certain of Genentech's antibody patents. Under terms of the agreement, Genentech exercised licenses under the patent licensing master agreement for its 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 royalty revenue from third quarter 2003 sales of Xolair beginning in the fourth quarter of 2003, and we commenced recognition of royalty revenue from Raptiva product sales in the first quarter of 2004.

In February 2004, in consideration for 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 recognized license exercise fees of approximately $1.1 million in the first quarter of 2004 and commenced recognition of royalty revenue from Avastin product sales in the second quarter of 2004.

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 Zamyl™, 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.

Seattle Genetics. In January 2004, we entered into certain agreements with Seattle Genetics, Inc. (SGI) in which we granted patent rights and a patent license to SGI under our humanization patents and paid $500,000 in cash in exchange for expanded access to SGI's drug conjugate and linker technology. Under the patent rights agreement, SGI also has the right to obtain additional patent licenses upon payment of additional fees, and upon the future commercialization of the products, SGI will pay us royalties on product sales. See Note 6.

Morphotek. In July 2004, we entered into an agreement with Morphotek, Inc. in which we granted patent rights and a commercial license under our humanization patents in exchange for broad access to Morphotek's MORPHODOMA® and Suppressor of Immunoglobulin Production technology. Under the agreement, Morphotek has the right to obtain additional patent licenses upon payment of additional fees. Upon the future commercialization of the products, Morphotek will pay us royalties on product sales. See Note 6.

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 Idec, Celltech Group plc, Chugai, Elan Pharmaceuticals, Eli Lilly and Company, Fujisawa Pharmaceuticals Co., 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 LOSS PER SHARE

In accordance with Financial Accounting Standards Board (FASB) Statement No. 128, "Earnings Per Share," basic and diluted net loss per share amounts have been computed using the weighted average number of shares of common stock outstanding during each period presented. For all periods presented, we incurred a net loss, and as such, we did not include the effect of any outstanding stock options or outstanding convertible notes in the diluted net loss per share calculations, as they were anti-dilutive.

The total number of shares excluded from the calculations of diluted net loss per share for outstanding convertible notes was 12,415,350, 16,389,450 and 3,974,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The total number of shares excluded from the calculation of diluted net loss per share for outstanding stock options was approximately 3,169,000, 1,843,000 and 1,587,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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-51 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-51 integrin antibody (F200) for ocular indications, including age-related macular degeneration. In December 2004, we initiated Phase II clinical trials for M200, and no further development of F200 is expected.

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)
	$ 38,814

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 and status of these programs at December 31, 2004 follows:

Program	Description	Status of Development	Value Assigned (in thousands)
Anti-angiogenesis (M200, Anti-α5β1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including melanoma, pancreatic, non-small lung and renal cancers	Phase II clinical trials initiated in December 2004	$ 24,067
Ocular Neovascular iz ation (F200, Anti-α5β1 Integrin Antibody)	Fab fragment of Anti-α5β1 Integrin Antibody for ocular indications, including age-related macular degeneration.	No further development expected	$ 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. RESTRUCTURING AND OTHER CHARGES

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials in June 2004, management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, in 2004 we incurred charges of approximately $305,000, including adjustments in the fourth quarter of 2004 related to the extension of a sublease of the facilities, included in research and development expense in the Consolidated Statement of Operations. The restructuring charge included approximately $164,000 of severance-related amounts, $119,000 of committed cost for our New Jersey leased facility, primarily related to rent expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005, partially offset by expected proceeds from a short-term sublease entered into during October 2004. The workforce reductions were completed by June 30, 2004. We expect to pay the balance of the accrued facility-related costs of approximately $58,000 at December 31, 2004 through October 2005.

During 2004, we completed a physical inventory of substantially all of our laboratory equipment at our Fremont, California, facilities. As a result, we recorded a charge to research and development expense in the Consolidated Statement of Operations of approximately $277,000, primarily in the second quarter of 2004 with minor adjustments in the fourth quarter of 2004, which represents the estimated amount of net book value of assets that are no longer in use.

6. NONMONETARY TRANSACTIONS

In January 2004, we entered into certain agreements with Seattle Genetics, Inc. (SGI) in which we granted patent rights and a patent license to SGI under our humanization patents and paid $500,000 in cash in exchange for expanded access to SGI's drug conjugate and linker technology. Under the patent rights agreement, SGI also has the right to obtain additional patent licenses upon payment of additional fees, and upon the future commercialization of the products, SGI will pay us royalties on product sales.

In accordance with APB Opinion No. 29, "Accounting for Nonmonetary Transactions" (APB 29), we established the value of the drug conjugate and linker technology that we acquired from SGI based on the fair value of the consideration given to SGI, which included the patent rights and patent license granted to SGI and cash consideration of $500,000. Based on the vendor-specific objective evidence of fair value of the patent rights and patent license granted to SGI, which is based on the terms of similar agreements that we have signed with third parties, we deemed the fair value of the patent rights and patent license to be $3.0 million. Therefore, the fair value of the drug conjugate and linker technology acquired from SGI was $3.5 million. As this early-stage technology has not reached technological feasibility and has no alternative future use in our research and development programs, in accordance with FASB Statement No. 2, "Accounting for Research and Development Costs," (FAS 2) we recognized the $3.5 million as research and development expense in the first quarter of 2004.

In accordance with EITF 00-21, we estimated the fair value of the patent rights and patent license granted to SGI to be $3.0 million. As we have completed the earnings process under this agreement and had no ongoing performance obligations, we recognized revenue of $3.0 million in the first quarter of 2004 upon the execution of the agreements.

In July 2004, we entered into an agreement with Morphotek, Inc. in which we granted patent rights and a commercial license under our humanization patents in exchange for broad access to Morphotek's MORPHODOMA® and Suppressor of Immunoglobulin Production technology. Under the agreement, Morphotek has the right to obtain additional patent licenses upon payment of additional fees. Upon the future commercialization of the products, Morphotek will pay us royalties on product sales.

In accordance with APB 29, we established the value of the technology that we acquired from Morphotek based on the fair value of the patent rights and commercial license granted to Morphotek. We deemed the fair value of the patent rights granted to Morphotek to be $1.0 million and the fair value of the commercial license to be $0.5 million, which is based on the terms of similar agreements that we have signed with third parties. As this technology has broad application across multiple preclinical and clinical programs, in accordance with FAS 2, we have capitalized the $1.5 million in Intangible Assets on the Consolidated Condensed Balance Sheet and we will amortize it over five years, the term of the agreement. During the third and fourth quarters of 2004, we recognized $150,000 in amortization expense related to this asset.

In accordance with EITF 00-21, we estimated the fair value of the patent rights and commercial license granted to Morphotek to be $1.0 million and $0.5 million, respectively. As we have completed the earnings process under this agreement and had no ongoing performance obligations, we recognized revenue of $1.0 million in the third quarter of 2004 upon the execution of the agreement. The remaining $500,000 has been recorded as deferred revenue and will be recognized once the commercial license is delivered to Morphotek.

7. 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. As of December 31, 2002, we estimated that the fair value of our investment in Signature had declined to $150,000 and that the impairment was other then 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 determined that our investment in Signature had become fully and permanently impaired. Accordingly, in the first quarter of 2003 we recorded an impairment charge of $150,000 to write off the remaining book value of our investment.

8. 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			
(In thousands)	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2004				
Securities of the U.S. Government and its agencies maturing:				
within 1 year	$ 44,964	$ —	$ (79)	$ 44,885
between 1-3 years	149,494	9	(1,032)	148,471
U.S. corporate debt securities maturing:				
within 1 year	87,777	3	(39)	87,741
between 1-3 years	10,000	—	(81)	9,919
Total marketable debt securities	$ 292,235	$ 12	$ (1,231)	$ 291,016
December 31, 2003				
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

During 2004, 2003 and 2002, there were no realized gains or losses on the sale of available-for-sale securities. In addition to our available-for-sale portfolio, at December 31, 2004 and 2003 we had $13.6 million and $20.7 million, respectively, of U.S. government securities classified as held-to-maturity under FASB Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities." As of December 31, 2004, all of our investments in unrealized loss positions had been in such positions for less than 12 months due to the changes in market interest rates. Further, we do not believe that any of our

marketable securities have suffered any other-than-temporary declines in value as of December 31, 2004 since we do not expect to sell any securities in significant unrealized loss positions prior to their maturities.

In July 2003, we issued 2.75% Convertible Subordinated Notes due August 16, 2023 with a principal amount of $250.0 million (see Note 15 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, which approximated $13.6 million at December 31, 2004 and $20.8 million at December 31, 2003, consists of securities of the U.S. Government and its agencies. As of December 31, 2004, the portion related to payments to be made within one year, $6.9 million, is reflected on the Consolidated Balance Sheet within marketable securities, and the portion related to payments to be made thereafter, $6.7 million, is reflected on the balance sheet as long-term restricted investments. The basis for the carrying value of these restricted investments is the amortized cost of the investments, which approximates the fair market value at December 31, 2004.

9. LAND, PROPERTY AND EQUIPMENT

Land, property, and equipment consisted of the following:

(In thousands)	December 31, 2004	2003
Land	**$ 10,743**	$ 10,743
Buildings and improvements	**41,001**	23,766
Leasehold improvements	**19,846**	18,887
Laboratory and manufacturing equipment	**28,787**	27,225
Construction-in-process	**157,073**	93,097
Computer and office equipment	**17,493**	11,278
Furniture and fixtures	**3,627**	2,540
	278,570	187,536
Less accumulated depreciation and amortization	**(40,493)**	(32,623)
	$ 238,077	$ 154,913

Depreciation and amortization expense for 2004, 2003 and 2002 was $11.8 million, $8.2 million, and $4.9 million, respectively.

10. INTANGIBLE ASSETS

Intangible assets consisted of the following at December 31, 2004 and 2003 (in thousands):

	2004			2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Assembled workforce	**$ 1,410**	**$ (1,234)**	**$ 176**	$ 1,410	$ (528)	$ 882
Core technology	**16,053**	**(2,058)**	**13,995**	16,053	(412)	15,641
Roche reversion right	**15,788**	**—**	**15,788**	15,788	—	15,788
Licensed research technology	**1,500**	**150**	**1,350**	—	—	—
Net intangible assets	**$ 34,751**	**$ (3,442)**	**$ 31,309**	$ 33,251	$ (940)	$ 32,311

Amortization expense for our intangible assets during the years ended December 31, 2004, 2003 and 2002 was approximately $2.5 million, $940,000 and $0, respectively. 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.

During 2004, we entered into an agreement with Morphotek in which we obtained broad access to certain of Morphotek's technology for which we recorded intangible assets of $1.5 million. See Note 6 for details of the agreement.

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

	Assembled Workforce	Core Technology	Licensed Research Technology
For the year ending December 31,			
2005	176	1,646	300
2006	—	1,646	300
2007	—	1,646	300
2008	—	1,646	300
2009	—	1,646	150
Thereafter	—	5,765	—
Total amortization expense	$ 176	$ 13,995	$ 1,350

11. ACCRUED LIABILITIES

Other accrued liabilities consisted of the following (in thousands):

	December 31, 2004	2003

Construction-in-process	**$ 3,810**	$ 14,568
Consulting and services	**5,229**	3,832
Other	**288**	742
Total	**$ 9,327**	$ 19,142

12. 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. Coverage for eligible retirees is noncontributory, but retirees are required to contribute 25% of dependent premium cost. In addition, coverage under the Plan ceases when participants become eligible for Medicare benefits. For the years ended December 31, 2004 and for the period from the inception of the Plan (June 1, 2003) through December 31, 2003, we have recognized net periodic postretirement benefit cost of approximately $243,000 and $118,000, respectively, using a measurement date of June 30, 2003.

The following table sets forth the change in benefit obligation for the Plan (in thousands):

	December 31,	
	2004	**2003**
Accumulated postretirement benefit obligation at beginning of year	**$ 1,039**	$ 816
Service cost	**98**	44
Interest cost	**67**	31
Actuarial loss	**115**	148
Plan participants' contributions	**4**	—
Benefits paid	**(27)**	—
Accumulated postretirement benefit obligation at end of year	**$ 1,296**	$ 1,039

We calculated the accumulated postretirement benefit obligation using an assumed discount rate of 5.75% and 6.50% for the years ended December 31, 2004 and 2003, respectively. In 2004, we assumed the rate of increase in per capita costs of covered health care benefits to be 9%, decreasing gradually to 5.5% by the year 2009, and in 2003, we assumed the rate of increase in per capita costs of covered health care benefits to be 10%, decreasing gradually to 5.5% by the year 2009. The benefit amounts recognized in our balance sheets in accrued compensation and other long-term liabilities are as follows (in thousands):

	December 31,	
	2004	**2003**
Funded status	**$ (1,296)**	$ (1,039)
Unrecognized net actuarial loss	**258**	148
Unrecognized prior service cost	**699**	773
Net liability recognized	**$ (339)**	$ (118)

Net periodic benefit cost for the Plan consists of the following (in thousands):

	December 31,	
	2004	**2003**
Service cost	**$ 98**	$ 44
Interest cost	**67**	31
Amortization of prior service cost	**74**	43
Other	**4**	—
Net periodic benefit cost	**$ 243**	$ 118

Assumed health care trend rates could have a significant effect on the amounts reported for healthcare plans. A one-percentage-point change in assumed health care cost trend rate would have the following effects (in thousands):

	One percentage point increase	**One percentage point decrease**
Effect on accumulated postretirement benefit obligation as of December 31, 2004	$ 25	$ (22)
Effect on total of service and interest cost in 2004	138	(122)

In connection with the Plan, we expect to pay health care net premiums aggregating approximately $164,000 and $316,000 during the years 2005 through 2009, and during the years 2010 through 2014, respectively.

13. COMMITMENTS

We occupy leased facilities under agreements that have expiration dates between 2005 and 2013. We also have leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately $2.5 million, $2.3 million and $1.3 million for the years ended December 31, 2004, 2003 and 2002, respectively. Future payments under non-cancelable operating leases at December 31, 2004, are as follows:

Year Ending December 31,	
2005	$ 2,879
2006	2,848
2007	1,132
2008	865
2009	223

Thereafter	330
	$ 8,277

Moreover, 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. Total commitments under these construction agreements total approximately $15.2 million and $1.7 million for the years ending December 31, 2005 and 2006, respectively.

In addition, as of December 31, 2004, we have made payments totaling $5.6 million to ICOS Corporation pursuant to a manufacturing agreement for the manufacture of supplies of clinical trial materials for one of our products. The aggregate amount of all committed future payments that we may make under that agreement is $1.8 million, payable in the first quarter of 2005.

14. 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 have an approximate carrying amount of $7.9 million at December 31, 2004, 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. 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 facility and equipment loans at December 31, 2004 are as follows (in thousands):

Year Ending December 31,	
2005	$ 1,583
2006	1,243
2007	1,139
2008	1,139
2009	1,139
Thereafter	5,505
Total	11,748
Less amount representing interest	(3,356)
Present value of future payments	8,392
Less current portion	(923)
Non-current portion	$ 7,469

We believe that the fair values of the facility and equipment loans at December 31, 2004 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.

15. CONVERTIBLE NOTES

In February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million (see Note 20).

In July 2003, we issued 2.75% Convertible Subordinated Notes due August 16, 2023 with a principal amount of $250.0 million (2003 Notes). The 2003 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 2003 Notes is payable semiannually in arrears on February 16 and August 16 of each year. The 2003 Notes are unsecured and are subordinated to all our existing and future senior indebtedness. The 2003 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 2003 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 any 2003 Notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of any 2003 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 2003 Notes and the common stock issuable upon conversion of the 2003 Notes.

Issuance costs associated with the 2003 Notes aggregating $8.4 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, 2004 was $1.8 million. The estimated fair value of the 2003 Notes at December 31, 2004 was approximately $319.3 million based upon publicly available pricing information.

We pledged a portfolio of U.S. government securities as security for certain interest payable on the 2003 Notes (see Note 8).

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 for the year ended December 31, 2003.

16. STOCKHOLDERS' EQUITY

Common Stock Reserved for Future Issuance

Shares of our common stock reserved for future issuance at December 31, 2004 were as follows (in thousands):

All stock option plans	21,526
Employee stock purchase plan	815
Convertible debt	12,415
Total	34,756

Stock Option Plans

At December 31, 2004, 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 $1.2 million in 2004, $276,000 in 2003, and immaterial in 2002.

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, 601,484 additional shares have been transferred to and are available for grant under the 1999 Stock Option Plan as of December 31, 2004.

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, 601,484 additional shares have been transferred to and are available for grant under the 1999 Stock Option Plan as of December 31, 2004.

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 the 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, 2004, 2003 and 2002, and changes during the years then ended, is presented below.

	2004		2003		2002	
(In thousands, except exercise price data)	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	**14,537**	**$ 15.69**	12,310	$ 17.18	10,528	$ 18.40
Granted	**3,367**	**17.59**	3,228	10.37	3,427	13.46
Exercised	**(1,807)**	**8.69**	(317)	6.75	(516)	5.63
Forfeited	**(882)**	**25.73**	(684)	21.65	(1,129)	22.45
Outstanding at end of year	**15,215**	**16.36**	14,537	15.69	12,310	17.18
Exercisable at end of year	**9,377**		8,230		5,975	
Weighted average fair value of options granted during the year		**$ 6.93**		$ 7.27		$ 10.72

The following information applies to all stock options outstanding under our stock option plans at December 31, 2004:

	Outstanding			Exercisable	
Range of Exercise Prices	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 - $10.94	5,514	5.84	$ 7.56	3,757	$ 7.28
$11.22 - $20.51	5349	8.67	16.20	1,946	16.07
$21.02 - $30.00	3,449	6.33	24.36	2,817	24.23
$30.11 - $40.08	504	6.17	36.16	463	36.12
$41.69 - $56.84	399	5.67	45.97	394	45.99
Totals	15,215		$ 16.36	9,377	$ 17.25

To date, an aggregate of approximately 35,740,000 shares have been authorized for grant under our stock option plans and as of December 31, 2004, approximately 6,311,000 are available for future 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, 2004, 814,806 shares remain available for future 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 2004, an aggregate of 165,393 shares were purchased by employees under the Employee Purchase Plan at prices of $15.66 or $15.86 per share. 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.

17. INCOME TAXES

The provision for income taxes consists of the following:

	Years Ended December 31,		
(in thousands)	2004	2003	2002
Current:			
Federal	**$ —**	$ —	$ —
State	**20**	18	12
Foreign	**60**	55	30
Total Current	**$ 80**	$ 73	$ 42

A reconciliation of the income tax provision computed using the U.S. 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,		
(in thousands)	2004	2003	2002
Computed at U.S. statutory rate			

At statutory rate	**$ (18,074)**	$ (44,107)	$ (5,079)
Unutilized net operating losses	**18,074**	31,243	5,079
Nondeductible acquired in-process research and development	**—**	12,864	—
State taxes	**20**	18	12
Foreign taxes	**60**	55	30
Total	**$ 80**	$ 73	$ 42

As of December 31, 2004, we have federal and California state net operating loss carryforwards of approximately $407.0 million and $158.7 million, respectively. We also have federal and California state research and other tax credit carryforwards of approximately $12.6 million and $11.6 million, respectively. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in the year 2005 through 2024, if not utilized. The California state net operating losses will expire at various dates beginning in 2005 through 2014, if not utilized. The majority of the state tax credits do not expire.

Utilization of the federal and California 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:

(in thousands)	December 31, 2004	2003
Deferred tax assets:		
Net operating loss carryforwards	**$ 147,909**	$ 117,210
Research and other tax credits	**20,237**	15,940
Intangible assets	**17,481**	18,770
Capitalized research and development costs	**9,145**	10,610
Other	**1,974**	1,220
Total deferred tax assets	**196,746**	163,750
Valuation allowance	**(196,746)**	(163,400)
Total deferred tax assets	**—**	350
Deferred tax liabilities:		
Unrealized gains on investments	**—**	350
Total deferred tax liabilities	**—**	350
Net deferred tax assets	**$ —**	$ —

Because of our lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $33.3 million, $55.7 million and $4.4 million during the years ended December 31, 2004, 2003 and 2002, respectively.

Approximately $78.3 million of the deferred tax assets at December 31, 2004 relates to benefits of stock option deductions which, when recognized, will be allocated directly to contributed capital.

18. 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.

At an oral hearing in February 2005, the Opposition Division of the European Patent Office decided to revoke the claims in our second European antibody humanization patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We appealed the decision to the Technical Board of Appeal at the European Patent Office. The appeal suspends the legal effect of the decision of the Opposition Division during the appeal process, which is likely to take several years.

We intend to vigorously defend the European patents 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 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. As the outcome of these matters can not be predicted, we have no amounts accrued at December 31, 2004.

In regard to our Japanese humanization patent, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court decision upholding revocation of the patent by the Japanese Patent Office. The Japanese Supreme Court decision concludes the proceedings in the matter and the Japanese Patent Office decision to revoke our patent is final.

19. RELATED-PARTY TRANSACTION

Pursuant to an agreement with Dr. Laurence Korn regarding his resignation as an officer of the Company, Dr. Korn resigned on June 30, 2004 as Chairman of the Board of Directors and as an employee of the Company. Dr. Korn remains a member of the Board. Under the agreement, Dr. Korn received a cash severance payment of $515,000 in addition to the acceleration of an additional 12 months' of vesting of certain stock options previously granted to him. During the year ended December 31, 2004, in connection with the agreement, we recognized $515,000 in compensation expense for his severance payment and approximately $58,000 in stock-based compensation expense in connection with the accelerated vesting of stock options. Additionally, Dr. Korn will continue to receive certain fringe benefits for a period of one year from his resignation date and 51,668 of his unvested, outstanding stock options as of June 30, 2004 will continue to vest under the terms of the original stock option agreements. As this represents a change in grantee status under FASB Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation, and Interpretation of APB Opinion No. 25," we expect to recognize additional stock-based compensation expense over the next two years as these stock options vest under the fair value method of accounting.

20. SUBSEQUENT EVENTS

In January 2005, we entered into a definitive agreement with ESP Pharma Holding Company, Inc. (ESP), a privately held, hospital-focused pharmaceutical company, under which PDL will acquire ESP for $300 million in cash and approximately $175 million in PDL common stock, or an aggregate value of approximately $475 million. In February 2005, this agreement was amended to reflect ESP's agreement to acquire from Centocor, Inc. (Centocor), a biopharmaceutical operating company of Johnson & Johnson, rights to manufacture, develop, market and distribute Retavase® (reteplase) in the United States and Canada, including an increase in the purchase price by $25 million in cash payable to the ESP stockholders at the closing of the ESP acquisition. The acquisition price to be paid to Centocor for the rights to Retavase is $110 million. Milestone payments of up to $45 million may be made if additional conditions relating to ongoing clinical trials and manufacturing arrangements are satisfied. In February 2005, we entered into a loan commitment agreement with ESP to ensure that the $110 million purchase price payable to Centocor would be available to complete the purchase of Retavase by ESP. No amount has been drawn under this commitment as of March 11, 2005.

The aggregate preliminary purchase price is expected to be approximately $503.0 million, including the cash to be paid to ESP stockholders of $325.0 million, the fair market value of PDL's common stock to be issued to ESP stockholders totaling approximately $172.5 million, and estimated direct transaction costs of approximately $5.3 million. In the event that there is a significant change in our stock price from the announcement of the acquisition to the closing date, we may be required to issue additional shares to ESP, which could increase the purchase price by an amount up to $19.2 million. We expect this transaction to close late during the first quarter or early during the second quarter of 2005. We currently estimate between 80% and 85% of the aggregate purchase price will be allocated to capitalizable intangible assets and goodwill, with a smaller portion, or approximately 10%-15%, allocated to acquired in-process research and development expense.

In February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million (2005 Notes). The 2005 Notes are convertible into our common stock at a conversion price of $23.69 per share, subject to adjustment in certain events. Interest on the 2005 Notes is payable semiannually in arrears on February 15 and August 15 of each year. The 2005 Notes are unsecured and subordinated to all our existing and future indebtedness and may be redeemed at our option, in whole or in part, beginning on February 19, 2010 at par value.

We plan to use the proceeds from the 2005 Notes to acquire ESP pursuant to the agreement described above.

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders of
Protein Design Labs, Inc.

We have audited the accompanying consolidated balance sheets of Protein Design Labs, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (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, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Protein Design Labs, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 11, 2005

QUARTERLY FINANCIAL DATA (UNAUDITED)

	2004 Quarter Ended			
(in thousands, except per share data)	**December 31**	**September 30**	**June 30**	**March 31**
Revenues:				
Royalties	**$ 19,935**	**$ 17,131**	**$ 24,731**	**$ 22,010**
License and other	**2,894**	**2,653**	**1,052**	**5,618**
Total revenues	**22,829**	**19,784**	**25,783**	**27,628**
Costs and expenses:				
Research and development	**30,199**	**27,326**	**32,009**	**33,029**
General and administrative	**8,624**	**7,664**	**7,450**	**8,068**
Total costs and expenses	**38,823**	**34,990**	**39,459**	**41,097**
Operating loss	**(15,994)**	**(15,206)**	**(13,676)**	**(13,469)**
Interest and other income, net	**2,523**	**2,822**	**2,583**	**2,284**
Interest expense	**(1,099)**	**(1,193)**	**(1,351)**	**(1,385)**
Loss before income taxes	**(14,570)**	**(13,577)**	**(12,444)**	**(12,570)**
Provision for income taxes	**(12)**	**(12)**	**(8)**	**(48)**
Net loss	**(14,582)**	**(13,589)**	**(12,452)**	**(12,618)**
Basic and diluted net loss per share	**$ (0.15)**	**$ (0.14)**	**$ (0.13)**	**$ (0.13)**
Shares used in computation of basic and diluted net loss per share	**95,613**	**95,196**	**94,587**	**94,000**

	2003 Quarter Ended			
(in thousands, except per share data)	**December 31**	**September 30**	**June 30**	**March 31**
Revenues:				
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**
Costs and expenses:				
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**
Operating loss	**(67,103)**	**(19,450)**	**(44,564)**	**1,465**
Interest and other income, net	**(3,320)(3)**	**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**
Net income (loss)	**$ (72,859)**	**$ (18,875)**	**$ (42,149)**	**$ 4,069**
Net income (loss) per share:				
Basic	**$ (0.78)**	**$ (0.20)**	**$ (0.45)**	**$ 0.05**
Diluted	**$ (0.78)**	**$ (0.20)**	**$ (0.45)**	**$ 0.05**
Shares used in computation of net income (loss) per share:				
Basic	**93,764**	**93,665**	**93,301**	**89,182**
Diluted	**93,764**	**93,665**	**93,301**	**90,150**

(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 15 to the Consolidated Financial Statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures*: Under the supervision and with the participation of PDL's management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in reaching a reasonable level of assurance that information required to be disclosed by PDL in the reports that it files or submits under the Securities Exchange Act of 1934 (the Exchange Act) is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms.

(b) *Management's Annual Report on Internal Control Over Financial Reporting*: PDL, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, is responsible for the preparation and integrity of our Consolidated Financial Statements, establishing and maintaining adequate internal control over financial reporting for PDL and all related information appearing in this Annual Report. The Company employed the Internal Control-Integrated Framework founded by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its internal control over financial reporting. Based on our evaluation under the framework in Internal Control-Integrated Framework, our management has assessed our internal control over financial reporting to be effective as of December 31, 2004.

The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an audit report on management's assessment of our internal control over financial reporting as well as on the effectiveness of the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appearing below and the report on the audit of the consolidated financial statements appears on or about page 86 of this Annual Report on Form 10-K.

(c) *Changes in Internal Control Over Financial Reporting*: The Chief Executive Officer and Chief Financial Officer also conducted an evaluation of our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) ("Internal Control") to determine whether any changes in internal control occurred during the quarter ended December 31, 2004, that have materially effected or which are reasonable likely to materially affect internal control. Based on that evaluation, there has been no such change during such period.

(d) Report of Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Protein Design Labs, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that Protein Design Labs, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Protein Design Labs, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Protein Design Labs, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Protein Design Labs, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Protein Design Labs, Inc, as of December 31, 2004 and 2003, and the related consolidated statements of operations, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2004 and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 11, 2005

PART III

ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS

Certain information concerning our current directors as of December 31, 2004, except as otherwise noted, is set forth below.

Director	Positions with the Company	Age	Director Since
Karen A. Dawes	Director	53	2003
L. Patrick Gage, Ph.D.	Director	62	2003
George M. Gould, Esq.	Director	67	1989
Laurence Jay Korn, Ph.D.	Director	55	1986
Max Link, Ph.D.	Director, Chairman of the Board	64	1993
Mark McDade	Chief Executive Officer, Director	49	2002
Cary L. Queen, Ph.D.	Director	54	1987
Jon S. Saxe, Esq.	Director	68	1989

Karen A. Dawes has been 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, Zoloft, and Cardura. Ms. Dawes is also a director of Genaissance Pharmaceuticals, Inc.

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 Serono SA, and retired as Chairman of the Dublin Molecular Medicine Centre in Ireland in June 2004. Dr. Gage is a part-time venture partner with Flagship Ventures in Cambridge, Massachusetts. He serves as the Executive Chairman of Compound Therapeutics, and as Chairman of Acceleron Pharma, both private biotechnology companies. Dr. Gage also serves as the Chair of the Science Advisory Board of Perkin Elmer Life and Analytical Sciences Company, and is a member of the Life Sciences Advisory Board of Warburg Pincus, a private equity investment company.

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 of the Company since July 1986. From July 1986 until June 2004, Dr. Korn served as Chairman of the Board and from January 1987 until April 2002, Dr. Korn served as Chief Executive Officer. Dr. Korn continued to serve as an executive officer of the Company until June 2004. 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 and became Chairman of the Board of the Company in June 2004. 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 also serves both as a director and an audit committee member of Access Pharmaceuticals, Inc., Alexion Pharmaceuticals, Inc., Cell Therapeutics, Inc., 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 Questcor Pharmaceuticals, Inc., First Horizon Pharmaceuticals, Inc., InSite Vision, Inc., SciClone Pharmaceuticals, Inc., ID Biomedical Corporation, Durect Corporation and several private companies.

Executive Officers

Certain information with respect to our executive officers as of December 31, 2004, except as otherwise noted, is set forth below. See “DIRECTORS” for information regarding Mr. McDade, our chief executive officer.

Name	Age	Position
Steven E. Benner, M.D., M.H.S.	45	Senior Vice President and Chief Medical Officer
Douglas O. Ebersole	49	Senior Vice President, Legal and Corporate Development and Secretary
Brett L. Schmidli	53	Senior Vice President, Technical Operations
Glen Y. Sato	45	Senior Vice President and Chief Financial Officer
Richard Murray, Ph.D.	46	Senior Vice President and Chief Scientific Officer
Sergio Garcia-Rodriguez	43	Vice President, Legal, General Counsel and Assistant Secretary
Jaisim Shah	44	Vice President, Marketing
Laurie Torres	44	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., served as our Vice President, Research since April 2003 and was promoted to Senior Vice President and Chief Scientific Officer in March 2004. 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.

Audit Committee Matters

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/documents/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, 2004, under Section 16(a) by our directors, executive officers and greater than 10% beneficial owners were timely filed.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information concerning the compensation during the fiscal years ended December 31, 2004, 2003, and 2002, 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, 2004 and Laurence Jay Korn, an individual for whom disclosure would have been required but for the fact that he was not serving as an executive officer of the Company at December 31, 2004 (collectively, the “Named Executive Officers”):

SUMMARY COMPENSATION TABLE

		Annual Compensation(1)			Long-Term Compensation Awards	
Name and Principal Positions	Year	Salary ($)	Bonus ($)	Other Annual Compensation(2) ($)	Securities Underlying Options (#)	All Other Compensation(3) ($)
Mark McDade	2004	517,477	250,000(4)	—	140,000	2,000
Chief Executive Officer	2003	500,844	500,000(5)	129,262	140,000	2,000
	2002	62,601	100,000(6)	—	900,000	—
Brett Schmidli	2004	348,689	80,000(4)	26,390	60,000	—
Senior Vice President,	2003	338,169(8)	—	47,336	72,500	—
Technical Operations(7)	2002	246,709	132,786(5)	15,772	162,500	—
Richard Murray	2004	298,085	151,000(10)	—	105,000	2,000
Senior Vice President and	2003	202,600	—	—	105,000	2,000
Chief Scientific Officer(9)	2002	—	—	—	—	—
Steven E. Benner	2004	367,605	80,000(4)	—	70,000	—
Senior Vice President and	2003	355,874	400,000(5)	15,139	60,000	—
Chief Medical Officer(11)	2002	50,578	125,000(5)	9,007	150,000	—
Laurie Torres	2004	216,787	209,110(13)	—	37,500	2,000
Vice President, Human	2003	94,067	—	—	205,000	—
Resources(12)	2002	—	—	—	—	—

Laurence Jay Korn	2004	361,657(15)	—	515,000(16)	—	—
Director(14)	2003	516,242	—	—	20,000	2,000
	2002	512,075	—	—	300,000	2,000

(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 relocation costs reimbursed by the Company.

(3) Reflects Company matching 401(k) contributions.

(4) Represents a management bonus paid by the Company.

(5) Represents a relocation bonus paid by the Company.

(6) Represents a hiring bonus paid by the Company.

(7) Brett Schmidli has served as our Senior Vice President, Technical Operations since January 2002.

(8) 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.

(9) Richard Murray has been our Senior Vice President and Chief Scientific Officer since March 2004, and served as our Vice President, Research from April 2003 through February 2004.

(10) Includes $91,000 as retention bonus and $60,000 as management bonus.

(11) Steve E. Benner has been our Senior Vice President and Chief Medical Officer since November 2002.

(12) Laurie Torres has been our Vice President, Human Resources since November 2003.

(13) Includes $204,110 relocation bonus and $5,000 management bonus.

(14) Dr. Korn resigned as an executive officer of the Company and as Chairman of the Board of Directors in June 2004, but remains a member of the Board of Directors.

(15) Includes approximately $100,000 in accrued, but unused, vacation time.

(16) Represents a severance payment to Dr. Korn upon his resignation as an executive officer of the Company in June 2004.

Stock Options Granted in Fiscal 2004

The following table provides the specified information concerning grants of options to purchase our Common Stock made during the fiscal year ended December 31, 2004, to the Named Executive Officers:

OPTION GRANTS IN THE LAST FISCAL YEAR

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(4)	
Name	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	140,000	4.31	15.25	7/23/2014	1,342,690	3,402,640
Brett Schmidli	60,000	1.85	15.25	7/23/2014	575,439	1,458,274
Richard Murray	105,000	3.23	15.25	7/23/2014	1,007,018	2,551,980
Steven E. Benner	70,000	2.15	15.25	7/23/2014	671,345	1701,320
Laurie Torres	37,500	1.15	15.25	7/23/2014	359,649	911,421
Laurence Jay Korn	—	—	—	—	—	—

(1) Options granted vest over a four year period at the rate of one fourth one year after the date specified at the time of grant (typically the hire date or an anniversary of the hire date) and $^1/_{48}$ per month thereafter for each full month of the optionee's continuous employment with the Company. Only vested shares are exercisable. 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 $20.66 in 2004 (closing price as of December 31, 2004) would yield profits of $12.99 per share at 5% appreciation per year over ten years or $32.93 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.

Option Exercises and Fiscal 2004 Year End Values

The following table provides the specified information concerning exercises of options to purchase our Common Stock in the fiscal year ended December 31, 2004, and unexercised options held as of December 31, 2004, 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 12/31/04		Value of Unexercised In-the-Money Options at 12/31/04(1)	
			Unexercisable	Exercisable	Unexercisable	Exercisable
Mark McDade	100,000	1,072,370	641,251	438,749	6,910,931	5,101,569
Brett Schmidli	—	—	136,042	158,958	728,522	479,103
Richard Murray	17,500	213,123	142,188	50,312	1,222,487	466,438
Steven E. Benner	56,250	607,114	169,584	54,166	1,570,856	504,682
Laurie Torres	—	—	105,470	37,030	720,656	256,069
Laurence Jay Korn	306,400	4,946,605	11,668	2,108,332	63,907	12,231,143

(1) Based on a value of $20.66, which was the closing price of our Common Stock as of December 31, 2004.

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 $4,500 each fiscal quarter and may be reimbursed for expenses incurred in attending each Board and committee meeting. Each Outside Director is also authorized to receive an additional fee of $1,000 for each Board meeting at which the director is present in person and $500 for each Board meeting at which the director is present by telephone. In addition to the fees described for attendance at Board meetings, each member of the Audit Committee will also receive an annual retainer of $7,000, the Chair of the Audit Committee will receive an annual retainer of $9,000, members of the Compensation, Nominating and Governance and Scientific Review Committees will receive an annual retainer of $6,000 and the Chair of each of these latter committees will receive an annual retainer of $8,000. The Chairman of the Board is also authorized to receive cash compensation in the amount of $25,000 each fiscal quarter. In addition, in 2004, 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 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, 2004, 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, 2004, 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 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 Executive Team will be subject to acceleration. The Executive 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 Executive 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 Executive 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 Executive 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 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, effective on May 1, 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 was entitled to receive the same salary, benefits and vesting of stock options as before his resignation, provided that, after April 30, 2004, his salary was subject to re-negotiation. On March 26, 2004, the Company and Dr. Korn entered into Amendment No. 1 to the Special Compensation and Continued Employment Agreement (the "Amended Agreement"). Pursuant to the Amended Agreement, on June 30, 2004 Dr. Korn resigned as

Chairman of the Company's Board and as an employee of the Company, delivered to the Company a signed general release as provided under the Amended Agreement and received a lump sum payment of $515,000 in addition to his accrued but unused vacation time, less applicable withholding taxes. Dr. Korn also became vested in 12 months of unvested stock options previously granted to him under the Company's stock option plans. Dr. Korn will continue to receive certain current fringe benefits until June 30, 2005. The Company provided Dr. Korn with leased office space without charge until February 28, 2005.

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 AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding beneficial ownership of our Common Stock as of December 31, 2004, 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	14,381,014	15%
Delaware Management Holdings(3) 2005 Market Street Philadelphia, PA 19103	7,262,301	7.58%
Mark McDade(4)	400,833	*
Rich Murray(5)	104,570	*
Steven E. Benner, M.D., M.H.S.(4)	67,291	*
Brett L. Schmidli(4)	172,500	*
Laurie Torres(4)	43,749	*
Laurence Jay Korn, Ph.D.(6)	3,048,592	3.11%
Karen A. Dawes(4)	26,000	*
L. Patrick Gage, Ph.D.(7)	35,000	*
George M. Gould, Esq.(8)	224,000	*
Max Link, Ph.D.(9)	135,666	*
Jon S. Saxe, Esq.(10)	622,930	*
Cary L. Queen, Ph.D.(11)	2,575,414	2.67%
All directors and executive officers as a group (17 persons)(12)	8,627,196	8.53%

*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 736,000,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 7,235,513 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, 2004.

(5) Includes 56,250 shares issuable upon the exercise of options which are currently, or which will become exercisable within 60 days after December 31, 2004.

(6) Includes 2,115,414 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2004.

(7) Includes 33,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2004.

(8) Includes 188,000 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2004.

(9) Includes 35,666 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2004.

(10) Includes 515,250 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2004.

(11) Includes 500,414 shares issuable upon the exercise of options which are currently, or which will become, exercisable within 60 days after December 31, 2004. 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.

(12) Total includes all directors and officers who served in that capacity as of December 31, 2004 and 5,307,701 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, 2004.

Equity Compensation Plan Information

The following table provides information as of December 31, 2004 concerning our equity compensation plans:

	(a) Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity Compensation Plans Approved by Stockholders	7,419,568	$ 13.49	5,166,925(1)
Equity Compensation Plans Not Approved by Stockholders(2)	7,795,480	$ 19.09	1,952,277
Total	15,215,048	$ 16.36	7,119,202

(1) Includes 807,894 shares available for future issuance under the Company's 1993 Employee Stock Purchase Plan.

(2) See footnote 16 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

None.

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 forth 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 2004 and 2003 and for other services rendered during 2004 and 2003 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:

(in thousands)	2004	% of Total	2003	% of Total
Fee Category:				

Audit Fees	**$ 537**	85%	**$ 507**	86%
Audit-Related Fees	**29**	5%	**22**	4%
Tax Fees	**63**	10%	**59**	10%
All Other Fees	**3**	—	**—**	—
Total Fees	**$ 632**		**$ 588**	

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 2004, audit fees included approximately $40,000 in services related to post-effective amendment filings for our registration statement on Form S-3 and approximately $200,000 for attestation services surrounding the effectiveness of our internal control environment. In 2003, audit fees include approximately $235,000 in 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.

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 2004 and 2003, these services primarily relate to accounting consultations in connection with potential collaborations and patent licensing agreements and consultations related to our compliance with Section 404 of the Sarbanes-Oxley Act.

Tax Fees: Tax fees consist of tax compliance/preparation and other tax services. In 2004 and 2003, 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 accounting literature subscription 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.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(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.

Item
Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statements of Cash Flows
Consolidated Statements of Stockholders' Equity
Notes to Consolidated Financial Statements
Report of Ernst & Young LLP, Independent Auditors

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

(3) 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.)
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.)
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. (Incorporated by reference to Exhibit 10.39 to Annual Report on Form 10-K filed on March 8, 2004)
*10.40	Offer Letter by and between the Company and Ms. Laurie Torres dated September 10, 2003. (Incorporated by reference to Exhibit 10.40 to Annual Report on Form 10-K filed March 8, 2004)
10.41	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).
10.42	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).
10.43	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). (Incorporated by reference to Exhibit 10.45 to Annual Report on Form 10K filed March 8, 2004.)
10.44	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). (Incorporated by reference to Exhibit 10.46 to Annual Report on Form 10K filed March 8, 2004.)
10.45	Amended No. 1 to the Herceptin License Agreement between the Company and Genentech, Inc., dated as of December 18, 2003. (Incorporated by reference to Exhibit 10.47 to Annual Report on Form 10K filed March 8, 2004.)
10.46	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). (Incorporated by reference to Exhibit 10.48 to Annual Report on Form 10K filed March 8, 2004.)
10.47	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). (Incorporated by reference to Exhibit 10.49 to Annual Report on Form 10K filed March 8, 2004.)
*10.48	Postretirement Healthcare Plan. (Incorporated by reference to Exhibit 10.50 to Annual Report on Form 10K filed March 8, 2004.)
10.49	Amendment No. 1 to Special Compensation and Employment Agreement Dated May 1, 2002 Between Laurence Jay Korn and Protein Design Labs, Inc. (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10Q filed May 5, 2004).
10.50	Co-Development and Commercialization Agreement between the Company and Hoffman-La Roche, dated September 14, 2004 (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 5, 2004.)
10.51	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 (updated redacted version filed herewith with certain confidential portions deleted and marked by notation indicating such deletion).
10.52	Manufacturing Agreement between the Company and ICOS Corporation, a Washington corporation, dated August 29, 2003 (updated redacted version filed herewith with certain confidential portions deleted and marked by notation indicating such deletion).
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 Independent Registered Public Accounting Firm.
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).

* Management contract or compensatory plan or arrangement.

(b) See (a)(3) above.

(c) See (a)(1) 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 14, 2005
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 11, 2005
/s/ GLEN SATO (Glen Sato)	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2005
/s/ LAURENCE JAY KORN (Laurence Jay Korn)	Director	March 11, 2005
/s/ (JON S. SAXE (Jon S. Saxe)	Director	March 11, 2005
/s/ CARY L. QUEEN (Cary L. Queen)	Director	March 11, 2005
/s/ GEORGE M. GOULD (George M. Gould)	Director	March 11, 2005
/s/ MAX LINK (Max Link)	Chairman of the Board of Directors	March 11, 2005
/s/ L. PATRICK GAGE (L. Patrick Gage)	Director	March 11, 2005
/s/ KAREN A. DAWES (Karen A. Dawes)	Director	March 11, 2005

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.

AMENDED AND RESTATED WORLDWIDE AGREEMENT

This Amended and Restated Worldwide Agreement is entered into as of October 1, 2003 (the **"Effective Date"**), by and among, on the one hand, HOFFMANN-LA ROCHE INC., a New Jersey corporation having offices at 340 Kingsland Street, Nutley, New Jersey 07110 (**"Roche-Nutley"**) and F. HOFFMANN-LA ROCHE LTD of Basel, Switzerland (**"F. Roche**") (Roche-Nutley and F. Roche are hereinafter individually and collectively referred to as **"Roche**") and, on the other hand, PROTEIN DESIGN LABS, INC., a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555 (**"PDL"**).

RECITALS

Roche and PDL were originally parties to agreements dated January 31, 1989, as amended (the **"1989 Agreements"**) pertaining to humanized and chimeric antibodies against the interleukin-2 receptor (**"IL-2R"**).

Under the 1989 Agreements, PDL exclusively licensed to Roche rights to a humanized antibody now known as Daclizumab (as defined below).

Roche is currently marketing Daclizumab under the trademark Zenapax® for the prevention of acute organ rejection in patients receiving kidney transplants.

In 1999, Roche and PDL replaced the 1989 Agreements with two new agreements (as amended, known separately as the **"1999 PDL/Roche Agreement"** and the **"F. Roche Agreement,"** respectively, and collectively as the **"1999 Agreements"**) which provided PDL with rights to develop and, if successful, promote Daclizumab in autoimmune indications for increased compensation from the 1989 Agreements.

Roche and PDL now desire to replace the 1999 Agreements with this Amended and Restated Worldwide Agreement that (1) reverts to PDL all IL-2R antibody rights licensed to Roche by PDL under the 1999 Agreements, subject to Roche's continuing exclusive license to market and sell Daclizumab for Transplant Indications in the Roche Territory and develop and commercialize products based on **[*]** that **[*]** to the **[*]** of **[*]**; (2) grants to PDL the sole and exclusive worldwide rights under Roche's relevant intellectual property to develop, and, if successful, market and sell Daclizumab for Autoimmune Indications and Other Indications; and (3) grants PDL the right to purchase all of Roche's remaining rights to Daclizumab, subject to Roche's right to retain its exclusive license from PDL to develop and commercialize products based on **[*]** that **[*]** to the **[*]** of **[*]**.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants set forth below, PDL and Roche mutually agree to amend and restate the 1999 Agreements in this single Amended and Restated Worldwide Agreement as follows:

I. DEFINITIONS

For the purposes of this Amended and Restated Worldwide Agreement, the following terms, when written with an initial capital letter, shall have the meaning ascribed to them below. All references to particular Appendices, Articles and Sections shall mean the Appendices to, and Articles and Sections of, this Amended and Restated Worldwide Agreement, unless otherwise specified.

1.1 **"AAGS"** shall mean the average annualized Roche Adjusted Gross Sales of Daclizumab calculated according to the following:

[*]

where **[*]** is the **[*]** for the period from **[*]** through the most recent **[*]** ended **[*]** the **[*]** of (i) the date of **[*]** that **[*]** the **[*]**; or (ii) the date of **[*]** that **[*]** the **[*]**;

[*] is that portion of **[*]** that **[*]**, to **[*]** reasonable satisfaction, to be **[*]** to **[*]** for **[*]** in **[*]** or **[*]**; and

[*] is the **[*]** of **[*]** from (and including) **[*]** through the end of the **[*]** ended **[*]** to the **[*]** of (i) the date of **[*]** that **[*]** the **[*]**; or (ii) the date of **[*]** that **[*]** the **[*]**.

By way of illustration and without limitation, **[*]**

1.2 **"Acting Party"** has the meaning set forth in Section 12.1(c).

1.3 **"Affiliates"** 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, or more than a fifty percent (50%) interest in the income of, such corporation or other business entity. Anything to the contrary in this paragraph notwithstanding, **[*]**

1.4 **"AI Trademarks"** means all trademarks used in connection with the marketing, promotion, and sale of Daclizumab by PDL or its sublicensee(s) and all trademark registrations and applications therefor, and all goodwill associated therewith.

1.5 **"Application"** means a new application, or a supplement or an amendment to an existing application, for marketing approval for an Autoimmune Indication in the Territory.

1.6 **"Autoimmune Indications"** or **"AI"** means all indications that involve pathogenic consequences, including tissue injury, produced by autoantibodies or autoreactive T lymphocytes interacting with self epitopes, i.e., autoantigens. Autoimmune Indications shall

include, without limitation, asthma, psoriasis, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, juvenile rheumatoid arthritis, polymytosis, Type I diabetes, sarcoidosis, Sjogrens syndrome, chronic active non-pathogenic hepatitis, non-infectious uveitis (Behcets), aplastic anemia, regional non-pathogenic enteritis (including ulcerative colitis, Crohn's Disease and inflammatory bowel disease), Kawasaki's disease, post-infectious encephalitis, multiple sclerosis, and tropic spastic paraparesis.

1.7 **"Change of Control"** means a transaction in which Roche either (a) sells, conveys or otherwise disposes of all or substantially all of its property or business; or (b) either (i) merges or consolidates with any other entity (other than a wholly-owned subsidiary of Roche); or (ii) effects any other transaction or series of transactions, in each case of clause (i) or (ii), such that the voting stockholders of Roche immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving entity following the closing of such merger, consolidation, other transaction or series of transactions.

1.8 **"Combination Product"** means any product containing both an ingredient that causes it to be considered a Licensed Product and one or more other therapeutically active ingredients.

1.9 **"Commercialization Term"** means the period commencing on the Effective Date and ending on the earliest of (a) the Reversion Effective Date; (b) the Put Right Effective Date; and (c) if Roche does not exercise the Roche Put Right and the Exercise Period ends without PDL exercising the Transplant Reversion, the date Roche ceases to sell Daclizumab in every country in the Roche Territory, as permitted under this Amended and Restated Worldwide Agreement.

1.10 **"Controlled"** means, with respect to any intellectual property right, that the party has a license to such intellectual property right and has the ability to grant to the other party a sublicense to such intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such party would be first required hereunder to grant the other party such sublicense.

1.11 **"Cost of Goods"** means the manufacturing cost of either (a) unformulated bulk Daclizumab, or (b) finished Daclizumab product made from unformulated bulk, as the case may be, calculated in accordance with internal cost accounting methods consistently applied by a party for its other biologics pharmaceutical products, provided that such methods comply with **[*]**. Cost of Goods shall include **[*]**. As used in this Amended and Restated Worldwide Agreement, the Cost of Goods shall not exceed **[*]**

1.12 **"Cover"** (including variations thereof such as "Covering" or "Covered"), means that the manufacture, use, sale, offer for sale, or importation of a particular product would infringe a Valid Claim of a patent in the absence of rights under such patent. The determination of whether a particular product is Covered by particular Valid Claims shall be made on a country-by-country basis.

1.13 **"Daclizumab"** means any product that contains humanized anti-Tac (as defined under "Field").

1.14 **"Daclizumab Assets"** means all assets owned by Roche or its Affiliates and relevant solely to the development or commercialization of Daclizumab, other than the Trademarks and the Roche Owned Patents. Daclizumab Assets include, without limitation:

(a) domain names used in connection with the sale or promotion of Daclizumab;

(b) all then current promotional materials, including brochures, leave-behind materials, product fact sheets, advertisements in all media;

(c) all then current packaging art copy, and all trade dress rights thereto;

(d) rights to any "look and feel" of any materials referenced in (a) through (c) above and used in connection with the marketing, sale or promotion of Daclizumab and any and all copyrights or other intellectual property rights appurtenant thereto;

(e) all then current sales training materials and medical education materials;

(f) copies of market research surveys, analyses, and reports;

(g) then current customer lists, sales records, lists of distributors;

(h) regulatory filings, INDs, agreements related to physician sponsored INDs (to the extent assignable), CTXs, BLAs, and foreign equivalents of the foregoing, and all associated communications with regulatory authorities in the Roche Territory (excluding manufacturing approvals); and

(i) then current contracts with managed care groups, hospitals, transplant centers, pharmaceutical benefit managers, distributors and other similar Third Parties.

1.15 **"Excluded Field"** means **[*]** that (a) **[*]** to the **[*]** of **[*]**, (b) **[*]** the **[*]** of **[*]**, and (c) may also **[*]**. The Parties agree that Daclizumab is not in the Excluded Field.

1.16 **"Excluded Product"** means any product in the Excluded Field, including any Combination Product, that contains an **[*]** that was **[*]** by **[*]** on behalf of **[*]** pursuant to the **[*]**. **[*]** shall be deemed to be an Excluded Product.

1.17 **"Exercise Period"** has the meaning set forth in Section 5.2(a).

1.18 **"FDA"** means the United States Food and Drug Administration and any successor agency thereto, and/or any equivalent foreign governmental agency, depending on the context.

1.19 **"Field"** means any humanized or chimeric antibody that binds to IL-2R, where "humanized" means a genetically engineered combination of a substantially human framework region and constant region, and complementarity determining regions from non-human antibodies, and where "chimeric" means a genetically engineered combination of human constant region and non-human variable region. **"Antibodies in the Field**" means humanized and chimeric antibodies that bind to IL-2R. It is believed that these Antibodies in the Field may be useful for therapeutic, diagnostic, imaging and similar purposes. It is understood that the Field includes, but is not limited to, that certain humanized murine monoclonal antibody prepared against the p55 component of IL-2R (**"humanized anti-Tac"**). Furthermore, the Field includes, but is not limited to, all improvements relating to humanized anti-Tac, including without limitation modifications in structure introduced by genetic engineering, or by chemical or enzymatic cleavage. Also included within the Field shall be alternate hosts for producing humanized anti-Tac, methods for purification, formulations incorporating humanized anti-Tac, and uses and methods of use for humanized anti-Tac in human medicine.

1.20 **"Joint Inventions"** means any inventions in the Field, whether patented or not, that are jointly made during the period beginning on January 31, 1989 and continuing until the end of the Commercialization Term by at least one (1) PDL employee or person contractually required to assign or license patent rights covering such inventions to PDL and at least one (1) Roche-Nutley or F. Roche employee or person contractually required to assign or license patent rights covering such inventions to Roche-Nutley or F. Roche.

1.21 **"Licensed Product"** means any product, other than an Excluded Product, in the Field, including any Combination Product, the making, importation, use, offer for sale, or sale of which utilizes Roche Know-How, Roche Patents, or Joint Inventions or would, in the absence of this Amended and Restated Worldwide Agreement, infringe a Valid Claim of a Roche Patent. Daclizumab shall be deemed to be a Licensed Product.

1.22 **"Major Country"** means the United States, United Kingdom, France, Italy and Germany.

1.23 **"Other Indications"** means all indications other than Transplant Indications and Autoimmune Indications.

1.24 "**Other Licensed Products"** means all Licensed Products other than Daclizumab.

1.25 **"PDL Adjusted Gross Sales"** means the gross invoice price of Daclizumab sold or otherwise disposed of for consideration in the Roche Territory by PDL, its Affiliates or sublicensees (other than Roche and its Affiliates hereunder) to independent Third Parties not an Affiliate of the seller, reduced by the following amounts: (a) the amounts actually allowed as volume or quantity discounts, rebates, price reductions, returns (including withdrawals and recalls); and (b) sales, excise and turnover taxes imposed directly on and actually paid by PDL, its Affiliates or sublicensees.

When calculating the PDL Adjusted Gross Sales, the amount of such sales in foreign currencies shall be converted into U.S. dollars at the average rate of exchange at the time for the applicable calendar quarter in accordance with PDL's then-current standard practices.

In the case of Combination Products for which Daclizumab and each of the other therapeutically active ingredients contained in the Combination Product have established market prices when sold separately, PDL Adjusted Gross Sales shall be determined by multiplying the PDL Adjusted Gross Sales for each such Combination Product by a fraction, the numerator of which shall be the established market price for the form and formulation of Daclizumab contained in the Combination Product, and the denominator of which shall be the sum of the established market prices for such form and formulation of Daclizumab plus the other active ingredients contained in the Combination Product. When such separate market prices are not established, then the parties shall negotiate in good faith to determine the method of calculating PDL Adjusted Gross Sales for Combination Products.

If PDL or its Affiliates or sublicensees receive non-cash consideration for Daclizumab sold or otherwise transferred to an independent Third Party not an Affiliate of the seller or transferor, the fair market value of such non-cash consideration on the date of the transfer as known to PDL, or as reasonably estimated by PDL if unknown, shall be deemed the PDL Adjusted Gross Sales for such Daclizumab sold or otherwise transferred.

1.26 **PDL Know-How"** means, except as otherwise set forth in this Section 1.26, all inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results in the Field, and improvements thereon, including any information regarding the physical, chemical, biological, toxicological, pharmacological, clinical, and veterinary data, dosage regimens, control assays and specifications of Daclizumab (collectively, **"Know-How in the Field"**), that is owned or Controlled by PDL or its Affiliates as of the Effective Date or that is developed or Controlled by PDL or its Affiliates during the term of this Amended and Restated Worldwide Agreement, and which Know-How in the Field is reasonably required or useful for manufacturing, using or selling Daclizumab; provided, however, that PDL Know-How excludes any Know-How in the Field of any kind concerning generic methods of manufacturing, designing, developing or preparing antibodies including, but not limited to, methods of humanizing antibodies, methods of reducing the immunogenicity of antibodies, and methods of increasing the affinity of antibodies.

1.27 **"PDL Net Sales"** means the amount determined by deducting **[*]** from PDL Adjusted Gross Sales to cover all other expenses or discounts, including but not limited to cash discounts, custom duties, transportation and insurance charges and other direct expenses, to the extent not already deducted from the amount invoiced.

1.28 **"PDL Patents"** means all patent applications owned or Controlled by PDL alone or with a Third Party (**"Sole PDL Patents"**) and all patent applications resulting from Joint Inventions (**"Joint Roche-PDL Patents"**) Covering Daclizumab, which are filed prior to or during the term of the 1989 Agreements, the 1999 Agreements or this Amended and Restated Worldwide Agreement in the United States or any foreign jurisdiction, including any addition,

continuation, continuation-in-part or division thereof or any substitute application therefor; any patent issued with respect to 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; and any other United States or foreign patent or inventor's certificate covering products in the Field.

1.29 "**PDL Sole Territory**" means all countries of the world, as listed in Appendix C (which the parties may agree to update from time to time), with respect to which Roche has granted an exclusive license to PDL, in connection with the previous return or reversion of Roche's rights under the 1999 Agreements.

1.30 **"Product Operating Committee"** or **"POC"** has the meaning set forth in Section 6.2(a).

1.31 **"Put Exercise Fee"** has the meaning set forth in Section 5.3(b).

1.32 **"Put Right Effective Date"** has the meaning set forth in Section 5.3(a).

1.33 **"Queen et al. Patents"** means those Sole PDL Patents in the Territory claiming priority under 35 USC 120 to U.S. Patent Application Serial No. 290,975, filed December 28, 1988.

1.34 **"Reasonable Diligence"** means the same level of effort used by Roche in developing, registering, marketing and selling its own protein-based products that must be approved by the FDA before they can be sold in the Roche Territory. The parties acknowledge that Roche does not develop, register, market and sell its own protein-based products in every country within the Roche Territory, and it is understood that the exercise by Roche of reasonable diligence shall be determined by judging its efforts in the Roche Territory taken as a whole.

1.35 **"Regulatory Approval"** means the granting of all governmental regulatory approvals required, if any, for the sale of a Licensed Product in a given country or jurisdiction within the Territory.

1.36 **"Reversion Effective Date"** has the meaning set forth in Section 5.2(b).

1.37 **"Reversion Exercise Fee"** has the meaning set forth in Section 5.2(c).

1.38 **"Roche Adjusted Gross Sales"** means the gross invoice price of Daclizumab sold or otherwise disposed of for consideration by Roche, its Affiliates or sublicensees (other than PDL and its Affiliates hereunder) to independent Third Parties not an Affiliate of the seller, reduced by the following amounts: (a) the amounts actually allowed as volume or quantity discounts, rebates, price reductions, returns (including withdrawals and recalls); and (b) sales, excise and turnover taxes imposed directly on and actually paid by Roche, its Affiliates or sublicensees.

When calculating the Roche Adjusted Gross Sales, the amount of such sales in foreign currencies shall be converted into U.S. dollars at the average rate of exchange at the time for the applicable calendar quarter in accordance with Roche's then-current standard practices.

In the case of Combination Products for which Daclizumab and each of the other therapeutically active ingredients contained in the Combination Product have established market prices when sold separately, Roche Adjusted Gross Sales shall be determined by multiplying the Roche Adjusted Gross Sales for each such Combination Product by a fraction, the numerator of which shall be the established market price for the form and formulation of Daclizumab contained in the Combination Product, and the denominator of which shall be the sum of the established market prices for such form and formulation of Daclizumab plus the other active ingredients contained in the Combination Product. When such separate market prices are not established, then the parties shall negotiate in good faith to determine the method of calculating Roche Adjusted Gross Sales for Combination Products.

If Roche or its Affiliates or sublicensees receive non-cash consideration for Daclizumab sold or otherwise transferred to an independent Third Party not an Affiliate of the seller or transferor, the fair market value of such non-cash consideration on the date of the transfer as known to Roche, or as reasonably estimated by Roche if unknown, shall be deemed the Roche Adjusted Gross Sales for such Daclizumab sold or otherwise transferred.

1.39 **"Roche Commercialization Activities"** has the meaning set forth in Section 4.1(a).

1.40 **"Roche Controlled Patents"** means all patent applications Controlled by Roche or its Affiliates and not Controlled by PDL or its Affiliates Covering inventions in the Field that are filed prior to or during the term of this Amended and Restated Worldwide Agreement in the United States or any foreign jurisdiction, including any addition, continuation, continuation-in-part or division thereof or any substitute application therefor; any patent issued with respect to 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; and any other United States or foreign patent or inventor's certificate covering inventions in the Field. Roche Controlled Patents are, specifically, those listed on Schedule 2.8(b).

1.41 **"Roche Inventions"** means any inventions in the Field that are made prior to or during the term of this Amended and Restated Worldwide Agreement by employees of Roche or persons contractually required to assign or license patent rights covering such inventions to Roche.

1.42 **"Roche Know-How"** means all Know-How in the Field that is owned or Controlled by Roche or its Affiliates as of the Effective Date, or that is developed or Controlled by Roche or its Affiliates during the Commercialization Term and which Know-How in the Field is reasonably required or useful for seeking registration of, manufacturing, using or selling Daclizumab, as the case may be, provided, however, that this portion of Roche Know-How excludes any Know-How in the Field of any kind concerning generic methods of manufacturing,

designing, developing or preparing antibodies including, but not limited to, methods of humanizing antibodies, methods of reducing the immunogenicity of antibodies, and methods of increasing the affinity of antibodies. For clarity, Roche Know-How includes all Know-How in the Field provided to PDL by

Roche or its Affiliates under the 1989 Agreements and 1999 Agreements.

1.43 "**Roche Licensed Know-How"** means that portion of Roche Know-How that is reasonably required or useful for seeking registration of, manufacturing, using or selling Daclizumab for Autoimmune Indications or any Other Indication, but shall not include **[*]**.

1.44 **"Roche Licensed Patents"** means those Roche Patents that Cover in whole or in part the manufacture, importation, offer for sale or sale of Daclizumab or any Other Licensed Products, or the use of Daclizumab or any Other Licensed Products in Autoimmune Indications or Other Indications.

1.45 **"Roche Net Sales"** means the amount determined by deducting **[*]** from Roche Adjusted Gross Sales to cover all other expenses or discounts, including but not limited to cash discounts, custom duties, transportation and insurance charges and other direct expenses, to the extent not already deducted from the amount invoiced. Notwithstanding the foregoing, **"Roche Net Sales of Excluded Products"** shall be calculated in the same manner as Roche Net Sales, except that for the purpose of such calculation, Roche Adjusted Gross Sales shall be based on the gross invoice price of Excluded Products.

1.46 **"Roche Owned Patents"** means all patent applications owned by Roche or its Affiliates (**"Sole Roche Patents"**) alone or with a Third Party, and all patent applications resulting from Joint Inventions (**"Joint Roche-PDL Patents"**) covering inventions in the Field that are filed prior to or during the term of this Amended and Restated Worldwide Agreement in the United States or any foreign jurisdiction, including any addition, continuation, continuation-in-part or division thereof or any substitute application therefor; any patent issued with respect to 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; and any other United States or foreign patent or inventor's certificate covering inventions in the Field. Roche Owned Patents as of the Effective Date are, specifically, those listed on Schedule 2.8(a).

1.47 **"Roche Patents"** means both the Roche Owned Patents and the Roche Controlled Patents.

1.48 **"Roche Products"** means Daclizumab and any Excluded Products.

1.49 **"Roche Put Right"** has the meaning set forth in Section 5.3(a).

1.50 **"Roche Territory"** means, collectively, (a) the United States of America ("**U.S.**" or "**U.S.A.**" or "**United States**") and its territories and possessions where the patent laws of the

United States are in force and (b) all other countries in the Territory, excluding the PDL Sole Territory (the "**Roche ROW Territory**").

1.51 **"Territory"** means all the countries of the world.

1.52 **"Third Party"** means any person or entity other than PDL, Roche, and their respective Affiliates.

1.53 **"Third Party License"** means (a) any of the license agreements set forth on Appendix B that were entered into by either party, prior to the Effective Date, in order for Roche or PDL to manufacture, use, import, offer for sale or sell Daclizumab or (b) any license agreement entered into with a Third Party by either party in accordance with Section 7.4(b).

1.54 **"Trademarks**" means the trademark "Zenapax®," and all trademark registrations and applications therefor, and all goodwill associated therewith, and all other trademarks owned by Roche (except for any Roche housemarks or trade names) and used in connection with the sale or promotion of Daclizumab in the Roche Territory.

1.55 **"Transplant Foreign Filing Expenses"** means ex parte out-of-pocket expenses (a) incurred by PDL after January 31, 1989, but prior to the Effective Date, in connection with the prosecution and maintenance in the Roche ROW Territory of patent applications and patents included within the PDL Patents or Joint Roche-PDL Patents and (b) reimbursed by Roche pursuant to Section 7.2(a) of the 1999 PDL/Roche Agreement or Section 5.3(a) of the F. Roche Agreement.

1.56 **"Transplant Indications"** means all indications that involve the suppression of rejection of transplanted organs, bone marrow or other tissue, including, without limitation, solid organ transplantation (including tolerance induction and xenotransplantation), bone marrow transplantation, graft versus host disease and cell transplantation. In any event, if a given indication satisfies the criteria for both an Autoimmune Indication and a Transplant Indication, such indication shall be deemed a Transplant Indication and not an Autoimmune Indication, provided that an Autoimmune Indication shall not be deemed a Transplant Indication merely because it may cause the need for a transplant (e.g., Type I diabetes, even if it causes the need for an organ transplant).

1.57 **"Transplant Reversion"** has the meaning set forth in Section 5.2(a).

1.58 **"Valid Claim"** means a claim in any issued patent that has not been disclaimed or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction by a decision beyond right of review.

II. LICENSE GRANTS

2.1 License Grant to PDL On Effective Date.

(a) Subject to the terms and conditions of this Amended and Restated Worldwide Agreement, Roche grants to PDL and to PDL's Affiliates the worldwide right and license under the Roche Licensed Know-How and Roche Licensed Patents, to (i) develop, use, market, promote, and detail Daclizumab in the Territory solely for use in Autoimmune Indications and/or the Other Indications, and (ii) sell and offer for sale Daclizumab in the Territory, under the AI Trademarks.

(b) The licenses set forth in Sections 2.1(a)(i) and 2.1(a)(ii) shall be exclusive (even as to Roche) with respect to the Roche Licensed Know-How and Roche Licensed Patents that Roche or its Affiliate solely owns or has an exclusive license. With respect to the Roche Licensed Know-How and Roche Licensed Patents to which Roche or its Affiliate has a non-exclusive license, such licenses shall be sole, non-exclusive licenses. With respect to the Roche Licensed Know-How and Roche Licensed Patents that Roche or its Affiliate jointly owns, such licenses shall be sole licenses under Roche's interest in such Roche Licensed Know-How and Roche Licensed Patents. As used in this Section 2.1(b) a "sole" license means that the Roche will not grant to any Third Party a license that overlaps with the scope of the licenses granted to PDL under Section 2.1(a).

(c) Roche grants to PDL and to PDL's Affiliates, the nonexclusive right under the Roche Licensed Know-How and Roche Licensed Patents to make, have made, and import Daclizumab.

(d) PDL and its Affiliates may sublicense the rights and licenses granted to them under Sections 2.1(a) and (c) to any Affiliate or Third Party, with the right to further sublicense; provided, however, that without Roche's written consent, PDL shall not have the right to sublicense, during the Commercialization Term, any of the **[*]** rights or licenses in Section 2.1(a) to any other entity, that is, as of the time of such sublicensing, **[*]** in the **[*]** (in at least one **[*]** with **[*]**), or **[*]** in the **[*]** any **[*]** for the **[*]** of **[*]** in any **[*]**. It is expressly understood and agreed by Roche that PDL shall have the right to sublicense its rights under Sections 2.1(a) and (c) to **[*]**. Notwithstanding the preceding limitation on sublicensing, PDL and its Affiliates may use Third Party distributors in accordance with their customary practices.

(e) Subject to the terms and conditions of this Amended and Restated Worldwide Agreement, Roche grants to PDL and to PDL's Affiliates a worldwide right and license (or sublicense, as the case may be) under the Roche Licensed Know-How received by PDL pursuant to the 1989 Agreements, 1999 Agreements or Section 2.4 hereof, the Roche Controlled Patents and only those Roche Owned Patents listed in Schedule 2.8(a), to (i) develop, use, market, promote, and detail Other Licensed Products in the Territory solely for use in Autoimmune Indications and/or the Other Indications; (ii) sell and offer for sale Other Licensed Products in the Territory; and (iii) to make, have made, and import Other Licensed Products in the Territory.

(f) The license set forth in Section 2.1(e) shall be exclusive (even as to Roche) with respect to the Roche Controlled Patents that Roche or its Affiliate solely owns or has an exclusive license. With respect to the Roche Controlled Patents to which Roche or its Affiliate has a non-exclusive license, such license shall be a sole, non-exclusive license. With respect to

the Roche Owned Patents that Roche or its Affiliate jointly owns, such license shall be a sole license under Roche's interest in such Roche Owned Patents. PDL and its Affiliates shall have the right freely to sublicense, through multiple tiers, the rights and licenses granted to them under Section 2.1(e). Notwithstanding anything to the contrary in Section 2.1(e), the license to Roche Licensed Know-How shall be non-exclusive. Roche hereby covenants that, until the termination, pursuant to Section 2.2(a), of the license set forth in Section 2.1(e), it will not grant to any Third Party any right or license under the (i) Roche Controlled Patents to which Roche or its Affiliate has a non-exclusive license or (ii) Roche Owned Patents that Roche or its Affiliate jointly owns, to (A) develop, use, market, promote, and detail Other Licensed Products in the Territory for use in Autoimmune Indications and/or the Other Indications; (B) sell and offer for sale Other Licensed Products in the Territory; and (C) make, have made, and import Other Licensed Products in the Territory.

(g) If PDL wishes to receive a license with respect to Other Licensed Products in Autoimmune Indications and/or Other Indication, under any Roche Owned Patents that are not listed in Schedule 2.8(a), it shall **[*]** and Roche shall **[*]**.

2.2 License Grant to PDL On Reversion Effective Date or Put Right Effective Date.

(a) Effective only on the Reversion Effective Date or the Put Right Effective Date, Roche hereby grants the following license to PDL: subject to the terms and conditions of this Amended and Restated Worldwide Agreement, Roche grants to PDL and to PDL's Affiliates a worldwide right and license under the Roche Know-How and Roche Patents, to develop, use, manufacture, have manufactured, market, promote, import, offer for sale, sell and have sold Daclizumab and all Other Licensed Products in the Field and in the Territory. On the effectiveness of the license set forth in this Section 2.2(a), the licenses granted in Section 2.1(a), (c) and (e) shall terminate. PDL and its Affiliates shall have the right freely to sublicense, with the right to further sublicense, the right and license granted to them under this Section 2.2(a).

(b) For Daclizumab, the license set forth in Section 2.2(a) shall be exclusive (even as to Roche) with respect to the Roche Know-How and Roche Patents that Roche or its Affiliate solely owns or has an exclusive license. With respect to the Roche Know-How and Roche Patents to which Roche or its Affiliate has a non-exclusive license, the license set forth in Section 2.2(a) shall be a sole, non-exclusive license. With respect to the Roche Know-How and Roche Patents that Roche or its Affiliate jointly owns, the license set forth in Section 2.2(a) shall be a sole license under Roche's interest in such Roche Know-How and Roche Patents. Roche hereby covenants that it will not grant to any Third Party any right or license, under (i) the Roche Know-How and Roche Patents to which Roche or its Affiliate has a non-exclusive license or (ii) the Roche Know-How and Roche Patents that Roche or its Affiliate jointly owns, to develop, use, manufacture, have manufactured, market, promote, import, offer for sale and sell Daclizumab in the Field and in the Territory.

(c) For Other Licensed Products, the license set forth in Section 2.2(a) shall be non-exclusive. Notwithstanding the preceding sentence, Roche hereby covenants that it will not

grant licenses to any Third Party under the Roche Patents to make, have made, use, sell, offer for sale or import any Other Licensed Product.

2.3 Certain **[*]** To PDL of **[*]** Intellectual Property. PDL acknowledges and understands that **[*]** are **[*]** as to **[*]** (a) Roche has received, prior to the Effective Date, a **[*]** license under certain **[*]** of **[*]** that **[*]** cover the manufacture, use, importation, offer for sale or sale of humanized antibodies against IL-2R, including Daclizumab and any Other Licensed Products, and/or (b) **[*]** Roche has the right to **[*]** such licensed **[*]**, to the extent granted to Roche. In the event that the parties agree that Roche is **[*]** such license **[*]**, PDL shall be deemed to have been **[*]** pursuant to the **[*]**, as applicable, and such **[*]** will be deemed part of the **[*]** licensed thereunder. In the event that the parties agree that Roche **[*]** such rights, and/or that Roche **[*]** such rights to PDL as part of the **[*]**, Roche agrees to use diligent efforts to itself secure or assist PDL in securing from **[*]**, a license to such **[*]** from **[*]**, which license rights will be documented under a separate agreement from this Amended and Restated Worldwide Agreement. If **[*]** obtains **[*]** consent to the terms of such

separate agreement, then it shall be deemed a **[*]** and **[*]** shall **[*]** the costs of such license rights, in the manner and as set forth in Section 7.4, **[*]** the **[*]** the costs and royalties owed to **[*]** shall be as follows: **[*]** shall bear **[*]** of the cost of such license rights and **[*]** shall bear **[*]** of the costs of such license rights; and provided, however, that this addition or offset shall not cause the amount to be paid by PDL to Roche pursuant to Section 7.2(c), in the aggregate and after payment to **[*]**, to be less than **[*]** of **[*]** in **[*]**. On either the **[*]** or the **[*]**, **[*]** shall be **[*]** responsible for paying the prospective costs of such license from that date forward, as further detailed in Section 7.4(e). If the Exercise Period expires without **[*]** or **[*]**, then the parties will proceed as detailed in Section 7.4(f) with respect to Third Party Licenses.

2.4 Transfer of Roche Licensed Know-How to PDL. Promptly after the Effective Date, Roche shall transfer all Roche Licensed Know-How to PDL in the manner in which and to the extent to which the parties, prior to the Effective Date, have transferred know-how under the Joint Development Committee or the Joint Commercialization Committee under the 1999 Agreements. Thereafter, and until the Reversion Effective Date or the Put Right Effective Date, if Roche develops or gains Control of additional Roche Licensed Know-How, Roche shall promptly provide such additional Roche Licensed Know-How to PDL through the parties' participation in the POC. On either the Reversion Effective Date or the Put Right Effective Date, Roche shall transfer to PDL any Roche Know-How not previously transferred to PDL, including in particular, any Roche Know-How related to the Transplant Indications.

2.5 License Grants to Roche.

(a) Subject to the terms and conditions of this Amended and Restated Worldwide Agreement, PDL grants to Roche and to Roche's Affiliates, during the Commercialization Term, the exclusive (even as to PDL) right and license under the PDL Know-How and PDL Patents to (i) market, promote, and detail Daclizumab in the Roche Territory solely for use in the Transplant Indications, and (ii) to sell and offer for sale Daclizumab in the Roche Territory under the Trademarks. In addition, PDL grants to Roche and to Roche's Affiliates, the nonexclusive right under the PDL Know-How and PDL Patents to make, have made and import

Daclizumab, but only to the extent reasonably necessary for Roche to carry out its rights and obligations under this Amended and Restated Worldwide Agreement. Roche may sublicense the rights and licenses granted to Roche under this Section 2.5, subject to PDL's written consent, which consent PDL may not unreasonably withhold. It shall be deemed reasonable for PDL to withhold consent with respect to sublicense by Roche of any of the rights or licenses to any other entity that is **[*]** (in at least one **[*]** with **[*]**), or **[*]** in a **[*]** any **[*]** for the **[*]** of any **[*]**. Notwithstanding the preceding sentence, Roche and its Affiliates may use Third Party distributors in accordance with their customary practices. All sublicenses granted by Roche or its Affiliates of the licenses set forth in this Section 2.5(a) shall automatically terminate on the Reversion Effective Date or Put Right Effective Date.

(b) Subject to the terms and conditions of this Amended and Restated Worldwide Agreement, in particular the restrictions set forth in Section 3.1(b), PDL grants to Roche and to Roche's Affiliates the exclusive (even as to PDL) right and license, including the right to grant sublicenses, under the PDL Know-How and PDL Patents to use, develop, make, have made, sell, offer for sale, and import the Excluded Products in the Roche Territory; provided, however that the license granted under this Section 2.5(b) under **[*]** shall be nonexclusive.

(c) PDL hereby covenants that, until the expiration of **[*]**, it will not make, have made, use, sell, offer for sale or import any product in the Excluded Field Covered by **[*]** in the Roche Territory, and it will not grant to any Third Party any right or license under **[*]** the right to make, have made, use, sell, offer for sale or import any product in the Excluded Field in the Roche Territory.

(d) If during the term of this Amended and Restated Worldwide Agreement, Roche or its Affiliate challenges the validity or enforceability in any jurisdiction of **[*]**, then PDL shall have the right to **[*]** to Roche under this Amended and Restated Worldwide Agreement to PDL Patents that include **[*]**.

(e) Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to:

(i) knowingly use or practice, directly or indirectly, any PDL Know-How or PDL Patents for any other purposes other than those expressly permitted by this Amended and Restated Worldwide Agreement or any other written agreements in the Field between the Parties currently in existence and not expressly superceded by this Amended and Restated Worldwide Agreement, or which may later be entered into by the Parties;

(ii) market, promote, detail, sell or offer for sale Daclizumab, during the Commercialization Term, in any manner outside the scope of the licenses set forth in Section 2.5(a), including, in particular, for any use in the treatment of Autoimmune Indications or Other Indications; or

(iii) use, develop, make, have made, sell, offer for sale or import Excluded Products in any manner outside the scope of the licenses set forth in Section 2.5(b).

(f) PDL hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to market, promote, detail, sell or offer for sale Daclizumab, during the Commercialization Term, in any manner outside the scope of the licenses set forth in Sections 2.1 and 2.2.

2.6 Identification of the Queen et al Patents. Set forth on Appendix A is a list identifying patents or patent applications that comprise the Queen et al. Patents in the Roche Territory as of the Effective Date. If there are any changes, PDL shall update this list by delivering a supplement to Roche no less frequently than once per year during the term of this Amended and Restated Worldwide Agreement.

2.7 Cooperation Regarding Third Party Licenses. In the event Roche negotiates and intends to enter into a license agreement with a Third Party with respect to the right to make, use, sell, import, offer for sale or sale of any **[*]** under such Third Party's intellectual property, it shall so inform PDL and provide PDL the opportunity to participate in such negotiations and enter into such license agreement or take a sublicense thereunder with respect to **[*]**, on such terms as are agreed by the parties.

2.8 Roche Representations, Warranties and Covenants. Roche hereby represents and warrants as of the Effective Date as follows:

(a) To the best of Roche's knowledge, Schedule 2.8(a) identifies the Roche Owned Patents existing as of the Effective Date. To the extent that it is not prohibited from doing so, Roche agrees to make available to PDL copies of such Roche Owned Patents promptly following the Effective Date. Roche covenants that, to the extent any additional Roche Owned Patents are identified by Roche subsequent to the Effective Date and to the extent that it is not prohibited from doing so, it shall promptly inform PDL, and Schedule 2.8(a) shall be revised to so reflect such additional Roche Owned Patents.

(b) Schedule 2.8(b) identifies all of the license agreements under which Roche has rights to Roche Controlled Patents existing as of the Effective Date (other than the license rights from Genentech referred to in Section 2.3). Roche agrees to make available to PDL copies of such license agreements pursuant to which the Roche Controlled Patents were licensed to Roche promptly following the Effective Date, to the extent not already in PDL's possession and to the extent that Roche has a right to do so. **[*]** further covenants that, where it is not **[*]** to **[*]** to **[*]** such **[*]**, it will **[*]** to **[*]** from the **[*]** its **[*]** to do so. Roche shall not, without the prior written consent of PDL, terminate any agreement that grants Roche a license under a Roche Controlled Patent. Roche covenants that, to the extent any additional licenses under which Roche has rights to Roche Controlled Patents are identified by Roche or come into existence subsequent to the Effective Date, Roche shall promptly inform PDL, and Schedule 2.8(b) shall be revised to so reflect such additional licenses; provided, however, that in the event any royalty or other payment is owed to the licensor of any such Roche Controlled Patent **[*]** PDL, **[*]** shall not be responsible for any such royalty payments, and **[*]** shall so notify **[*]** in writing and **[*]** shall have a period of ninety (90) days to evaluate whether it desires that such **[*]** be included within the **[*]**

licensed to **[*]** under **[*]** and if so, the mechanism for payment to the **[*]** thereunder. Where **[*]** elects not to **[*]** to such Roche Controlled Patent, it agrees to **[*]**

(c) Roche has not granted any Third Party a license or other right that is currently in effect under any of the Roche Owned Patents for any purpose.

(d) To Roche's knowledge, Roche has complied with its obligation under 37 CFR §1.56(a) to disclose to the United States Patent and Trademark Office, during the pendency of each United States patent application included in the Roche Owned Patents, information known to Roche to be material to the patentability of the pending claims in such application. None of the Roche Owned Patents is involved in any interference or opposition proceeding, and, to Roche's knowledge, no such proceeding is being threatened with respect to any of the Roche Owned Patents.

(e) **[*]**

(f) **[*]**

(g) Roche and its Affiliates have not granted to any Third Party in any Major Country, any sublicense, under the license(s) to the PDL Know-How and PDL Patents that Roche and its Affiliates received pursuant to the 1999 Agreements, to: (i) promote and sell Daclizumab generally, and/or for use in Autoimmune Indications or the Other Indications; or (ii) develop, make, use, import, offer for sale and sell Other Licensed Products for any indication in the Field. Roche shall, prior to the **[*]**, disclose in writing to PDL all sublicenses that Roche or its Affiliate have granted, under the PDL Know-How and PDL Patents, to develop, make, use, import, promote, offer for sale and sell Daclizumab and Other Licensed Products for any indication in the Field. If any such sublicenses exist at such time, the parties, through the POC, will work together to **[*]** (including **[*]**, where practicable) such sublicense.

(g) Roche covenants that, in the event that Roche **[*]** of the **[*]** of the **[*]** of **[*]**, through whatever means, on PDL's request, Roche will within **[*]** days of such request, meet and discuss with PDL the impact of such event on the relationship between PDL and Roche at such time, and modify this Amended and Restated Worldwide Agreement to the extent deemed appropriate by both parties.

2.9 Termination of Certain Sublicenses. If, prior to the Effective Date, PDL and Roche or an Affiliate of Roche entered into any agreement(s), other than the 1999 Agreements, wherein PDL granted Roche or such Affiliate a sublicense with respect to Daclizumab or Other Licensed Product(s), under any Third Party intellectual property rights licensed by PDL, then such sublicenses are hereby terminated and replaced by the licenses set forth in Section 2.5.

III. DEVELOPMENT; REGULATORY ISSUES

3.1 Development by Roche.

(a) Development of Daclizumab. Following the Effective Date, **[*]** after the Effective Date. In addition, to the extent Roche receives any data or other results of any clinical trials pursuant to ongoing physician sponsored trials, Roche will update the POC with respect to such trial results and data. Further, Roche shall promptly forward to PDL any requests for new **[*]** studies involving Daclizumab that Roche receives after the Effective Date.

(b) Development of Excluded Products. Roche shall be solely responsible, at its sole cost and expense and at its sole discretion, for the non-clinical, clinical, and regulatory development of any Excluded Product. Notwithstanding the foregoing, it is understood and agreed that **[*]** for any indication other than **[*]** without the written consent of PDL, such consent not to be unreasonably withheld. The Parties recognize that it may be desirable to develop the Excluded Products for **[*]**, in which case the POC shall discuss and recommend to the parties whether **[*]**. Following the Effective Date, Roche shall use Reasonable Diligence in proceeding with the development and registration of Excluded Products in the Roche Territory, to the extent permitted under this Section 3.1(b). If Roche fails to exercise such diligence, PDL may terminate the license granted to Roche under Section 2.5(b), but shall not be obligated to do so.

3.2 Development by PDL.

(a) General. Following the Effective Date, PDL shall be solely responsible, at its sole cost and expense and at its sole discretion, for the non-clinical, clinical, and regulatory development of Daclizumab for all indications in the Territory, other than those trials referenced in Section 3.1(a),

subject to the restrictions set forth in Section 3.2(b). All data and information generated by PDL development activities pursuant to this Section 3.2(a) shall be PDL Know-How.

(b) Restriction on PDL Development. During the period commencing on the Effective Date and ending at the end of the Commercialization Term, PDL agrees not to pursue the clinical or regulatory development of Daclizumab for use in the **[*]** in the Roche Territory.

3.3 Assistance by Roche. At no cost to PDL (except as provided in the following sentence), Roche will allow PDL to cross-reference Roche regulatory filings and clinical data with respect to Daclizumab and will grant PDL reasonable access during normal business hours to such regulatory filings and clinical data. To the extent Roche is required under applicable law, rule or regulation, Roche, at PDL's cost, shall promptly make all filings reasonably required or useful to permit the use of the clinical materials, if any, supplied pursuant to Section 4.5(a) (e.g., preparation and filing of required technical reports, data summaries, or a regulatory dossier).

3.4 Adverse Event Reporting. Each party shall notify the other of all information coming into its possession concerning any and all side effects, injury, toxicity, pregnancy or sensitivity event associated with commercial or clinical uses, studies, investigations or tests with Daclizumab, throughout the world, whether or not determined to be attributable to Daclizumab (**"Adverse Event Reports"**). The parties shall each identify a person to coordinate the exchange of Adverse Event Reports (**"Report Coordinators"**) so as to enable timely reporting of such Adverse Event Reports to appropriate governmental and regulatory authorities consistent with all

laws, rules and regulations. The parties, through their Report Coordinators, have agreed in writing on formal procedures for such exchange, which are embodied in the PDL-Roche Procedure for the Exchange of Daclizumab Adverse Event Reports, dated December 2000 (**"Pharmacovigilance Agreement"**). Promptly after the Effective Date, Roche and PDL agree to cause their Report Coordinators (a) to review the Pharmacovigilance Agreement and (b) to negotiate in good faith an amendment to the Pharmacovigilance Agreement to reflect the terms of this Amended and Restated Worldwide Agreement, if the Report Coordinators agree that such an amendment is required. Such Pharmacoviligance Agreement (as amended, if applicable) shall survive the end of the Commercialization Term.

3.5 Copies of Responses. Within a reasonable time frame prior to submission of responses to any regulatory authority on product safety issues regarding Daclizumab, a copy of a near final draft response will be provided to the other party for review. Final copies of responses submitted to any regulatory authority will be provided to the other party within five (5) business days of document finalization.

3.6 Regulatory Actions. The party responsible to interact with regulators on a specific safety issue regarding Daclizumab must communicate action requested by regulators to the other party without delay. Such actions may include, for example, change in label, Dear Doctor letter, trial on hold for clinical safety reasons and the like.

3.7 Other Safety Issues. Either party may request that specific safety issues be discussed, and the parties will establish a Joint Safety Committee (**"JDSC"**), consisting of an equal number of representatives from each party, for such purpose. JDSC discussion on such issues will be for the purpose of advising each party concerning the collection and evaluation of safety data, and responding to any significant safety issues raised, or requests made, by regulatory authorities.

3.8 Registration. PDL shall notify Roche in writing if PDL determines that clinical trial results for Daclizumab justify filing an Application. Roche shall provide cross reference letters reasonably required or useful to allow PDL to make any such filing and to allow PDL to carry out without delay any related clinical trial in the Territory. PDL shall be responsible for preparing periodic reports required by the FDA related to any such Applications and for timely filing such periodic reports with the FDA. Through the POC, each party shall advise and consult with the other with respect to any significant issues or questions raised by any regulatory authorities with respect to Daclizumab.

IV. COMMERCIALIZATION AND MANUFACTURING

4.1 Commercialization By Roche.

(a) Commercialization of Daclizumab by Roche. The parties intend that, following the Effective Date, Roche will continue to market and sell Daclizumab in the Transplant Indications in the Roche Territory for the duration of the Commercialization Term, under the Trademarks. In particular, and without limitation, during the Commercialization Term

and in the Roche Territory, Roche shall be responsible, at its sole cost and as permitted by applicable law, for (i) the marketing, promotion, and detailing of Daclizumab for use in the Transplant Indications; (ii) accepting and filling orders for Daclizumab received by it or its Affiliates, including the distribution of Daclizumab to fill such orders; (iii) booking all sales of Daclizumab attributable to such orders; and (iv) any other activities reasonably related to Daclizumab that are permitted under the license granted in Section 2.5(a) (the **"Roche Commercialization Activities"**). As provided in Article VII, Roche shall pay royalties to PDL on Roche Net Sales.

(b) Commercialization of Excluded Products by Roche. Roche, its Affiliates, or sublicensees shall be solely responsible for, at its or their sole cost and as permitted by law, all aspects of the commercialization of Excluded Products in the Roche Territory, including but not limited to the booking of all sales of Excluded Products in the Roche Territory. Roche shall use commercially diligent efforts to develop and commercialize such Excluded Products. Following receipt of regulatory approval, Roche shall use Reasonable Diligence in proceeding with the marketing, promotion and sale of Excluded Products in the Roche Territory. If Roche fails to exercise such diligence, PDL may terminate the license granted to Roche under Section 2.5(b), but shall not be obligated to do so. As provided in Article VII, Roche shall pay royalties to PDL on Roche Net Sales of Excluded Products.

4.2 Commercialization by PDL.

(a) Commercialization by PDL During Commercialization Term. In the Roche Territory, PDL, its Affiliates, or sublicensees shall have the right, but not the obligation, at its or their sole cost and as permitted by law, to pursue all aspects of the commercialization of Daclizumab and any Other Licensed Products, excluding the Roche Commercialization Activities. Without limiting the generality of the foregoing, in the Roche Territory and during the Commercialization Term, PDL, its Affiliates, or sublicensees shall have the right, but not the obligation, to commercialize Licensed Products in Autoimmune Indications and Other Indications and to commercialize Other Licensed Products in any indication. In particular, in the Roche Territory, PDL shall be responsible, at its sole cost and as permitted by applicable law, for (i) the marketing, promotion, and detailing of Daclizumab for use in the Autoimmune Indications or Other Indications; (ii) accepting and filling orders for Daclizumab received by it or its Affiliates, including the distribution of Daclizumab to fill such orders; (iii) booking all sales of Daclizumab attributable to such orders; and (iv) any other activities reasonably related to Daclizumab that are permitted under the license granted in Section 2.1. As provided in Article VII, PDL shall pay royalties to Roche on PDL Net Sales during the Commercialization Term.

(b) Commercialization by PDL Following Reversion Effective Date or Put Right Effective Date. Following the Reversion Effective Date or the Put Right Effective Date, PDL, its Affiliates, or sublicensees shall have the right, but not the obligation, to pursue, at its or their sole cost and as permitted by law, all aspects of the commercialization of Daclizumab for all indications and for all Other Licensed Products. Following the Reversion Effective Date or the Put Right Effective Date, in no event shall PDL owe any royalties or any other compensation to

Roche on sales of Daclizumab under Section 7.2(c) in the Territory, whether by PDL, its Affiliates, or their sublicensees.

4.3 Commercialization in the PDL Sole Territory. PDL, its Affiliates, or sublicensees shall have the right, but not the obligation, to pursue, at its or their sole cost and as permitted by law, all aspects of the commercialization of Licensed Products in the PDL Sole Territory, including but not limited to the booking of all sales of Licensed Products in the PDL Sole Territory.

4.4 Pricing. As between the parties, PDL has the sole right to determine the price for Daclizumab or any Other Licensed Product that it sells and distributes. As between the parties, Roche has the sole right to determine the price for any Excluded Product that it sells and distributes, and the sole right during the Commercialization Term to determine the price for Daclizumab that it sells and distributes; provided, however, that until the earlier of (a) **[*]** or (b) PDL's receipt of a **[*]** from **[*]** having the power to grant **[*]**, stating that **[*]** will grant **[*]** for Daclizumab in **[*]**, Roche shall provide PDL with **[*]** of any **[*]** in the **[*]** of Daclizumab and shall give **[*]** to any **[*]** or **[*]** by PDL regarding the **[*]** of Daclizumab whether **[*]**. It is expressly understood that following the date which is the earliest of (i) **[*]**, (ii) the receipt of **[*]** for Daclizumab in **[*]**, or (iii) the Reversion Effective Date or Put Right Effective Date, the obligations of either party in the foregoing sentence shall terminate, and PDL shall have sole control regarding the price of Daclizumab that it sells and distributes.

4.5 Manufacturing. References to Roche in Sections 4.5(a) and 4.5(b) shall include Roche, its Affiliates **[*]** and any sublicensees manufacturing Daclizumab for Roche or its Affiliates.

(a) Clinical Manufacturing.

(i) Supply. Subject to Section 4.5(a)(ii) and until **[*]**, Roche shall use commercially reasonable efforts to supply to PDL, **[*]** Daclizumab and placebo **[*]** for the development of Daclizumab for AI in the **[*]** and **[*]** specified by PDL. Notwithstanding the above, Roche shall not be obligated to **[*]** (A) any amount of Daclizumab or placebo not in accordance with the AI Development plan, (B) a number of units of placebo in excess of the units of Daclizumab supplied by Roche, or (C) any form or formulation of Daclizumab **[*]** for the **[*]**. In the event PDL requests Daclizumab in a form or formulation **[*]** for the **[*]**, Roche shall be obligated to supply to PDL **[*]** All Daclizumab for the development of Daclizumab for AI, regardless of form or formulation, shall be manufactured in accordance with cGMPs and any other applicable regulatory or legal requirements. Through the POC, the parties shall meet periodically and discuss the availability and timing of delivery of Daclizumab hereunder. **[*]**. At PDL's cost, PDL shall perform any bridging studies that are necessary to enable PDL to use PDL-manufactured Daclizumab to satisfy its clinical development requirements. On **[*]**, and any time thereafter, PDL shall have the sole responsibility for the manufacture of all Daclizumab and placebo required by PDL for the development of Daclizumab for AI.

(ii) Limitations. From the Effective Date until **[*]**, Roche shall supply to PDL **[*]** up to **[*]** of Daclizumab and an equivalent number of units of placebo. For supplies in excess of such maximum amount **[*]**, PDL shall pay to Roche for such additional supplies an amount equal to **[*]** of **[*]** (including for **[*]**) for such supplies up to **[*]** of **[*]** per gram]. Notwithstanding anything to the contrary herein, from the Effective Date until **[*]**, the **[*]** of Daclizumab that Roche shall be obligated to supply to PDL shall be **[*]** of Daclizumab.

(iii) Procedures. During the period commencing on the Effective Date and ending on **[*]**, PDL shall provide Roche with **[*]** purchase orders, or such other procedures as the POC determines, each setting forth the amount of Daclizumab and placebo to be supplied by Roche to PDL. To the extent that such purchase orders are consistent with the terms and conditions of this Section 4.5, Roche agrees to honor all such purchase orders and to deliver to PDL the amount of Daclizumab and placebo specified therein as soon as practicable but in any event not later than **[*]** days following Roche's receipt of each such purchase order, or under such other procedures as the POC determines.

(b) Commercial Manufacturing. Effective on the Effective Date and subject to Section 4.5(c) and this Section 4.5(b), each party shall each be solely responsible for the manufacturing of all Daclizumab necessary to satisfy the commercial requirements of itself, its Affiliates and its sublicensees. **[*]** shall keep **[*]** reasonably informed, via the POC, regarding its progress in **[*]** for its **[*]** to **[*]** for **[*]**. As needed, the parties shall discuss and agree upon a plan of action to address, among other things, **[*]** that could arise if **[*]** progress in **[*]** is delayed, which plan could include for **[*]** to supply commercial requirements to **[*]** on a **[*]** basis.

(c) Commercial Manufacturing Following Exercise of the Roche Put Right. In the event that Roche exercises the Roche Put Right, **[*]** shall **[*]** to supply **[*]** for Daclizumab in the Territory for the period commencing on **[*]** and ending on **[*]** unless PDL has not, despite **[*]** to **[*]** for **[*]** to **[*]** Daclizumab for sale in the United States, **[*]** at such time, in which case such period shall end on **[*]** of such **[*]**. In the event that Roche exercises the Roche Put Right, the parties shall negotiate in good faith a separate supply agreement that shall provide for procedures for PDL to submit to Roche **[*]** for

Daclizumab and Roche supplying Daclizumab thereafter at a price equal to **[*]**. Such procedures shall include PDL providing (i) **[*]** of **[*]** and (ii) firm purchase commitments no less than **[*]** prior to the time the order must be delivered to **[*]** by **[*]**.

4.6 Roche Diligence. Following the Effective Date, Roche shall use Reasonable Diligence in proceeding with the manufacturing, marketing and sale of Daclizumab for use in the Transplant Indications in the Territory as contemplated by this Amended and Restated Worldwide Agreement, and in a manner comparable to its conduct of the manufacturing, marketing and sale of Daclizumab **[*]** during the **[*]** prior to the Effective Date. If Roche fails to exercise such diligence, PDL may exercise its rights hereunder pursuant to Section 13.3 below, but shall not be obligated to do so. Roche's diligence obligations under this Section 4.6 shall expire on, (i) if PDL exercises the Transplant Reversion or Roche exercises the Roche Put Right, the completion of all activities and undertakings set forth in Sections 5.4(b), (c), (e) and (f), or (ii) if the Exercise Period expires without PDL exercising the Transplant Reversion. In the event of a dispute as to whether Roche has used Reasonable Diligence, the party that loses on this issue

in an arbitration brought pursuant to Article XV shall reimburse all of the other party's arbitration expenses, including reasonable attorneys' fees relating to such arbitration.

V. PDL RIGHT TO ACQUIRE TRANSPLANT BUSINESS FROM ROCHE

5.1 General. The parties intend that, subject to the terms and conditions of this Amended and Restated Worldwide Agreement, the commercialization of Daclizumab in the Transplant Indications in the Roche Territory will continue to be an exclusive Roche responsibility unless and until PDL decides to undertake commercialization of Daclizumab in the Transplant Indications under the terms provided in this Article V. Subject to the limitations set forth below, PDL shall have the option to terminate Roche's rights with respect to Daclizumab, which, if exercised, would allow PDL to replace Roche as the party responsible for the promotion, sales, distribution and manufacturing of Daclizumab for use in the Transplant Indications in the Roche Territory. In the event that PDL exercises such option, PDL shall pay an exercise fee as set forth in Section 5.2(c) below. In addition, Roche shall have the right to "put" to PDL the rights to commercialize Daclizumab in the Roche Territory prior to PDL's exercise of such option and payment of the exercise fee, as provided in Section 5.3 below.

5.2 PDL Transplant Reversion.

(a) Grant; Exercise Period. PDL is hereby granted the right, subject to the terms of this Section 5.2(a), to terminate Roche's license rights under Section 2.5 for Daclizumab (the **"Transplant Reversion"**). Such right may be exercised by PDL in its discretion at any time during the period commencing **[*]** and ending **[*]** (the **"Exercise Period"**) by written notice to Roche and payment of the Reversion Exercise Fee set forth in Section 5.2(c).

(b) Effective Date of Exercise. If, during the Exercise Period, PDL provides Roche with written notice that PDL desires to exercise the Transplant Reversion, **[*]** shall determine the effective date (the **"Reversion Effective Date"**) of such exercise and reversion of rights, which shall be at least **[*]** after the date of PDL's written notice that it desires to exercise the Transplant Reversion, but in no event be later than **[*]**.

(c) Reversion Exercise Fee. PDL shall pay to Roche an exercise fee based on the AAGS, which exercise price shall be calculated as follows (the **"Reversion Exercise Fee"**):

AAGS	Exercise Price
[*] or more	**[*]**
[*] or more but not more than **[*]**	**[*]**
[*] or more but not more than **[*]**	**[*]**
not more than **[*]**	**[*]**

(d) Payment of Reversion Exercise Fee. Payment of such Reversion Exercise Fee shall be made in two installments: **[*]** of such Reversion Exercise Fee shall be made within **[*]** of PDL's written notice that it is exercising the Transplant Reversion and the remaining **[*]** of such Reversion Exercise Fee shall be made on the later of the **[*]**, or the **[*]** after completion of all activities and undertakings set forth in Sections **[*]**.

5.3 Roche Put Right Regarding Transplant Reversion.

(a) If, at any time from the Effective Date until Roche receives written notice from PDL pursuant to Section 5.2(a) of PDL's exercise of the Transplant Reversion, Roche desires that all of its rights to market, sell, promote and otherwise commercialize Daclizumab in the Roche Territory should revert to PDL, Roche shall have such right, on **[*]** written notice to PDL (the **"Roche Put Right"**); provided, however, that such right shall not be exercisable by Roche before **[*]** or after **[*]**. If so exercised, the effective date of such reversion (the **"Put Right Effective Date"**) shall be deemed to be that date **[*]** following the date of such written notice. The Roche Put Right shall expire on **[*]** if not previously exercised.

(b) On receipt from Roche of its notice of exercise of the Roche Put Right, PDL would pay to Roche an exercise fee based on the AAGS, which exercise price shall be calculated as follows (the **"Put Exercise Fee"**):

AAGS	Exercise Price
[*] or more	**[*]**
[*] or more but not more than **[*]**	**[*]**
[*] or more but not more than **[*]**	**[*]**

not more than **[*]** **[*]**

(c) Payment of such Put Exercise Fee shall be made in two installments: **[*]** of such Put Exercise Fee shall be made within **[*]** of Roche's written notice that it is exercising the Roche Put Right and the remaining **[*]** of such Put Exercise Fee shall be made on the later of the **[*]**, or the **[*]** after completion of all activities and undertakings set forth in Sections **[*]**.

(d) In the event of exercise by Roche of the Roche Put Right, PDL agrees to do the following, until **[*]**:

(i) to the extent **[*]**, use **[*]** efforts to maintain **[*]** in effect as of the Put Right Effective Date by and between Roche and Third Party **[*]** with respect to Daclizumab for use in the Transplant Indications in the US; and

(ii) pay to Roche those payments provided in Section 7.2(d).

5.4 Transfer and Assignment of Daclizumab Assets; Cooperation. As soon as practicable following PDL's notice of its exercise of the Transplant Reversion, or on delivery by Roche of written exercise of the Roche Put Right, Roche shall take all steps reasonable and appropriate to facilitate and shall initiate, or to cause its Affiliates to facilitate or initiate, the assignment to PDL of all of Roche's and its Affiliates' right, title and interest in and to the Daclizumab Assets and the transfer of Daclizumab commercialization and regulatory responsibilities in the Roche Territory from Roche to PDL. Such actions shall include, without limitation:

(a) cooperate and communicate with PDL as PDL may reasonably request in effectuating such transfer, including responding in a reasonable time frame to all reasonable inquiries and requests of PDL with respect to the nature or extent of the Daclizumab Assets, including providing copies of all relevant documents for PDL's use **[*]**;

(b) assign and transfer all Regulatory Approvals and other Daclizumab Assets described in Section 1.14(h) from Roche to PDL (excluding manufacturing approvals);

(c) identify all distributors and other Third Parties involved in the promotion, sale and distribution of Daclizumab, and as and to the extent possible offering to assign agreements with such Third Parties to PDL, to the extent not adverse to the interests of Roche to do so;

(d) on PDL's request and at PDL's sole discretion, Roche shall assign and shall cause its Affiliates to assign, to PDL any contracts (or relevant portions thereof) then in force between Roche and any Third Parties regarding the marketing, promotion, and sale of Daclizumab, to the extent assignable, and where not so assignable, use its reasonably diligent efforts to obtain consent to such assignment;

(e) prepare, execute and deliver assignments to PDL of the Roche Owned Patents listed on Schedule 2.8(a) and record, where appropriate with the relevant authorities, such assignments to PDL of all of Roche's and its Affiliates' right, title and interest in and to the Roche Owned Patents listed on Schedule 2.8(a); and

(f) prepare, execute and deliver assignments to PDL of all of Roche's and its Affiliates' right, title, and interest in and to the Trademarks.

In such matters, Roche shall bear the **[*]** of its **[*]** and associated **[*]** but PDL shall **[*]** for any **[*]** to **[*]** (such as **[*]**) required in connection with such transfers, together with any **[*]** for **[*]** requested by PDL and agreed to by Roche. Roche shall use its commercially diligent efforts to ensure that all such transfer activities shall be completed as expeditiously as possible, but in any event by the Reversion Effective Date or the Put Right Effective Date. All such activities shall be coordinated through and overseen by the POC, as provided in Section 6.2.

5.5 Effect of Exercise. Effective immediately on either the Reversion Effective Date or the Put Right Effective Date:

(a) the license granted to Roche under Section 2.5(a) shall terminate and all such rights shall revert to PDL; except that, following any Put Right Effective Date, the license granted to Roche to manufacture Daclizumab in the second sentence of Section 2.5(a) shall survive, to the extent provided in Section 2.5(a);

(b) the license granted to PDL in Section 2.2 shall be in full force and effect;

(c) PDL shall have the right to purchase all or any portion of Roche's then existing inventory of bulk and/or finished Daclizumab, and Roche agrees to so sell such bulk and/or finished Daclizumab, at a price equal to **[*]**, as necessary to meet commercial requirements; and

(d) PDL thereafter shall commence booking all sales of Daclizumab in the Roche Territory, whether sold under a Trademark or the AI Trademark or any other trademark.

5.6 No Effect on Excluded Field and Excluded Products. Any exercise of either the Transplant Reversion or the Roche Put Right shall have no effect on Roche's rights in and to the Excluded Field and the Excluded Product, or on the license granted to Roche under Section 2.5(b), except as provided in Section 13.3.

5.7 No Assumption of Liabilities. Except as specifically assumed by PDL in writing in connection with an assignment and/or sublicense to PDL of any Third Party contracts comprising the Daclizumab Assets pursuant to Section 5.4, PDL shall assume no liabilities of Roche or its Affiliates as a result of either the exercise by PDL of the Transplant Reversion or the exercise by Roche of the Roche Put Right, including (a) tax liabilities; (b) any liabilities relating to accounts payable, indebtedness, accrued liabilities or legal services, accounting services, financial advisory services or investment banking services or other professional services; (c) any wages, salaries or benefits or any other liabilities relating to the employment of any current or former

employee; (d) any rent, wages or other obligations of any kind payable by Roche; (e) any environmental liabilities; and (f) any liabilities with respect to Third Party contracts not expressly assumed by PDL hereunder. Roche shall remain responsible for all liabilities associated with its sale, prior to the Reversion Effective Date or Put Right Effective Date (as applicable), of Daclizumab, and its manufacture of Daclizumab, including without limitation uncollected amounts, returns, recalls, and third party royalties (subject to Section 7.4) associated with such sales.

5.8 Effect of **[*]**. In the event of any **[*]**, the following shall occur:

(a) The Roche Put Right shall immediately terminate;

(b) The exercisability of the Transplant Reversion shall **[*]** and the Exercise Period shall be deemed to commence on the date that is **[*]** after the effective date of such **[*]** and shall extend until **[*]**. In the event PDL exercises such Transplant Reversion during such **[*]** time, PDL would pay to Roche an exercise fee based on the AAGS, which exercise price shall be calculated as follows (the **"[*] Exercise Fee"**):

AAGS	Exercise Price
more than **[*]**	**[*]**
more than **[*]** but not more than **[*]**	**[*]**
more than **[*]**	**[*]**
not more than **[*]**	**[*]**

and

(c) Payment of such **[*]** Exercise Fee shall be made in two installments: **[*]** of such **[*]** Exercise Fee shall be made within **[*]** of PDL's written notice that it is exercising the Transplant Reversion and the remaining **[*]** of such **[*]** Exercise Fee shall be made on the later of the **[*]**, or **[*]** after completion of all activities and undertakings set forth in Sections **[*]**.

VI. PRODUCT OPERATING COMMITTEE

6.1 Dissolution of Committees under 1999 Agreements**.** Effective as of the Effective Date, the Joint Development Committee and the Joint Commercialization Committee, as authorized under the 1999 Agreements, shall be dissolved.

6.2 Product Operating Committee.

(a) Within thirty (30) days after the Effective Date, PDL and Roche shall form a Product Operating Committee (**"POC"**) composed of **[*]** representatives of each party who shall be appointed (and may be replaced at any time, subject to the terms of this Section 6.2(a)) by such party with the prior written consent of the other party in accordance with this Amended and Restated Worldwide Agreement. Each POC representative shall have suitable experience and expertise in the development and commercialization of biopharmaceutical drugs. Each party shall each have the right to replace its representatives from time to time, provided that such party obtains the written consent of the other party on such replacement in advance thereof.

(b) The POC shall meet not less than **[*]** on such dates and at such times as agreed to by PDL and Roche, alternating between Fremont, California and Nutley, New Jersey or such other locations as the POC determines. On the determination of the POC, any such meetings may be conducted by teleconference or videoconference. Other representatives of the parties and their invitees may also attend the POC meetings.

(c) The POC shall be responsible for (i) exchanging information regarding the activities conducted by the parties, their sublicensees or their respective Affiliates under this Amended and Restated Worldwide Agreement, including without limitation, **[*]** of any **[*]** with respect to **[*]**, (ii) making recommendations to the parties regarding the **[*]** for **[*]** for the **[*]** of the **[*]**, (iii) discussing the **[*]** for **[*]** the **[*]** for **[*]** and the potential for a **[*]** between the **[*]** to

accomplish this goal, (iv) coordinating and overseeing the **[*]** to PDL of the **[*]** pursuant to Section **[*]**; and (vi) such other activities as mutually agreed by Roche and PDL**[*]**. If PDL elects to exercise its Transplant Reversion under Section 5.2, or Roche exercises its Roche Put Right under Section 5.3, the POC will coordinate transition of manufacturing and commercialization responsibilities to PDL over the period specified in this Amended and Restated Worldwide Agreement; the POC shall dissolve after the completion of such transition **[*]**. The POC shall have no authority to determine pricing of Daclizumab by either party in its respective indications nor shall the POC have any authority to make any decisions regarding Daclizumab that shall take effect or continue to remain in effect, after the Reversion Effective Date or Put Right Effective Date.

(d) In general, the POC is not intended to be a decision-making body with respect to either party's efforts to develop or commercialize Daclizumab. However, all required decision making with respect to matters before the POC shall be effected **[*]** of **[*]** representatives. Each party's representatives shall have a single vote. In the event such representatives of each party are unable to agree, the matter shall be referred to the **[*]** and to the **[*]** (or their successors) for resolution in good faith for a period of **[*]** days. In the event such **[*]** and such **[*]** are unable to resolve such dispute in such time frame, **[*]** shall have the final say on all such disputes related to the commercialization of Daclizumab for use in the **[*]**, except for **[*]**; and **[*]** shall have the final say on all other such disputes, including but not limited to those disputes related to development of Daclizumab in **[*]** or commercialization of Daclizumab for use in **[*]**

VII. COMPENSATION

7.1 Payment to Roche. In consideration for the rights and licenses granted by Roche under this Amended and Restated Worldwide Agreement, PDL shall pay to Roche a non-refundable, non-creditable fee in the sum of Eighty Million U.S. Dollars (US$80,000,000), due and payable no later than **[*]** after the Effective Date.

7.2 Royalties.

(a) Royalties to PDL on Daclizumab Sales.

(i) Royalty Rate. Roche shall pay PDL royalties on Roche Net Sales commencing as of the Effective Date, at a royalty rate determined by annual (or annualized, as the case may be for partial years) Roche Net Sales as follows:

Annual Roche Net Sales (US$)	Royalty Rate
Up to and including **[*]**	**[*]**
Amount in excess of **[*]** but not exceeding **[*]**	**[*]**
Amount in excess of **[*]** but not exceeding **[*]**	**[*]**
Amount in excess of **[*]** but not exceeding **[*]**	**[*]**
Amount in excess of **[*]**	**[*]**

No adjustment will be made to the royalty rates specified in this Section 7.2(a), regardless of whether the manufacture, use, sale, or importation of Daclizumab by Roche or its Affiliates in a particular country is covered by a Valid Claim of a PDL Patent.

(ii) Expiration of Roche's Royalty Obligations. Roche's obligation to pay royalties to PDL under this Article VII shall expire (A) with respect to sales of Daclizumab in the **[*]**, on **[*]**, and (B) with respect to sales of Daclizumab in the **[*]**, on **[*]**. Notwithstanding the above, Roche's obligation to pay royalties to PDL under this Section 7.2(a) shall expire on the first to occur, if any, of the Reversion Effective Date or the Put Right Effective Date.

(b) Royalties to PDL on Excluded Product Sales.

(i) Royalty Rate. Roche shall pay PDL royalties on Roche Net Sales of Excluded Products at a royalty rate determined by annual Roche Net Sales of Excluded Products as follows, as measured on a calendar year basis:

Annual Roche Net Sales of Excluded Products (US$)	Royalty Rate
Up to and including **[*]**	**[*]**
Amount in excess of **[*]**	**[*]**

(ii) Term of Royalty Obligations. Roche's obligation to pay royalties to PDL under Section 7.2(b)(i) with respect to any Excluded Product shall expire, on a country-by-country basis, on the later of (A) the last date on which the manufacture, use, sale, or importation in such country in the Roche Territory, by Roche, its Affiliates, or sublicensees (other than PDL, its Affiliates, and sublicensees) of such Excluded Product is covered under a Valid Claim of a PDL Patent (which determination, if not otherwise covered by a Valid Claim in the country of use, sale, or importation shall be based on whether or not covered by a Valid Claim in the country of manufacture), or (B) the **[*]** of the first commercial sale by Roche, its Affiliates, or sublicensees (other than PDL, its Affiliates, or sublicensees) of such Excluded Product in such country.

(c) Royalties to Roche.

(i) Royalty Rate. PDL shall pay Roche royalties on PDL Net Sales at a royalty rate determined by annual PDL Net Sales as follows, as measured on a calendar year basis:

Annual PDL Net Sales (US$)	Royalty Rate
Up to and including **[*]**	**[*]**
Amount in excess of **[*]**	**[*]**

(ii) Term of PDL's Royalty Obligations Where Transplant Reversion Exercised. PDL's obligation to pay royalties pursuant to Section 7.2(c)(i) shall expire on the earlier of the Put Right Effective Date or the Reversion Effective Date.

(iii) Term of PDL's Royalty Obligations Where No Transplant Reversion Exercised. In the event PDL does not exercise the Transplant Reversion and Roche does not exercise the Roche Put Right, PDL's obligation to pay royalties to Roche under Section 7.2(c)(i) shall expire, on a country-by-country basis, on the later of (A) the last date on which the manufacture, use, sale, or importation in such country in the Roche Territory, by PDL, its Affiliates, or sublicensees (other than Roche, its Affiliates, and sublicensees) of Daclizumab is covered under a Valid Claim of a Roche Patent (which

determination, if not otherwise covered by a Valid Claim in the country of use, sale or importation, shall be based on whether or not covered by a Valid Claim in the country of manufacture), or (B) the **[*]** of the first commercial sale by PDL, its Affiliates, or sublicensees (other than Roche, its Affiliates, or sublicensees) of Daclizumab in such country.

(d) Payment to Roche in Event of Roche Put Right Exercise. In the event Roche exercises the Roche Put Right, following the Put Right Effective Date, and until **[*]**, PDL shall pay Roche (i) for commercial supply of finished and packaged Daclizumab from Roche as set forth in Section 4.5(c), a transfer price equal to the **[*]** and (ii) an amount determined by the parties in good faith to be equal to **[*]** for its **[*]** and **[*]** efforts that are **[*]**; provided that, PDL's payment obligation under this Section 7.2(d) for any given calendar quarter shall in no event exceed a maximum (the "Payment Ceiling") calculated as follows:

Payment Ceiling = **[*]**

7.3 Foreign Filing Expenses Credited Against Royalties. Roche shall have the right to credit **[*]** of all Transplant Foreign Filing Expenses actually paid to PDL, less credits already taken under the 1989 and 1999 Agreements, against future royalties due to PDL on sales of Daclizumab pursuant to this Article VII, provided that such credits, when added to the offset provided for in Section 7.4 below, may not in the aggregate reduce the royalties to be paid to PDL to less than **[*]** of the amount that would otherwise be due pursuant to Section 7.2(a) hereof.

7.4 Offset for Third Party Licenses.

(a) Appendix B sets forth the allocation between the parties of the costs associated with each Third Party License entered into prior to the Effective Date. Such costs include license fees and any other fixed costs associated with the Third Party License as well as any royalties. After the Effective Date, the parties shall, within **[*]** of the end of each **[*]**, reimburse each other in accordance with this Section 7.4 to effect the agreed-on sharing of such license fees and other fixed costs. Both parties hereby acknowledge that **[*]** has obtained a required license from the **[*]** to use the **[*]** in order to carry out the activities anticipated by this Amended and Restated Worldwide Agreement and that **[*]** has reimbursed **[*]** under the 1989 Agreements so that the license fees and other fixed costs of the **[*]** license have been shared **[*]**

(b) If PDL and Roche agree in writing, after the Effective Date, that either party must obtain an additional license from an independent Third Party in order for Roche or PDL to manufacture, use, import, offer for sale or sell Daclizumab and if PDL and Roche agree on the terms of such license, then such license shall be deemed a Third Party License and the parties shall, subject to Sections 2.3, 7.4(c) and 7.4(d), share the cost of such Third Party License **[*]**. Such cost includes license fees and any other fixed costs associated with such Third Party License as well as any royalties. The parties shall, within **[*]** of the end of each **[*]**, reimburse each other in accordance with this Section 7.4 to effect a **[*]** of such license fees and other fixed costs.

(c) Notwithstanding anything to the contrary herein, the following mechanism shall apply to the royalty portion of any Third Party Licenses to the extent such royalties arise due to sales of Daclizumab by Roche or its Affiliates or sublicensees during the time that Roche is obligated to pay royalties to PDL pursuant to Section 7.2(a): (i) PDL's share of such Third Party royalties shall be accrued against and deducted from any amounts due to PDL from Roche pursuant to Section 7.2(a) if Roche pays the royalties due under the Third Party License to such Third Party, and (ii) Roche's share of the royalties portion of the cost of any Third Party License shall be accrued in favor of and added to any amounts due to PDL from Roche pursuant to Section 7.2(a) if PDL pays the royalties due under the Third Party License to such Third Party; provided, however, that the total amounts of all deductions made by Roche pursuant to clause (i) above (without taking into account any additions made pursuant to clause (ii)) shall not exceed **[*]** of the amount that would otherwise be due to PDL, pursuant to Section 7.2(a), in any calendar quarter if no adjustments were permitted to account for payments made pursuant to Third Party Licenses; provided further that the sum of Roche's royalty obligations to PDL under Section 7.2(a) in any calendar quarter, plus Roche's share of those royalties payable for such calendar quarter to Third Parties pursuant to Third Party Licenses shall not exceed **[*]** of the amount that would otherwise be due to PDL, pursuant to Section 7.2(a), in such calendar quarter if no adjustments were permitted to account for payments made pursuant to Third Party Licenses. Royalty payments made by Roche or PDL pursuant to Third Party Licenses that, due to the limitations set forth in the preceding sentence, cannot be deducted from, or added to, the amount to be paid to PDL by Roche under Section 7.2(a), may be carried forward to subsequent calendar quarters. An example of the foregoing principles is set forth in Appendix D.

(d) Notwithstanding anything to the contrary herein, the following mechanism shall apply to the royalty portion of any Third Party Licenses to the extent such royalties arise due to sales of Daclizumab by PDL or its Affiliates or sublicensees during the time that PDL is obligated to pay royalties to Roche, pursuant to Section 7.2(c): (i) Roche's share of such Third Party royalties shall be accrued against and deducted from any amounts due to Roche from PDL pursuant to Section 7.2(c) if PDL pays the royalties due under the Third Party License to such Third Party, and (ii) PDL's share of such Third Party royalties shall be accrued in favor of and added to any amounts due to Roche from PDL pursuant to Section 7.2(c) if Roche pays the royalties due under the Third Party License to such Third Party; provided, however, that the royalty payments made by PDL to Roche pursuant to Section 7.2(c) shall not, as a result of the adjustments set forth in this Section 7.4(d), be reduced to less than **[*]** of PDL Net Sales. Royalty payments made by Roche or PDL pursuant to Third Party Licenses that, due to the maximum royalty rate set forth in the preceding sentence, cannot be deducted from, or added to, the amount to be paid to PDL by Roche under Section 7.2(c), may be carried forward to subsequent calendar years.

(e) If PDL exercises the Transplant Reversion or Roche exercises the Roche Put Right, then commencing on the Reversion Effective Date or the Put Right Effective Date (as applicable): (i) Roche shall not have any further obligation pursuant to this Section 7.4 to share the costs of, or pay directly, any royalties pursuant to any Third Party Licenses on account of sales of Daclizumab by PDL or its Affiliates or sublicensees, and (ii) PDL shall thereafter have sole responsibility for paying such royalties.

(f) If the Exercise Period expires without PDL exercising the Transplant Reversion or Roche exercising the Roche Put Right, then:

(i) commencing on **[*]**, with respect to sales of Daclizumab in the **[*]** by Roche and its Affiliates and sublicensees, or **[*]**, with respect to sales of Daclizumab in the **[*]** by Roche and its Affiliates and sublicensees, (A) PDL shall not have any further obligation pursuant to this Section 7.4 to share the costs of, or pay directly, any royalties pursuant to any Third Party Licenses on account of sales of Daclizumab by Roche or its Affiliates or sublicensees, and (B) Roche shall thereafter have sole responsibility for paying such royalties.

(ii) commencing on, a country-by-country basis, with the expiration of PDL's obligations to pay royalties to Roche, pursuant to Section 7.2(c), in such country with respect to the sale of Daclizumab by PDL and its Affiliates and sublicensees, (A) Roche shall not have any further obligation pursuant to this Section 7.4 to share the costs of, or pay directly, any royalties pursuant to any Third Party Licenses on account of sales of Daclizumab by PDL or its Affiliates or sublicensees, and (B) PDL shall thereafter have sole responsibility for paying such royalties.

7.5 Royalties on Termination. If this Amended and Restated Worldwide Agreement is terminated pursuant to Sections 13.2, 13.3 or 13.4, then Roche shall continue to pay PDL, and PDL shall continue to pay Roche, as the case may be, any royalties earned pursuant to this Article VII prior to the date of termination.

7.6 Sublicenses.

(a) Any Roche Net Sales or Roche Net Sales of Excluded Products by a Roche sublicensee shall be treated as Roche Net Sales or Roche Net Sales of Excluded Products of Roche, as the case may be, for the purposes of payments under Article VII. If Roche, in accordance with Section 2.5(a) or (b), shall grant any sublicenses under this Amended and Restated Worldwide Agreement, then Roche shall obtain the written commitment of such sublicensees to abide by all applicable terms and conditions of this Amended and Restated Worldwide Agreement and Roche shall remain responsible to PDL for the performance by such sublicensee of any and all terms. All such sublicenses to any Excluded Products shall provide that such license terminates on any termination of the license granted pursuant to Section 2.5(b). Any sublicense granted under the license in Section 2.5(a) shall expire as set forth in that Section 2.5(a).

(b) Any PDL Net Sales by a PDL sublicensee shall be treated as PDL Net Sales of PDL for the purposes of payments under Article VII. If PDL, in accordance with Section 2.1, shall grant any sublicenses under this Amended and Restated Worldwide Agreement, then PDL shall obtain the written commitment of such sublicensees to abide by all applicable terms and conditions of this Amended and Restated Worldwide Agreement and PDL shall remain responsible to Roche for the performance by such sublicensee of any and all terms.

VIII. PAYMENTS, REPORTS, AND ACCOUNTING

8.1 Roche Quarterly Royalty Payments and Reports.

(a) Promptly after the Effective Date, the parties shall work in good faith to establish procedures for (a) compiling a final accounting, pursuant to the 1999 Agreements, for all sales of Daclizumab made during 2003 prior to the Effective Date and (b) Roche to make all royalty payments owed to PDL, pursuant to the 1999 Agreements, with respect to such sales.

(b) Beginning with the report for the last calendar quarter of 2003 and for each calendar quarter thereafter, Roche agrees to make payments and written reports to PDL within **[*]** after the end of each calendar quarter covering all sales of the Roche Products in the Roche Territory by Roche, its Affiliates or sublicensees (except PDL, its Affiliates and sublicensees) for which invoices were sent during such calendar quarter, each such written report stating for the period in question:

(i) for Roche Products disposed of by sale, the quantity and description of Roche Products and the calculation of Roche Net Sales or Roche Net Sales of Excluded Products,

(ii) for Roche Products disposed of other than by sale, the quantity, description, and nature of the disposition, and

(iii) the calculation of the amount due to PDL for such quarter pursuant to Article VII.

(c) The information contained in each report under Section 8.1(b) shall be considered confidential and PDL agrees not to disclose such information to any Third Party, other than its Affiliates and sublicensees or except as may be required by law, rule or regulation. Concurrent with the making of each quarterly report, Roche shall include payment due PDL hereunder for the calendar quarter covered by such report.

(d) It is understood that only one royalty payment under Article VII shall be payable on a given unit of Roche Product disposed of under this Amended and Restated Worldwide Agreement. In the case of transfers or sales of any Roche Product between Roche and an Affiliate or sublicensee of Roche, only one royalty payment under Article VII shall be due, and such royalty shall be payable with respect to, the sale of such Roche Product to (i) an independent Third Party not an Affiliate of the seller or (ii) if the end user is an Affiliate of the seller, then such end user.

8.2 PDL Quarterly Royalty Payments and Reports.

(a) Until the expiration of PDL's royalty obligations under Section 7.2(c), PDL agrees to make payments and written reports to Roche within **[*]** after the end of each calendar quarter covering all sales of Daclizumab in the Roche Territory by PDL for which invoices were sent during such calendar quarter, or, in the case of royalties from the PDL Net Sales of PDL's Affiliates or sublicensees (except Roche, its Affiliates and sublicensees), within **[*]** following the end of the quarter in which PDL receives the royalty report from the Affiliate or sublicensee. Each report shall state for the period in question:

(i) for Daclizumab disposed of by sale, the gross sales by PDL of Daclizumab and PDL Adjusted Gross Sales and the calculation of PDL Net Sales,

(ii) for Daclizumab disposed of other than by sale, the quantity, description, and nature of the disposition, and

(iii) the calculation of the amount due to Roche for such quarter pursuant to Article VII.

(b) The information contained in each report under Section 8.2(a) shall be considered confidential and Roche agrees not to disclose such information to any Third Party, other than its Affiliates and sublicensees or except as may be required by law, rule or regulation. Concurrent with the making of each quarterly report, PDL shall include payment due Roche hereunder for the calendar quarter covered by such report.

(c) It is understood that only one royalty payment under Article VII shall be payable on a given unit of Licensed Product disposed of under this Amended and Restated Worldwide Agreement. In the case of transfers or sales of any Licensed Product between PDL and an Affiliate or sublicensee of PDL, only one royalty payment under Article VII shall be due, and such royalty shall be payable with respect to the sale of such Licensed Product to (i) an

independent Third Party not an Affiliate of the seller or (ii) if the end user is an Affiliate of the seller, then such end user.

8.3 Termination Report. Roche agrees to make a written report to PDL within **[*]** after the date on which Roche, or its Affiliates or sublicensees last sell Daclizumab, stating in each such report the same information called for in each quarterly report by Section 8.1(b) for all Daclizumab made, sold or otherwise disposed of and which was not previously reported to PDL. Roche further agrees to make a written report to PDL within **[*]** after the date on which Roche, or its Affiliates or sublicensees last sell all Excluded Products, stating in each such report the same information called for in each quarterly report by Section 8.1(b) for all Excluded Product made, sold or otherwise disposed of and which was not previously reported to PDL. PDL agrees to make a written report to Roche within **[*]** after the date on which PDL, or its Affiliates or sublicensees last sell Daclizumab, stating in such report the same information called for in each quarterly report by Section 8.2(a) for all Daclizumab made, sold or otherwise disposed of and which was not previously reported to Roche; provided, however, that PDL need not file such report if such date of last sale of Daclizumab occurs after the expiration of PDL's royalty under Section 7.2(c)).

8.4 Accounting. Each Party (the **"Royalty Paying Party"**) agrees to keep full, clear and accurate records for a period of at least **[*]**, setting forth the manufacturing, sales and other disposition of Daclizumab, Roche Products (as the case may be), and Combination Products sold or otherwise disposed of under the license herein granted in sufficient detail to enable royalties and compensation payable to the other Party (the **"Royalty Receiving Party"**) hereunder to be determined. Each Royalty Paying Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the Royalty Receiving Party to verify reports provided for in this Article VIII. Unless the Royalty Receiving Party obtains the prior written consent of the Royalty Paying Party, such accounting firms must be selected from among the four largest U.S. accounting firms. Such audit shall not be performed more frequently that **[*]** per calendar year nor more frequently than **[*]** with respect to records covering any specific period of time. Such examination is to be made at the expense of the Royalty Receiving Party, except in the event that the results of the audit reveal a discrepancy in favor of the Royalty Paying Party of **[*]** or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Royalty Paying Party.

8.5 Methods of Payments. All payments due to either PDL or Roche under this Amended and Restated Worldwide Agreement shall be paid in United States dollars by wire transfer to a bank in the United States designated in writing by the party to which the payment is due.

8.6 Taxes. If provision is made in law or regulation of any country of the Roche Territory or the Territory (as applicable) for withholding of taxes of any type, levies or other charges with respect to the any amounts payable hereunder to a party, the other party (**"Withholding Party"**) shall promptly pay such tax, levy or charge for and on behalf of the party to the proper governmental authority, and shall promptly furnish the party with receipt of such payment. The Withholding Party shall have the right to deduct any such tax, levy or charge

actually paid from payment due the party or be promptly reimbursed by the party if no further payments are due the party. Each Withholding Party agrees to assist the other party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

IX. CELL LINES

9.1 Cell Lines.

(a) The parties acknowledge that PDL has delivered all cell lines to Roche as required under the 1989 Agreements. Roche agrees to deliver back to PDL viable samples of such cell lines as may be requested by PDL.

(b) Ownership of any cell lines developed under Article VI of the 1989 Agreements or delivered to Roche under Milestone #1 of Section 3.1 of the 1989 Agreements, together with their progeny and derivatives, shall remain vested at all times in PDL.

(c) Roche may use the cell lines delivered to it under the 1989 Agreements, or their progeny or derivatives or the plasmids contained therein (the **"Cell Line Derivatives"**) solely to perform the Roche Commercialization Activities. Furthermore, the Cell Line Derivatives may be used by Roche solely in connection with the genes encoding antibodies developed or provided by PDL.

(d) On the earliest to occur of **[*]** in the Roche Territory as permitted under this Amended and Restated Worldwide Agreement, Roche shall, on request by PDL, promptly return to PDL all cell lines provided by PDL under the 1989 Agreements and all Cell Line Derivatives.

(e) PDL MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY CELL LINES DELIVERED UNDER THE 1989 AGREEMENTS OR CELL LINE DERIVATIVES USED HEREUNDER, INCLUDING WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT. FOR CLARITY, PDL MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND THAT THE USE OF THE CELL LINES DELIVERED TO ROCHE OR THE CELL LINE DERIVATIVES WILL NOT INFRINGE ANY PATENT OR OTHER RIGHTS OF ANY THIRD PARTY.

X. OWNERSHIP OF TECHNOLOGY AND INTELLECTUAL PROPERTY

10.1 PDL Technology. Ownership of the PDL Know-How and PDL Patents shall remain vested at all times in PDL. PDL expressly reserves under this Amended and Restated Worldwide Agreement (i) all rights to use the PDL Know-How, PDL's rights under any Joint Roche-PDL Patents, and PDL Patents to make, have made, use, import, offer to sell and sell anywhere in the world all products within the Field that are other than Daclizumab for use in the Transplant Indications (unless and until the Roche Put Right or the Transplant Reversion is

exercised) and other than any Excluded Product or any other product in the Excluded Field; and (ii) for all uses outside of the Field. Following exercise of the Transplant Reversion or the Roche Put Right, PDL shall have the right to use such technology for any and all purposes other than products in the Excluded Field, which right shall be exclusive to Roche except as provided in Section 10.2.

10.2 Joint Inventions and Joint Roche-PDL Patents. Subject to Article XI, ownership of Joint Inventions and Joint Roche-PDL Patents shall be vested jointly in PDL and Roche. Both parties shall at all times have the co-exclusive right within the Territory to practice, or to make, have made, use, import, offer for sale or sell any Joint Invention outside the Field under any Joint Roche-PDL Patent, and neither party shall be obligated to account to the other. On the earlier of (i) the Reversion Effective Date, or (ii) the Put Right Effective Date, the following shall occur: (a) PDL shall have the exclusive right to practice, and to make, have made, use, import, offer for sale or sell any Joint Invention in the Field (but not in the Excluded Field) under any Joint Roche-PDL Patent, and (b) Roche shall have the exclusive right to practice, and to make, have made, use, import, offer for sale or sell any Joint Invention solely in the Excluded Field, in each case, without restriction and without any obligation to account to the other party. As used herein, a right to practice any Joint Roche-PDL Patent for a particular purpose without any obligation to account shall include the right to grant licenses for such purpose without the consent of the other party. To the extent either party needs the consent of the other party to exploit its co-exclusive or exclusive rights with respect to Joint Roche-PDL Patents, including the right to sublicense or enforce such Joint Roche-PDL Patents, the other party shall cooperate with the party making such a request and promptly supply all needed consents, signatures and the like. In the event the Roche Put Right and the Transplant Reversion both expire unexercised, each party shall have the co-exclusive right to practice, and to make, have made, use, import, offer for sale or sell any Joint Invention in the Field under any Joint Roche-PDL Patent, subject to the license grants set forth in Article II.

10.3 Roche Technology. PDL hereby acknowledges that, except as expressly provided herein, this Amended and Restated Worldwide Agreement does not grant PDL any ownership rights in the Roche Inventions, Roche Patents and Roche Know-How. Roche hereby confirms the rights of PDL to certain license grants to Roche Patents and Roche Know-How as provided in Section 2.1 of this Amended and Restated Worldwide Agreement.

10.4 Trademarks.

(a) Until the Reversion Effective Date or Put Right Effective Date, Roche shall exclusively own all Trademarks, and the exclusive right to use them in the Roche Territory in connection with the marketing and promotion of Daclizumab. Roche shall have no right to use the Trademarks, or any other marks confusingly similar to the Trademarks, in connection with the promotion, sale or marketing of any other product, including any Excluded Product.

(b) PDL shall have the right to select any and all AI Trademarks; provided such AI Trademarks are not confusingly similar to the Trademarks (unless otherwise agreed), and PDL

shall retain ownership of the AI Trademarks and the exclusive right to use them in connection with the promotion, marketing and sale of Daclizumab for AI or any Other Indications.

(c) Each party shall be responsible for selection, prosecution, maintenance and enforcement of its own trademarks, and shall indemnify and defend the other from any Third Party claims arising from the indemnifying party's use of such marks. At the request **[*]** of PDL, Roche shall file trademark registration applications for, and procure and maintain registration of, the trademark "Zenapax®" in any country in the Territory in which Roche, as of the Effective Date, has not made such application or procured such registration. All such applications and registrations shall be deemed to be Trademarks.

(d) Roche shall assign the Trademarks to PDL upon exercise of either the Transplant Reversion or the Roche Put Right, as provided for in Section 5.4(f).

XI. PATENT PROSECUTION

11.1 Sole PDL Patents and Roche Owned Patents.

(a) PDL agrees to prosecute and reasonably maintain all of the patents and applications included within the Sole PDL Patents, to the extent it has the rights to do so, and Roche agrees to prosecute and reasonably maintain the Roche Owned Patents, to the extent it has the rights to do so from any co-owner of such Roche Owned Patents. The parties agree and acknowledge that the Roche Owned Patents listed on Schedule 2.8(a) are co-owned by Roche and a Third Party, and are governed by the **[*]** (the "Joint Patent Agreement") which provides, among other things, that Roche undertake certain obligations in order to continue to maintain its **[*]** in the Roche Owned Patent. Promptly after the Effective Date, to the extent that Roche is permitted to do so, Roche shall provide to PDL a copy of the Joint Patent Agreement, and the Roche Owned Patent for PDL's review such that PDL may determine whether and to what extent, it intends that such Joint Patent Agreement and Roche Owned Patent be assigned to PDL in the event of the Transplant Reversion or the exercise of the Roche Put Right.

(b) The party responsible for such patent (**"Responsible Party"**) shall bear all costs and expenses for such prosecution and maintenance. On the reasonable request of the Responsible Party, the other party shall cooperate, in all reasonable ways, in connection with the prosecution of all patent applications included within the Sole PDL Patents or Roche Owned Patents, as the case may be. Should the Responsible Party decide that it is no

longer interested in maintaining or prosecuting a Sole PDL Patent or Roche Owned Patent, as the case may be, it shall promptly advise the other party thereof and, at the request of such other party, PDL and Roche shall negotiate in good faith to determine an appropriate course of action in the interests of both parties. If any Sole PDL Patents are assigned to Roche, Roche will thereafter prosecute and reasonably maintain such Sole PDL Patents at Roche's own cost to the extent that Roche desires to do so, provided that to the extent such Sole PDL Patent contains claims outside the Field (or, following either the Reversion Effective Date or the Put Right Effective Date, outside the Excluded Field only), PDL and its Affiliates shall have a worldwide immunity from suit thereunder. If Roche's interest in any Roche Owned Patents is assigned to PDL, PDL will

thereafter prosecute and reasonably maintain such Roche Owned Patent at PDL's own cost to the extent that PDL desires to do so, provided that to the extent such Roche Owned Patent contains claims outside the Field (or following either the Reversion Effective Date or the Put Right Effective Date, outside the Excluded Field only), Roche and its Affiliates shall have a worldwide immunity from suit thereunder. In the event Roche's interest in the Roche Owned Patents is assigned to PDL pursuant to Section 5.4(e), Roche shall have no further rights with respect thereto under this Section 11.1 except those set forth in the penultimate sentence of this Section 11.1.

11.2 Joint Inventions.

(a) PDL will have the first right of election to file priority patent applications for Joint Inventions in any country in the world. If PDL declines to file such applications then Roche may do so.

(b) The party not performing the priority patent filings for Joint Inventions pursuant to this Section 11.2 undertakes without cost to the filing party to obtain all necessary assignment documents for the filing party, to render all signatures that shall be necessary for such patent filings and to assist the filing party in all other reasonable ways that are necessary for the issuance of the patents involved as well as for the maintenance and prosecution of such patents. The party not performing the patent filings shall on request be authorized by the other party to have access to the files concerning such patents in any patent offices in the world.

(c) The party performing the priority patent filings for Joint Inventions pursuant to this Section 11.2 undertakes to perform, at its cost and expense, the corresponding convention filings from case to case, after having discussed the countries for foreign filings with the other party.

(d) Should the Responsible Party decide that it is no longer interested in maintaining or prosecuting a Joint Roche-PDL Patent, it shall promptly advise the other party thereof. On the written request of such other party, such Joint Roche-PDL Patent shall be assigned to the other party at no cost to the assignee. If any such patents or patent applications are assigned to Roche, they shall then be deemed to be a Sole Roche Patent and, to the extent such Joint Roche-PDL Patent contains claims outside the Field (or, following the Reversion Effective Date or the Put Right Effective Date, outside the Excluded Field), PDL and its Affiliates shall have a worldwide immunity from suit thereunder. If any such patents or patent applications are assigned to PDL, they shall then be deemed to be a Sole PDL Patent and, to the extent such Joint Roche-PDL Patents contain claims outside the Field, Roche and its Affiliates shall have a worldwide immunity from suit thereunder.

11.3 General Procedures. Until the Reversion Effective Date, the Put Right Effective Date or the expiration of the Exercise Period without PDL exercising the Transplant Reversion, the parties shall observe the following procedures for patent applications for inventions arising from this Amended and Restated Worldwide Agreement:

(a) As soon as one of the parties concludes that it wishes to file a patent application covering an invention in the Field, it shall immediately inform the other party thereof and consult about the filing procedures concerning such patent application. For this purpose, such party will provide the other party with the determination of inventors and scope of claims as early as possible. Should a party be faced with possible loss of rights, such communications may take place promptly after filing a convention application.

(b) The party performing any priority patent filings as described above shall be obliged to prosecute and reasonably maintain such applications and any patents resulting therefrom and will have to bear the costs associated therewith. On request of the party performing the filing, the other party will cooperate, in all reasonable ways, in connection with the prosecution of all such patent applications relating to inventions. The party performing the filing shall advise the other party of any substantial action or development in the prosecution of its patent applications and patents, in particular of the question of scope, the issuance of, or the rejection of, an interference involving or an opposition to any respective patent application or patent.

(c) Inventions and other intellectual property made by either party outside the Field shall be excluded from the provisions of this Amended and Restated Worldwide Agreement and shall belong solely to the party having made the invention or other intellectual property.

11.4 Reimbursement for Costs of Patent Applications for Transplant Indications.

(a) **No Reimbursement**. As of the Effective Date, PDL shall be responsible for all ex parte out-of-pocket expenses incurred by PDL after the Effective Date in connection with the prosecution and maintenance in the Territory of patent applications and patents included within the PDL Patents or Joint Roche-PDL Patents for which PDL makes filings with respect to Transplant Indications pursuant to Article XI of this Amended and Restated Worldwide Agreement.

(b) **PDL Control**. After either the Reversion Effective Date or the Put Right Effective Date, PDL shall have full control over the strategy and decisions with respect to the filing of any patent applications and patents related to Transplant Indications in the Territory. Roche agrees to cooperate with and reasonably assist PDL in the preparation of any patent applications and the maintenance of any patents. Prior to the Reversion Effective Date or the Put Right Effective Date, PDL shall consult Roche with respect to its patent prosecution strategy and decisions, as follows: Prior to the filing of a patent application in the Territory for Transplant Indications, PDL shall inform Roche concerning such proposed filing and shall consult with Roche concerning the proposed filing procedures, including specifically the determination of scope of any such patent and countries in which such application is to be filed. PDL shall regularly advise Roche of any substantial action or development in the prosecution of its patent applications and patents in the Territory

related to the Transplant Indications, in particular of the question of scope of, the issuance of, the rejection of, or an opposition to any respective patent application or patent.

(c) **Accrued Transplant Foreign Filing Expenses**. Transplant Foreign Filing Expenses accrued prior to **[*]** shall remain creditable against royalties payable by Roche to PDL in the Territory (excluding the U.S., including its territories and possessions), as provided in Section 7.3 of this Amended and Restated Worldwide Agreement.

11.5 Reimbursement for Costs of Patent Applications for Autoimmune Indications.

(a) **No Reimbursement**. PDL shall be responsible for all ex parte out-of-pocket expenses incurred by PDL after the Effective Date in connection with the prosecution and maintenance in the Territory of patent applications and patents included within the PDL Patents or Joint Roche-PDL Patents for which PDL makes filings with respect to Autoimmune Indications pursuant to Article XI of this Amended and Restated Worldwide Agreement.

(b) **PDL Control.** PDL shall have full control over the strategy and decisions with respect to the filing of any patent applications and patents related to Autoimmune Indications in the Territory. Roche agrees to cooperate with and reasonably assist PDL in the preparation of any patent applications and the maintenance of any patents.

11.6 No Reimbursement for Roche's Costs of Patent Applications. Roche shall be responsible for all ex parte out-of-pocket expenses incurred by Roche after the Effective Date in connection with the prosecution and maintenance in the Territory of patent applications and patents included within the Roche Owned Patents or Joint Roche-PDL Patents for which Roche makes filings pursuant to this Article XI of this Amended and Restated Worldwide Agreement.

XII. ENFORCEMENT AND DEFENSE OF PATENTS

12.1 Sole Patents.

(a) Except for enforcement or revocation actions involving Sole PDL Patents or Roche Owned Patents outside the Field, in the event of any action against a Third Party for infringement of any claim in any issued patent within the Sole PDL Patents or Roche Owned Patents, as the case may be, or the institution by a Third Party of any proceedings for the revocation of any such claim, each party will notify the other promptly and, following such notification, the parties shall confer. **[*]** shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the Sole PDL Patents at its own expense, in its own name and entirely under its own direction and control. **[*]** shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the Roche Owned Patents at its own expense, in its own name and entirely under its own direction and control.

(b) If a party with the first right hereunder elects not to prosecute any action for infringement or to defend any proceeding for revocation of any claims in any issued patent within the Sole PDL Patents (other than those Sole PDL Patents for which PDL **[*]**) or Roche Owned Patents (other than those Roche Owned Patents **[*]**), as the case may be, within **[*]** of being requested by the other party to do so, the other party may prosecute such action or defend such

proceeding at its own expense, in its own name and entirely under its own direction and control. This Section 12.1(b) shall expire on the Reversion Effective Date or the Put Right Effective Date.

(c) In any event, the party bringing an action (**"Acting Party"**) pursuant to this Section 12.1 shall solicit, and seriously consider in good faith the non-acting party's input with respect to all material aspects of such action, including without limitation, the development of the litigation strategy and the execution thereof. In furtherance and not in limitation of the foregoing, the Acting Party shall keep the other party promptly and fully informed of the status of any such action, and the non-acting party shall have the right to review and comment on the Acting Party's activities related thereto. The obligations of this Section 12.1(c) shall not apply to PDL as the Acting Party after either the Reversion Effective Date or the Put Right Effective Date.

(d) Each party will reasonably assist the Acting Party in any such action or proceeding being prosecuted or defended by the Acting Party, if so requested by the Acting Party or required by law. Without limiting the generality of the foregoing, the non-acting party agrees to join such action or proceeding if required by law to maintain such action or proceeding. The Acting Party will pay or reimburse the assisting party for all costs, expenses and liabilities that the assisting party may incur or suffer in affording assistance to such actions or proceedings. No settlement of any such action or defense that restricts the scope or affects the enforceability of PDL Know-How or Sole PDL Patents may be entered into by either PDL (if it would affect Roche's rights under this Agreement) or Roche without the prior consent of the other party hereto, **[*]**. No settlement of any such action or defense that restricts the scope or affects the enforceability of Roche Know-How or Roche Owned Patents may be entered into by either PDL or Roche without the prior consent of the other party hereto (if it would affect the other party's rights under this Agreement)**[*]**. The consent obligations of this Section 12.1(d) shall not apply to PDL as the Acting Party after either the Reversion Effective Date or the Put Right Effective Date.

(e) If either party elects to prosecute an action for infringement or to defend any proceedings for revocation of any claims pursuant to this Section 12.1 and subsequently ceases to continue or withdraws from such action or defense, it shall forthwith so notify the other party in writing and the other party may substitute itself for the withdrawing party and the parties' respective rights and obligations under this Section 12.1 shall be reversed. The obligations of this Section 12.1(e) shall not apply to PDL as the Acting Party after either the Reversion Effective Date or the Put Right Effective Date.

12.2 Joint Roche-PDL Patents. In the event of any action against a Third Party for infringement of any claim in any issued patent within the Joint Roche-PDL Patents, or the institution by a Third Party of any proceedings for the revocation of any such claim, each party will notify the other promptly and, following such notification, the parties shall confer to determine whether either or both parties shall control the prosecution or defense of such action or proceeding and who shall bear the costs thereof. If both parties wish to control the prosecution or defense of such action or proceeding and the parties are unable to reach agreement within **[*]** of the notification referred to above, then (a) with respect to alleged infringement in the **[*]**, **[*]** shall have the exclusive

right to bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction, (b) with respect to alleged infringement in

the **[*]**, **[*]** shall have the exclusive right to bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction; and (c) with respect to alleged infringement **[*]**, **[*]** shall have the right to bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction and control; provided, however, that if both parties elect to prosecute or defend, each party shall bear its own expenses but both parties shall have equal control over such prosecution or defense. No settlement of any action or defense that restricts the scope or affects the enforceability of Joint Roche-PDL Patents may be entered into by either PDL or Roche without the prior consent of the other party hereto, which consent shall not be unreasonably withheld. In any event, the Acting Party pursuant to this Section 12.2 shall solicit, and seriously consider in good faith the other party's input with respect to all material aspects of such action, including without limitation, the development of the litigation strategy and the execution thereof. In furtherance and not in limitation of the foregoing, the Acting Party shall keep the other party promptly and fully informed of the status of any such action, and the other party shall have the right to review and comment on the Acting Party's activities related thereto.

12.3 Distribution of Proceeds. In the event either party exercises the rights conferred in Section 12.1 or 12.2 hereof, and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to reimburse the parties for all costs and expenses incurred in connection therewith, including reasonable attorneys' fees necessarily involved in the prosecution and/or defense of any suit or proceeding and, if after such reimbursement any funds shall remain from such damages or other sums recovered, said remaining recovery shall belong to **[*]**; provided, however, that any remaining recovery by the party exercising its rights for a Joint Roche-PDL Patent with respect to alleged infringement outside the Field shall be shared, with **[*]** of such remaining recovery to Roche and **[*]** of such remaining recovery to PDL.

12.4 Defense of Infringement Actions.

(a) Roche shall defend at its own cost any infringement suit that may be brought against PDL or Roche on account of the development, manufacture, production, use, importation, offer for sale, or sale of Daclizumab or Excluded Products by Roche, and shall indemnify and hold PDL harmless against any such patent or other infringement suits, and any claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and cost, that may be incurred by PDL therein or in settlement thereof. Any and all settlements that restrict the scope or enforceability of PDL Know-How or PDL Patents must be approved by PDL, in its sole and absolute discretion, before execution by Roche. Any and all settlements that restrict the scope or enforceability of Joint Roche-PDL Patents or Sole Roche Patents (other than those Sole Roche Patents co-owned by a Third Party) must be approved by PDL before execution by Roche, such approval not to be unreasonably withheld. PDL shall not be required to approve any settlement that does not include as a condition thereof the granting to PDL of a full and unconditional release of claims.

(b) PDL shall defend at its own cost any infringement suit that may be brought against Roche or PDL on account of the development, manufacture, production, use, importation,

offer for sale, or sale of Licensed Products by PDL, and shall indemnify and hold Roche harmless against any such patent or other infringement suits, and any claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and cost, that may be incurred by Roche therein or in settlement thereof. Any and all settlements that restrict the scope or enforceability of Roche Know-How or Roche Patents must be approved by Roche, in its sole and absolute discretion, before execution by PDL. Any and all settlements that restrict the scope or enforceability of Joint Roche-PDL Patents must be approved by Roche before execution by PDL, such approval not to be unreasonably withheld. Roche shall not be required to approve any settlement that does not include as a condition thereof the granting to Roche of a full and unconditional release of claims. **[*]**

12.5 Right to Counsel. Each party to this Amended and Restated Worldwide Agreement shall always have the right to be represented by counsel of its own selection and its own expense in any suit or other action instituted by the other for infringement, under the terms of this Amended and Restated Worldwide Agreement.

XIII. TERM AND TERMINATION

13.1 Term. Unless earlier terminated pursuant to the terms of this Article XIII, this Amended and Restated Worldwide Agreement shall go into effect on the Effective Date and shall remain in effect until the latest of (i) expiration of the last to expire PDL Patents; (ii) expiration of the last to expire Roche Patents; (iii) expiration of PDL's payment obligations hereunder; or (iv) expiration of Roche's payment obligations hereunder. On expiration of this Amended and Restated Worldwide Agreement, any exclusive licenses then in effect under any Roche Know-How or PDL Know-How will convert to fully paid, non-exclusive licenses.

13.2 Termination by Mutual Agreement. This Amended and Restated Worldwide Agreement may be terminated by the written agreement of both parties.

13.3 Termination by PDL on Roche Default. If, during the period commencing on the Effective Date and terminating on the earlier of Reversion Effective Date or the Put Right Effective Date, Roche defaults in the performance of, or fails to be in compliance with, any material agreement, condition or covenant of this Amended and Restated Worldwide Agreement with respect to either (a) the rights PDL grants to Roche under Article II of this Amended and Restated Worldwide Agreement, including royalties and consideration due from Roche to PDL under Article VII, or (b) the Transplant Reversion granted under Article V, then PDL may terminate any or all of the rights and licenses granted to Roche under Section 2.5 of this Amended and Restated Worldwide Agreement at its option, at which time Roche's right to promote, distribute and sell Daclizumab in the Roche Territory shall terminate as though PDL had exercised its Transplant Reversion, with all the same effect as though that were the case, but without the need for any payment of the Reversion Exercise Fee. PDL shall have such right to so terminate Roche's rights under this Section 13.3 only if such default or noncompliance shall not have been remedied, or steps initiated to remedy the same to PDL's reasonable satisfaction, within **[*]** after receipt by Roche of a written notice thereof from PDL. It is expressly understood that PDL's rights to terminate under this Section 13.3 are in effect only until the earlier of the

Reversion Effective Date or the Put Right Effective Date, and that such rights expire with the expiration, without exercise, of the Transplant Reversion and the Roche Put Right.

13.4 Voluntary Termination Of License by Roche.

(a) Roche shall have the right, in the event the Transplant Reversion and the Roche Put Right expire unexercised, to voluntarily terminate its licenses under Section 2.5(a), on six (6) months written notice. On notice of such voluntary termination, Roche shall notify PDL of the amount of Daclizumab that Roche, its Affiliates, sublicensees and distributors then have on hand (**"Inventory"**). Roche and its Affiliates, sublicensees and distributors shall thereupon be permitted to sell the Inventory, provided that PDL shall have the first option for a period not to exceed **[*]** to purchase all or part of the Inventory at **[*]**. If PDL fails to exercise its option to purchase all of the Inventory or for that part of the Inventory with respect to which the option is not exercised, then Roche will be free to sell such Inventory to Third Parties for a period not to exceed **[*]** from the termination of PDL's option. In any event, Roche shall pay the royalties or other consideration due, if any, on the sale of such Inventory in the amounts and manner provided for in Articles VII and VIII.

(b) Roche shall have the right at any time during the term of this Amended and Restated Worldwide Agreement, to voluntarily terminate its license granted under Section 2.5(b), on **[*]** written notice to PDL. In the event of such unilateral termination, Roche agrees to negotiate with PDL, on PDL's request, for the transfer and/or license of any Roche owned or licensed intellectual property or technology relevant to the development and/or commercialization of the Excluded Products, in return for **[*]**.

13.5 Return of Materials. On termination of this Amended and Restated Worldwide Agreement in whole by both parties pursuant to Section 13.2, by PDL pursuant to Section 13.3, or by Roche pursuant to Section 13.4, Roche forthwith shall (a) return to PDL all cell lines and their progeny, antibodies and other biological materials provided by PDL under the 1989 Agreements; and (b) subject to Section 13.4, at PDL's cost, shall deliver to PDL then available supplies of Daclizumab.

13.6 Rights and Obligations on Termination or Expiration. Unless expressly provided to the contrary, the provisions of Sections 2.1(g), 2.3, 2.7, 3.4, 5.7, 7.4, 7.5, 9.1(c), 9.1(e), 13.4, 13.5, 13.6, 13.7, 17.4, 17.5, 17.6, 17.8, and 17.11, and Articles VIII, X, XI, XII, XIV and XV shall survive the termination of this Amended and Restated Worldwide Agreement and shall expire on their own terms, or if no expiration is expressly indicated therein, shall continue indefinitely.

XIV. CONFIDENTIALITY, DISCLOSURE AND PUBLICATIONS

14.1 Confidentiality.

(a) Generally. During the term of this Amended and Restated Worldwide Agreement and for a period of **[*]** following expiration or termination of this Amended and

Restated Worldwide Agreement, each party shall maintain in confidence all information and materials including, but not limited to, cell lines, their progeny, and antibodies, disclosed by the other party hereto that such party knows or has reason to know are or contain trade secrets or other proprietary information of the other, including, without limitation, information relating to the PDL Know-How, PDL Patents, Roche Know-How, Roche Patents, Joint Roche-PDL Patents, Joint Inventions and inventions of the other party, and the business plans of the other party, including, without limitation, information provided by either party to the other party hereto prior to the Effective Date, and shall not use such trade secrets or proprietary information for any purpose, including, without limitation, for the purpose of developing products in the Field except as permitted by this Amended and Restated Worldwide Agreement or disclose the same to anyone other than those of its Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents or subcontractors as are necessary in connection with such party's activities as contemplated in this Amended and Restated Worldwide Agreement. Each party shall be responsible for ensuring compliance with these obligations by such party's Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents and subcontractors. Each party shall use a similar effort to that which it uses to protect its own **[*]** trade secrets or proprietary information to ensure that its Affiliates, sublicensees, employees, consultants, agents and subcontractors do not disclose or make any unauthorized use of trade secrets or proprietary information of the other party hereto. Each party shall notify the other promptly on discovery of any unauthorized use or disclosure of the other's trade secrets or proprietary information.

(b) Additional Roche Obligations. During the period commencing on the Effective Date and terminating on the earlier of Reversion Effective Date or the Put Right Effective Date, Roche agrees to maintain in confidence the Roche Know-How related to Daclizumab in a manner consistent with Roche's maintenance of confidentiality with respect to know-how and trade secrets related to its other products and technologies and consistent with Roche's past practices with respect to such Roche Know-How.

14.2 Exceptions. The obligation of confidentiality contained in this Amended and Restated Worldwide Agreement shall not apply to the extent that (a) either party (the **"Recipient"**) is required to disclose information by order or regulation of a governmental agency or a court of competent jurisdiction or (b) the Recipient can demonstrate that (i) the disclosed information was at the time of such disclosure by the Recipient already in the public domain other than as a result of actions of the Recipient, its Affiliates, employees, licensees, agents or subcontractors, in violation hereof; (ii) the disclosed information was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient in connection with the negotiation, execution or performance of this Amended and Restated Worldwide Agreement; or (iii) the disclosed information was received by the Recipient or its Affiliates on an unrestricted basis from a source unrelated to any party to this Amended and Restated Worldwide Agreement and not under a duty of confidentiality to the other party, or (c) the Recipient can demonstrate that disclosure to a regulatory authority is required by its product license approval process.

14.3 Publications.

(a) Scientific Publications. Prior to public disclosure or submission for publication of a manuscript describing the results of any scientific activity or collaboration between PDL and Roche in the Field, the party disclosing or submitting such a manuscript (**"Disclosing Party"**) shall send the other party (**"Responding Party"**) by expedited delivery a copy of the manuscript to be submitted and shall allow the Responding Party a reasonable time period (not to exceed forty-five (45) days from the date of confirmed receipt) in which to determine whether the manuscript contains subject matter of which patent protection should be sought (prior to publication of such manuscript) for the purpose of protecting an invention, or whether the manuscript contains confidential information belonging to the Responding Party. After the expiration of forty-five (45) days from the date of confirmed receipt of such manuscript, the Disclosing Party shall be free to submit such manuscript for publication and publish or otherwise disclose to the public such research results. Should the Responding Party believe the subject matter of the manuscript contains confidential information or a patentable invention of substantial commercial value to the Responding Party, then prior to the expiration of forty-five (45) days from the date of confirmed receipt of such manuscript by the Responding Party, the Responding Party shall notify the Disclosing Party in writing of its determination that such manuscript contains such information or subject matter for which patent protection should be sought. On receipt of such written notice from the Responding Party, the Disclosing Party shall delay public disclosure of such information or submission of the manuscript for an additional period of sixty (60) days to permit preparation and filing of a patent application on the disclosed subject matter. The Disclosing Party shall thereafter be free to publish or disclose such information, except that the Disclosing Party may not disclose any confidential information of the Responding Party in violation of Sections 14.1 and 14.2 hereof. Determination of authorship for any paper or patent shall be in accordance with accepted scientific practice. Should any questions on authorship arise, this will be determined by good faith consultation between the respective heads of research for each of the parties.

(b) Clinical Studies. At any time prior to PDL's exercise of the Transplant Reversion or Roche's exercise of the Roche Put Right, if a party intends to publicly disclose or submit for publication a manuscript describing the results of any permitted scientific, preclinical or clinical study involving Daclizumab conducted by or on behalf of such party (the **"Publishing Party**") or its Affiliates, the Publishing Party shall send the other party by expedited delivery a copy of the manuscript to be submitted and shall allow the other party a reasonable time period (such period to be stated in the transmittal and not to exceed forty-five (45) days from the date of confirmed receipt by the other party) to review the manuscript, including for the purpose of determining whether the manuscript contains information which is reasonably likely to have a material adverse impact on Daclizumab for either Transplant Indications or Autoimmune Indications, as the case may be, in the Territory or confidential information belonging to the other party. After the expiration of such stated reasonable period from the date of confirmed receipt by the other party of such manuscript, the Publishing Party shall be free to submit such manuscript for publication and publish or otherwise disclose to the public such research results. During such stated reasonable period, if the other party believes the manuscript contains information that is reasonably likely to have a material adverse impact on Daclizumab for Transplant Indications or Autoimmune Indications, as the case may be, in the Territory, then prior to the expiration of the

stated period above, the other party shall notify the Publishing Party in writing of its determination and the reasons therefor. On receipt of such written notice from the other party, the Publishing Party shall confer with the other party and shall attempt in good faith to resolve such concerns before the Publishing Party makes any public disclosure of such information or submission of the manuscript. After the Reversion Effective Date or the Put Right Effective Date, PDL shall have the sole right to publish or otherwise publicly disclose, without the consent of Roche, the results of any scientific, preclinical and clinical data involving Daclizumab conducted by or on behalf of PDL or Roche or their Affiliates.

XV. DISPUTE RESOLUTION

15.1 Arbitration. Except as expressly provided herein, any claim, dispute or controversy arising out of or in connection with or relating to this Amended and Restated Worldwide Agreement or the breach or alleged breach thereof shall be submitted by the parties to arbitration by the American Arbitration Association ("AAA") in Santa Clara County, California, under the commercial rules then in effect for that AAA except as provided herein. All proceedings shall be held in English and a transcribed record prepared in English. The parties shall choose, by mutual agreement, one arbitrator within thirty (30) days of receipt of notice of the intent to arbitrate. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the AAA shall make such appointment within thirty (30) days of such failure. The award rendered by the arbitrator shall include costs of arbitration, reasonable attorneys' fees and reasonable costs for expert and other witnesses, and judgment on such award may be entered in any court having jurisdiction thereof. The parties shall be entitled to discovery as provided in Sections 1283.05 and 1283.1 of the Code of Civil Procedure of the State of California, whether or not the California Arbitration Act is deemed to apply to said arbitration. Nothing in this Amended and Restated Worldwide Agreement shall be deemed as preventing either party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the parties and the subject matter of the dispute as necessary to protect either party's name, proprietary information, trade secrets, know-how or any other proprietary right. If the issues in dispute involve scientific or technical matters, any arbitrator chosen hereunder shall have educational training and/or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

XVI. FORCE MAJEURE

16.1 No Control. If either party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, strike or labor differences, governmental enactment, rule or regulation, or any other cause beyond such party's control, such party shall not be liable to the other therefor; and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. The party invoking such force majeure rights of this Section 16.1 must notify the other party by courier or overnight dispatch (e.g., Federal Express) within a period of fifteen (15) days of both the first and last day of the force majeure

unless the force majeure renders such notification impossible in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds six (6) months, both parties shall consult together to find an appropriate solution.

XVII. MISCELLANEOUS

17.1 Representations. Each party represents and warrants to the other party hereto that, except as may otherwise be disclosed in writing to such party:

(a) each party has the full right and authority to enter into this Amended and Restated Worldwide Agreement; and

(b) to the best knowledge of the party after reasonable investigation, no Third Party has any right, title or interest in the PDL Patents or PDL Know-How, Roche Know-How or Roche Patents, as the case may be, or in the Joint PDL-Roche Patents, as the result of such Third Party's former employment of any employee of that party.

17.2 Assignment. Either party may assign this Amended and Restated Worldwide Agreement and the licenses herein granted (a) to any Affiliate of such party without the consent of the other party, provided that such party remains fully liable for the performance of such party's obligations hereunder by such Affiliate, or (b) to any Third Party, on the prior written consent of the other party, not to be unreasonably withheld; and (c) without the consent of the other party, to any Third Party purchaser of all or substantially all of the business unit to which this Amended and Restated Worldwide Agreement relates, which in the case of PDL, shall mean the Daclizumab business, and in the case of Roche, shall mean Roche's therapeutic antibody business or transplant therapeutic business. The parties agree that it would be reasonable for a party to withhold consent to the other party's proposed assignment of this Amended and Restated Worldwide Agreement to an entity, that is, as of the time of such proposed assignment, **[*]** (in at least one **[*]** with **[*]**), or **[*]** in any **[*]** any **[*]** for the **[*]** of **[*]** in any **[*]**. This Amended and Restated Worldwide Agreement shall be binding on and shall inure to the benefit of the permitted successors and assigns of the parties hereto.

17.3 Entire Agreement. This Amended and Restated Worldwide Agreement, the Reversion Agreement between F. Roche and PDL dated March 4, 2002 (**"Japan Reversion Agreement"**), the Pharmacovigilance Agreement, and the Joint Defense Agreement dated June 20, 2000, constitute the entire agreement between the parties hereto with respect to the subject matter herein and, effective on the Effective Date, supersede all previous agreements (including the 1999 Agreements), whether written or oral, such superseding resulting in, among other things, the licenses granted thereunder having no further force or effect and being replaced by the licenses set forth in Article II of this Amended and Restated Worldwide Agreement. Notwithstanding the foregoing, (a) certain provisions of the 1999 Agreements shall remain in force and effect, to the extent this Amended and Restated Worldwide Agreement so indicates by specific reference, and (b) any royalties or other payments accruing under the 1999 Agreements prior to the Effective Date shall remain due and payable. This Amended and Restated

Worldwide Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both parties.

17.4 Releases. The parties hereby confirm the releases contained in Section 15.4 of the 1999 PDL/Roche Agreement and in Section 11.4 of the F. Roche Agreement.

17.5 Severability. If any provision of this Amended and Restated Worldwide Agreement is declared invalid by an arbitrator pursuant to Section 15.1 or by a court of last resort or by any court or other governmental body from the decision of which an appeal is not taken within the time provided by law, then and in such event, this Amended and Restated Worldwide Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Amended and Restated Worldwide 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 Amended and Restated Worldwide 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 intent of the parties, and, failing such amendment, either party may submit the matter to arbitration for resolution pursuant to Section 15.1.

17.6 Indemnification.

(a) Roche agrees to defend, indemnify and hold harmless PDL, its trustees, officers, agents and employees from and against any and all Third Party suits, claims, acts, liabilities, demands, damages, expenses, and losses of any kind, including those resulting from death, personal injury, illness or property damage arising (i) out of the manufacture, distribution, use, testing, promotion, marketing or sale or other disposition, by Roche, an Affiliate of Roche, or any distributor, customer, sublicensee or representative of Roche or anyone in privity therewith (other than PDL), of (A) any Licensed Product, as defined in the 1999 Agreements, prior to the Effective Date, (B) Daclizumab or any Excluded Product on or after the Effective Date, or (C) any cell lines, their progeny, or other biological materials, method, process, device or apparatus licensed or provided by PDL pursuant to the 1989 Agreements, the 1999 Agreements or this Amended and Restated Worldwide Agreement; (ii) as a result of practicing a Joint Invention, or using PDL Know-How or PDL Patents licensed to Roche under this Amended and Restated Worldwide Agreement, except where such claim is based on the negligent acts of commission or omission of PDL; (iii) out of any breach by Roche of any representation, warranty or covenant of this Amended and Restated Worldwide Agreement; (iv) out of any violation of applicable law by an action, policy or procedure of Roche or its Affiliates; or (v) out of any negligence or willful misconduct of Roche or its Affiliates.

(b) PDL agrees to defend, indemnify and hold harmless Roche, its trustees, officers, agents and employees harmless from and against any and all Third Party suits, claims, actions, liabilities, demands, damages, expenses, and losses of any kind, including those resulting from death, personal injury, illness or property damage arising (i) out of the manufacture, distribution, use, testing, promotion, marketing or sale or other disposition, by PDL, an Affiliate of PDL, or any distributor, customer, sublicensee or representative of PDL or anyone in privity

therewith (other than Roche), of (A) Daclizumab prior to the Effective Date, or (B) Daclizumab or any Other Licensed Product on or after the Effective Date, or (C) any biological materials, method, process, device or apparatus licensed or provided by Roche pursuant to this Amended and Restated Worldwide Agreement; (ii) as a result of practicing a Joint Invention, or using Roche Know-How or Roche Patents licensed to PDL under this Amended and Restated Worldwide Agreement, except where such claim is based on the negligent acts of commission or omission of Roche; (iii) out of any breach by PDL of any representation, warranty or covenant of this Amended and Restated Worldwide Agreement; (iv) out of any violation of applicable law by an action, policy or procedure of PDL or its Affiliates; (v) out of any negligence or willful misconduct of PDL or its Affiliates; or (vi) from any claim for failure to pay any license fee, royalty or other payment due on sales of Daclizumab or any Other Licensed Product by PDL or its Affiliates or sublicensees under any license

agreement for any Roche Controlled Patents between Roche and any Third Party licensor that PDL elected not to take a sublicense under as provided in Section 2.8(b).

(c) Procedure. In the event of a claim by a Third Party against a party entitled to indemnification under this Amended and Restated Worldwide Agreement (**"Indemnified Party"**), the Indemnified Party shall promptly notify the other party (**"Indemnifying Party"**) in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party, including, as requested by the Indemnifying Party and at the Indemnifying Party's cost, entering into a joint defense agreement. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

17.7 Notices. Any notice or report required or permitted to be given under this Amended and Restated Worldwide Agreement shall be in writing and shall be mailed by certified or registered mail, or telexed or telecopied and confirmed by mailing, as follows and shall be effective five (5) days after such mailing:

If to PDL:
Protein Design Labs, Inc.
34801 Campus Drive
Fremont, California U.S.A. 94555
Attention: Chief Executive Officer

and
Protein Design Labs, Inc.
34801 Campus Drive
Fremont, California U.S.A. 94555
Attention: General Counsel

If to Roche:
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110
Attention: Corporate Secretary

and
F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
CH-4002 Basel, Switzerland
Attention: Law Department

17.8 Choice of Law. The validity, performance, construction, and effect of this Amended and Restated Worldwide Agreement shall be governed by the laws of the State of California, U.S.A, without regard to conflicts of law principles that would provide for application of the law of a jurisdiction outside California and excluding the United Nations Convention on Contracts for the International Sales of Goods.

17.9 Publicity. The parties agree to issue press releases in an agreed-on form and format concerning their entry into this Amended and Restated Worldwide Agreement, with the content of such releases to be approved in advance by the parties. In all other respects, no party to this Amended and Restated Worldwide Agreement shall use the name of the other parties in any publicity release without the prior written permission of such other party, which shall not be unreasonably withheld. The other party shall have a reasonable opportunity to review and comment on any such proposed publicity release. Except as required by law, no party hereto shall publicly disclose the terms of this Amended and Restated Worldwide Agreement, the 1989 Agreements, the 1999 Agreements, the Japan Reversion Agreement, or their terms and conditions unless expressly authorized to do so by the other party which authorization shall not be unreasonably withheld. In the event that disclosure is authorized, the parties will work together to develop a mutually acceptable disclosure. Notwithstanding anything to the contrary herein, if not otherwise disclosed by Roche, PDL shall not disclose to any Third Party the amount of sales of Roche, or royalties or consideration paid by Roche with respect to, Daclizumab or Excluded Products without the prior written consent of Roche, except that PDL shall have the right to disclose the terms of this Amended and Restated Worldwide Agreement to any bona fide investors, advisors, investment banking representatives, or prospective strategic partners or collaborators, under binder of confidentiality. If not otherwise disclosed by PDL, Roche shall not disclose to any Third Party the amount of sales of PDL, or royalties or consideration paid by PDL with respect to, Daclizumab without the prior written consent of PDL, which consent shall not be unreasonably withheld.

17.10 Further Assurances. The parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Amended and Restated Worldwide Agreement, and shall (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Amended and Restated Worldwide Agreement), all as the other party may reasonably request for the purpose of carrying out the intent of this Amended and Restated Worldwide Agreement.

17.11 Tax Treatment and Tax Structure Disclosure. Notwithstanding anything herein to the contrary, any party to this Amended and Restated Worldwide Agreement (and any employee, representative, or other agent of any party to this Amended and Restated Worldwide Agreement) may disclose to any and all persons, without limitation of any kind, the tax treatment and tax structure of the transactions contemplated by this Amended and Restated Worldwide Agreement and all materials of any kind (including opinions or other tax analyses) that are provided to it relating to such tax treatment and tax structure; *provided however*, that such disclosure may not be made to the extent a lack of disclosure is reasonably necessary to comply with any applicable federal or state securities laws. For the purposes of the foregoing sentence, (a) the "tax treatment" of a transaction means the purported or claimed federal

income tax treatment of the transaction, and (b) the "tax structure" of a transaction means any fact that may be relevant to understanding the purported or claimed federal income tax treatment of the transaction.

17.12 Agency. Neither party is, nor will be deemed to be an employee, agent or representative of the other party for any purpose. Each party is an independent contractor, not an employee or partner of the other party. Neither party shall have the authority to speak for, represent or obligate the other party in any way without prior written authority from the other party.

17.13 No Waiver. Any omission or delay by either party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other party, shall not constitute a waiver of such party's rights to the future enforcement of its rights under this Amended and Restated Worldwide Agreement. Any waiver by a party of a particular breach or default by the other party shall not operate or be construed as a waiver of any subsequent breach or default by the other party.

17.14 No Strict Construction. This Amended and Restated Worldwide Agreement has been prepared jointly by the parties and shall not be strictly construed against either party.

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

17.16 Counterparts. This Amended and Restated Worldwide 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 have executed this Amended and Restated Worldwide Agreement through their duly authorized representatives to be effective as of the Effective Date.

PROTEIN DESIGN LABS, INC.

By: _____
Title: Chief Executive Officer
Date: _____

HOFFMANN-LA ROCHE INC.

By: _____
Title: _____
Date: _____

F. HOFFMANN-LA ROCHE LTD

By: _____
Title: _____
Date: _____

By: _____
Title: _____
Date: _____

Appendix A

PDL Patent Rights

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: March 5, 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.:

		Patent No.	Country	Title*
Issued	9/29/00	AR 254487 V1	Argentina	"Novel Immunoglobulins, Their Production and Use"
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	“
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	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	“

[*]

* Exact titles may differ in different countries.
(1) and corresponding European national patents issued therefrom**.**
(2) registration date
[*]

Appendix B

Third Party Licenses as of the Effective Date

[*]

Appendix C

PDL Sole Territory: Countries or Jurisdictions in which All Rights Have Reverted to PDL

[*]

Appendix D

Example of Section 7.4(c) Royalty Adjustments

[*]

Schedule 2.8(a)

Certain Roche Owned Patents

[*]

Schedule 2.8(b)

Certain Roche Controlled Patents

All patents and patent applications licensed to Roche in the following agreements:

[*]

Schedule 2.8(e)

Notices of Third Party IP Rights

[*]

Schedule 2.8(f)

Third Party Licenses

[*]

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

ICOS CORPORATION
MANUFACTURING AGREEMENT

THIS MANUFACTURING AGREEMENT (this "Agreement") between ICOS Corporation, a Washington corporation, having its principal offices at 22021 20th Avenue, Bothell, WA 98021 ("ICOS"), and Protein Design Labs, Inc., a Delaware corporation, having its principal offices at34801 Campus Drive, Fremont, CA 94555 ("PDL"), is effective as of August 29, 2003.

RECITALS

A. PDL is engaged in the discovery, development, and commercialization of new pharmaceutical candidates;

B. ICOS is in the business of providing biological development and manufacturing services; and

C. PDL has discussed certain of its areas of interest with ICOS and is familiar with ICOS's facilities and expertise and, as a result, wishes to retain ICOS to provide certain services associated with manufacturing and/or supplying certain quantities of specific product(s) for use in clinical trials, as more fully set forth in various Work and Quality Statements (as defined herein) to be attached to this Agreement, and ICOS is willing to so perform, all in accordance with the applicable Work and Quality Statements and subject to the terms of this Agreement.

NOW, THEREFORE, the parties agree as follows:

AGREEMENT

1. Definitions

1.1 "Acceptance Criteria" means the composition, quality, purity, identity and strength of a Product to be set forth in Work and Quality Statements and which must be met by ICOS in Processing the Product.

1.2 "Affiliate" means any entity that controls, is controlled by, or is under common control with a party. A corporation or other entity shall be deemed to control a corporation or entity if it directly or indirectly owns or controls at least fifty percent (50%) of the voting stock or other ownership interest of that corporation or entity.

1.3 "CMC" means Chemistry Manufacturing and Control information required by the FDA for the filing of an IND, as set forth in 21 CFR 312.23(a)(7), *et. seq*., as amended or any successor information.

1.4 "Confidential Information" means any business or technical information, trade secrets, know-how, techniques, data or other information, disclosed by the disclosing party to the receiving party in writing and marked "confidential" or that is disclosed orally and confirmed in

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writing as confidential within thirty (30) days following such disclosure. Confidential Information shall not include any information that is: (a) already known to the receiving party at the time of disclosure hereunder (other than from the other party hereto) as demonstrated by its written records; (b) now or hereafter becomes publicly known other than through acts or omissions of the receiving party, or anyone to whom the receiving party disclosed such information; (c) disclosed to the receiving party on a nonconfidential basis by a third party under no obligation of confidentiality to the disclosing party; or (d) independently developed by the receiving party without reliance on the Confidential Information of the disclosing party as shown by its written records. All PDL Materials, PDL Trade Secrets, and all results of the services shall be deemed Confidential Information of PDL, except to the extent any such information falls within any of the categories described in clauses (a) through (d) above.

1.5 "cGMP" means the current Good Manufacturing Practices and General Biologics Products Standards as promulgated under each of the following as in effect on the date of this Agreement and as amended or revised after the date of this Agreement:

(a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. Sect. 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210, 211, 600 and 610) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; and

(b) the ICH guide Q7a, "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients," as applied to investigational drugs (Section 19).

1.6 "PDL Materials" means those materials supplied by PDL to ICOS (if any) pursuant to this Agreement or a particular Work or Quality Statement, except those materials provided by PDL to ICOS that are both (a) not proprietary to PDL and (b) paid for by ICOS.

1.7 "PDL Patent Rights" means patents and patent applications owned by PDL, and all divisions, continuations, continuations-in-part, and substitutions thereof; all foreign patent applications corresponding to the preceding applications; and all U.S. and foreign patents issuing on any of the preceding applications, including extensions, reissues and re-examinations (including, without limitation, all claims and causes of action for infringement, misappropriation or violation thereof).

1.8 "PDL Trade Secrets" means unpatented and/or unpatentable trade-secret information and proprietary technology of any kind or nature owned by PDL (including, without limitation, all claims and causes of action for infringement, misappropriation or violation thereof), which is disclosed by or on behalf of PDL for purposes of assisting ICOS in performing the Services.

1.9 "FDA" means the United States Food and Drug Administration, or its successor agency, and or its European counterpart(s) (currently, the European Medicines Evaluation Agency, or "EMEA"), as the case may be.

1.10 "IND" means an Investigational New Drug application to begin studies of a new drug or biologic for humans that is filed with the FDA, as set forth in 21 CFR 312.22, et. seq., as amended, or its European counterpart(s) (currently, EMEA), as the case may be, or any successor application.

1.11 "Intellectual Property Rights" means any patent, copyright, trademark, trade secret or other intellectual or industrial property rights or proprietary rights arising under the laws of any jurisdiction (including, without limitation, all claims and causes of action for infringement, misappropriation or violation thereof and all rights in any registrations and renewals).

1.12 "Manufacture and Release Requirements" means those specifications, methodologies, analytical tests, process parameters, acceptance criteria, and cGMP requirements necessary to manufacture and release to PDL the Product in conformity with a particular set of agreed on Acceptance Criteria. All Manufacture and Release Requirements are set forth in the Work and Quality Statements.

1.13 "Price and Payment Terms" means the amounts, as stated in a Work Statement, that are payable by PDL to ICOS in consideration for ICOS performing the Services pursuant to such Work Statement.

1.14 "Process," "Processed" or "Processing" means those activities associated with the Product as described in the Work and Quality Statements, which ICOS will perform for and on behalf of PDL in accordance with this Agreement.

1.15 "Product" means the Product defined in the Work and Quality Statements.

1.16 "Quality Statement" means the Quality Statement executed by the parties and attached hereto as Appendix E, and incorporated hereing by this reference, as revised by the written agreement of the parties from time to time, which shall describe the regulatory and compliance roles and responsibilities of both PDL and ICOS.

1.17 "Schedule" means the estimated, target or required timeline for Processing the Product as agreed on by the parties and set forth in a Work Statement.

1.18 "Services" means the services to be provided by ICOS for the benefit of PDL, including Processing specific Product, pursuant to the particular Work and Quality Statements, which services shall be performed subject to the terms and conditions of this Agreement.

1.19 "Work Statement" means each Work Statement executed by the parties and attached hereto as an Exhibit (including the Quality Statement described above), and incorporated herein by this reference, as revised by the written agreement of the parties from time to time, which shall contain at a minimum (a) a description of all the Services to be performed, (b) a description of the Product, Acceptance Criteria, Process, and the Manufacture and Release Requirements, (c) the Price and Payment Terms, (d) the quantity of Product to be delivered, and (e) an estimated Schedule.

2. Work and Quality Statements

Except as provided in Section 3.3, ICOS shall have no obligation to perform any services except in accordance with any Work and Quality Statements. From time to time with respect to the manufacture, analysis and/or supply of the M200 Product, they will execute and attach to this Agreement Work and Quality Statements describing the Services to be performed and related information. This Agreement and each specific Work or Quality Statement, as the same shall be completed, shall collectively, independent from any other Work or Quality Statement, constitute the entire agreement for the specific Services identified in such Work or Quality Statement. No Work or Quality Statement shall be binding unless executed by both parties.

Subject to Section 3.2C, by unanimous written decision of the Project Leaders (as defined in Section 3.5), the parties may revise the Work or Quality Statements at any time.

With respect to all services provided by ICOS from time to time that are agreed on by the parties but are outside the scope of the Services ("Additional Services"), PDL shall pay to ICOS **[*]** as described in the Work Statement. Such Additional Services and PDL's payment obligations will be governed by the terms of this Agreement. ICOS will invoice PDL monthly for all Additional Services performed, with each such invoice containing a reference to the services performed and the personnel used. All such invoices will be payable under the terms described in Section 7. Notwithstanding the foregoing, and subject to the terms of this Agreement, ICOS must complete all the tasks necessary to complete the Services that are within the scope of the Work and Quality Statements to ensure that the Product is Processed in compliance with the applicable Manufacturing and Release Requirements in all material respects, and PDL shall compensate ICOS in performing such Services at the rate specified in the Work Statement.

Promptly following conclusion of the Services, if PDL reasonably determines that further services are required beyond the Services (as described in the Work and Quality Statements) to permit PDL to complete the CMC section of documents necessary to file an IND or IND Amendment with the FDA with respect to the Product, ICOS shall consider performing any such further services provided that (i) such further services are within ICOS's then current manufacturing services offerings, and (ii) ICOS has resources available (during normal working hours) to provide such further services. ICOS reserves the right to request further compensation prior to agreeing to perform such further services, considering other commercial opportunities. Such written description of supplemental services and compensation shall be an amendment to the pertinent Work and Quality Statements and shall be governed by the terms of this Agreement.

3. Scope of Services

3.1 Processing Services

Subject to the terms of this Agreement and pursuant to each Work or Quality Statement, ICOS will perform the Services as set forth in each Work or Quality Statement and, as applicable, use commercially reasonable best efforts (based on biologics manufacturing industry

standards) to (a) Process the Product in accordance with the related Manufacture and Release Requirements, including without limitation cGMP, so that when released to PDL the Product will conform in all material respects with the applicable Acceptance Criteria, (b) maintain all records regarding the Process and the Product as agreed to from time to time by the parties and in conformity with cGMP, (c) subject to the last paragraph of Section 2, provide suitable CMC support documentation to allow PDL to file an IND or IND Amendment with the FDA and (d) supply the Product to PDL in accordance with the applicable Schedule.

The parties agree that the Services, as described in the Work and Quality Statements, may not be changed without both parties' prior written agreement. PDL acknowledges that ICOS is given flexibility to conduct such activities, although not expressly stated in the Work and Quality Statements, at the time and in the manner that ICOS deems necessary as an independent contractor to fulfill its obligations in completing the Services.

3.2 Changes to Schedules and Specifications

A. Due to the unpredictable nature of the biological processes, the Schedules set down for the performance of the Services (including without limitation the dates for production and delivery of Product) set out in the Work Statement are best current estimates only. ICOS **[*]** shall keep PDL regularly informed of any changes to the Schedules. ICOS understands that any such changes to the Schedules may have a material impact on PDL's business and agrees that the effect on the Schedules caused by any changes to the Schedules will be made to the minimum extent reasonably necessary.

B. The Acceptance Criteria and the Manufacturing and Release Requirements may be amended from time to time only as described in Section 3.2C or as dictated by the FDA and applicable laws.

C. ICOS will not implement any Material Changes relating to any agreed on Acceptance Criteria or Manufacture and Release Requirements without PDL's prior written approval of such changes. ICOS may, however, make non-Material Changes without PDL's prior written approval, but with timely notification to PDL. For purposes of this Section 3.2C, a "Material Change" is defined as any variation in the written procedures currently in place that (i) impacts the regulatory commitments for the Product, (ii) may affect the quality, purity, identity or strength of the Product, or (iii) would necessarily result in changing, altering or modifying the Acceptance Criteria and/or the Manufacture and Release Requirements.

D. With respect to (i) amendments dictated by the FDA or applicable laws and (ii) Material Changes, as described in this Section 3.2, PDL shall be responsible for (a) the costs specific to the Product in making such amendments to the Acceptance Criteria and/or Manufacturing and Release Requirements, including without limitation capital costs specific to the Product (but excluding **[*]**), (b) the costs in validating the Process after such amendment, and (c) any increases in cost of manufacturing the Product as a result of such amendment. With respect to amendments dictated by the FDA or applicable laws, the parties will promptly meet to discuss the actions necessary to comply with such amendments and the costs associated

therewith. ICOS shall invoice PDL in accordance with Section 7.2 for all cost that PDL is responsible to pay pursuant to this Section 3.2.D.

3.3 Technical Difficulties

If it becomes apparent to either ICOS or PDL at any stage in the provision of any Services that, as a result of scientific or technical reasons out of the reasonable control of either party, it will not be possible to complete the Services in the manner described in this Agreement or the applicable Work and Quality Statements, the parties shall **[*]** to resolve such problems in a commercially reasonable manner.

3.4 Safety Procedures

ICOS will have responsibility for adopting and enforcing safety procedures for ICOS's internal handling and production of each Product, which procedures will comply in all material respects with applicable federal, state and local environmental and occupational safety and health requirements.

3.5 Project Leaders

Each party will, within ten (10) days of signing this Agreement, select an individual to serve as its Project Leader (collectively, the "Project Leaders") and inform the other party of such selection. Each party's Project Leader will (a) be authorized to manage the relationship of the parties under this Agreement, (b) oversee the performance of the Services, (c) take the actions specifically delegated to them under this Agreement, and (d) be the principal contact of such party for matters relating to this Agreement. Each party may change its Project Leader at any time on written notice to the other party. The Project Leaders shall meet on request of either party, but in any event no less frequently than monthly. Meetings may be held by telephone conference call and may be attended by other representatives of each party, in addition to the Project Leader, as the applicable Project Leader may desire. Decisions of the Project Leaders must be unanimous.

3.6 Ownership of Products; License to Know-How

PDL will own all rights, title and interest to all Products, PDL Materials, PDL Intellectual Property Rights, PDL Patent Rights and PDL Trade Secrets including, without limitation, all in process materials used to produce Products and paid for by PDL, cell lines, cell banks, data, marketing plans, product lines, product plans and records (except to the extent the data or records contain ICOS's Intellectual Property Rights or Confidential Information) produced pursuant to such Work and Quality Statements and all Intellectual Property Rights in and to all of the foregoing (collectively, "PDL Property"); provided, however, that PDL Property will not include any right, title or interest in or to any Intellectual Property Rights or Confidential Information owned by ICOS, including without limitation **[*]**. ICOS grants to PDL a non-exclusive, non-sublicensable (except to third parties for purposes of manufacturing as described in the last sentence of this Section 3.6), royalty free license, to use ICOS's Intellectual Property Rights developed only as a result of performing the Services for PDL under the Work and

Quality Statements, including but not limited to batch records and other such information (the "ICOS Project Related IP"), solely for the purpose of permitting PDL to perform clinical trials and file for an IND or an IND Amendment with the FDA. PDL shall have the right to sublicense its rights in ICOS Project Related IP granted pursuant to this Section 3.6 for the sole purpose of permitting the third party sublicensees to perform manufacturing services that are substantially similar to the Services and related to such PDL Property, provided that each sublicensee agrees in writing to be bound by the provisions of Section 10 to the same extent as PDL is bound. In the event that PDL's license rights granted under this Section 3.6 are terminated at any time for any reason, all such sublicenses shall terminate. PDL shall include in all of its sublicense agreements granted hereunder provisions for such termination.

3.7 Assistance with Transfer of PDL Property.

ICOS agrees that during or after the term of this Agreement, PDL, at its option, may elect to engage a third party to perform the same services or services substantially similar to the Services at any time during or after the term of this Agreement. Subject to both (a) the availability of ICOS personnel, which shall not be unreasonably or unduly withheld, and (b) PDL compensating ICOS for its time spent in complying with its obligations under this paragraph **[*]** in connection with such obligations, ICOS agrees to provide all necessary assistance to PDL in transferring PDL Property to such third parties that PDL engages to perform such services. In addition, ICOS agrees that in connection with such transfer, PDL may **[*]** that is directly related to the PDL Property and necessary for such third parties to perform manufacturing services that are substantially similar to the Services and related to such PDL Property and the ICOS Project Related IP licensed to PDL under Section 3.6, on behalf of PDL under a confidentiality agreement containing provisions at least as protective as those of Article 10, provided that PDL **[*]**.

4. PDL Supply of Information

4.1 Proprietary Information to Provide Services

As soon as practicable after the parties' execution of Work and Quality Statements, PDL shall supply to ICOS all PDL Materials and shall disclose to ICOS all PDL Trade Secrets necessary for ICOS to perform the Services to be provided under such Work and Quality Statements. PDL hereby grants ICOS during the term of the applicable Work and Quality Statements the non-exclusive right to use such PDL Patent Rights, PDL Trade Secrets and PDL Materials as are necessary for ICOS to perform the Services for the sole purpose of providing the related Services. ICOS acknowledges it may not use any such rights, information or materials for any purpose other than as required to perform the Services.

4.2 Information Regarding Hazards

PDL shall also provide to ICOS on an ongoing basis throughout the term of this Agreement prompt notice of any information it receives involving the PDL Materials or Product that relates to any hazards to the health or safety of any personnel of ICOS or the possibility of

cross-contamination of any other products being manufactured or stored by ICOS. ICOS shall promptly notify PDL of any information it receives relating to (a) the safety of the PDL Materials or Product, including any confirmed or unconfirmed information on adverse, serious, or unexpected events, including health or safety risks, associated with the use or toxicity of the Product, or (b) the possibility that cross-contamination has occurred with other Products manufactured or stored by ICOS.

5. Shipping

ICOS agrees to work with PDL to deliver and transfer title to the Product in such locations and in such a manner as directed by PDL, provided that any such arrangement shall not materially alter ICOS's obligations, or expose ICOS to any additional liabilities, under or arising out of this Agreement. Notwithstanding, all Product that ICOS Processes pursuant to this Agreement shall be packaged and shipped FOB ICOS's facilities and in accordance with PDL's written instructions and in compliance with all applicable shipping regulations. The parties acknowledge that, according to the Quality Statement, ICOS may not ship the Product to PDL until PDL has authorized such shipment. In the event PDL does not grant such shipping authorization within **[*]** following the date that ICOS has provided notice to PDL that it is prepared to ship the Product, the Product will be deemed to have been delivered to PDL upon the expiration of such **[*]** period for all purposes under this Agreement (including, without limitation, to determine whether ICOS has timely delivered the Product to PDL, to begin the evaluation period of the Product as described in Section 6.1A, and to transfer the title and risk of loss in the Product to PDL). All risk in and title to the Product shall pass to PDL on delivery by ICOS. Unless the parties agree otherwise in the applicable Work Statement, PDL shall designate a shipping company, coordinate with such shipping company for the shipment of the Product, and be billed directly by the shipping company for all related shipping costs. Notwithstanding the foregoing, shipment may, on agreement of the parties, be arranged by ICOS and at terms and with a carrier reasonably acceptable to PDL.

6. Inspection and Acceptance

6.1 Evaluation Period

A. All Product shipped from ICOS to PDL shall comply in all material respects with the applicable Acceptance Criteria and Manufacture and Release Requirements and shall be accompanied by a certificate of analysis in a form to be agreed on by the parties. PDL shall have **[*]** from the date the Product is delivered to PDL to evaluate the Product and reject the acceptance thereof; provided, however, that PDL may reject any Product only if (i) ICOS fails to deliver a certificate of analysis, (ii) the Product does not meet the Acceptance Criteria as of the date of delivery in any material respect, (iii) the Product was not Processed according to the Manufacture and Release Specifications in any material respect, or (iv) the Product was not manufactured according to cGMPs in any material respect. In the absence of PDL notifying ICOS of rejection within the above described **[*]** period, PDL will be deemed to have accepted the Product as delivered.

B. In the event that the Schedules in a particular Work Statement are estimates only, PDL shall not be entitled to cancel any unfulfilled part of the Services or refuse acceptance of Product related to such Work Statement on grounds of reasonably late performance of the Services or reasonably late delivery of the Product, as described in section 3.2.A. In such event, and notwithstanding Section 12, ICOS shall not be liable for any loss, damage, costs or expenses of any nature, whether direct or consequential, arising out of any delay in performance or delivery howsoever caused; or arising out of any failure to produce the estimated quantities of Product for delivery on the estimated schedule.

6.2 Rejection of Product

A. If PDL rejects any of the Product pursuant to Section 6.1A, PDL shall (i) immediately provide to ICOS written notice of rejection which shall state in reasonable detail the reasons for such rejection and (ii) provide ICOS with the opportunity to conduct its own tests on such rejected Product. PDL shall return all remaining unused Product to ICOS and require that ICOS replace such rejected Product; provided, however, that PDL may retain only that portion of the rejected Product that is then being used for laboratory testing, and may use such retained portion solely to complete such tests but in no event may PDL use any of the rejected Product for any human clinical testing or trials after becoming aware of the basis for such rejection (and PDL shall indemnify ICOS for all liabilities, costs and damages incurred by ICOS resulting from PDL's breach of this limitation on use). ICOS shall replace the Product (as mutually agreed) as soon as practicable. In no case shall ICOS take more than **[*]** to replace such Product.

B. Notwithstanding the foregoing, if PDL rejects the Product for the reasons stated in Section 6.1A(ii) or (iii) and the parties disagree on whether PDL is entitled to so reject such Product, then (i) analysts from both parties shall promptly meet to determine that the methods of analysis are the same and are being executed in the same manner, (ii) carefully controlled and split samples shall be sent from one site to another for testing in an attempt to reach agreement, and (iii) the parties shall use good faith efforts for a period of **[*]** after completing such tests to resolve whether PDL is entitled to reject such Product. In the event that the parties cannot resolve their dispute in the manner described, an independent laboratory acceptable to both parties shall be qualified and shall utilize agreed on test methods to test the Product in dispute ("Disputed Product"). The costs of such independent laboratory shall be borne by the parties equally; provided, however, that the party that is determined to be incorrect in the dispute shall be responsible for all such costs and shall reimburse the correct party for its share of such costs incurred. The decision of such independent laboratory shall be in writing and shall be binding on both ICOS and PDL.

C. If PDL properly rejects Product pursuant to Section 6.1A and 6.2B, or if ICOS breaches its warranty stated in Section 10.1B subject to the time limitation regarding notice of breach as stated therein, and ICOS cannot replace the Product with conforming Product within the time period set forth in Section 6.2A, then ICOS **[*]**; provided, however, that ICOS will not wait for the time period in Section 6.2A to expire before **[*]** if ICOS has earlier knowledge that it will be unable to replace the Product **[*]**. Nothing in this Section shall permit ICOS to cancel its remaining obligations under the Work and Quality Statements (e.g., obligations regarding

transfer of PDL Property and confidentiality) or terminate this Agreement as it relates to other Work Statements. The provisions of this Section 6.2 shall be the sole remedies available to PDL with respect to Product that PDL properly rejects.

7. Fees and Invoices

7.1 Fees

In consideration for ICOS performing the Services, PDL shall pay to ICOS such amounts as described in the Price and Payment Terms section of the applicable Work Statement. All fees are exclusive of sales tax or of any other applicable taxes, levies, duties and fees of whatever nature imposed by or under the authority of any governmental authority, which shall be paid by PDL (other than taxes based on ICOS's income).

7.2 Invoices

ICOS shall invoice PDL as provided in the Price and Payment Terms section of the applicable Work Statement. PDL shall pay the total amount of each invoice within **[*]** of receipt of the invoice. If ICOS has not received full payment prior to the expiration of such **[*]** period, ICOS shall provide written notice to PDL of such non-payment. In the event PDL fails to make payment within **[*]** of the date of such notice, then (a) all unpaid amounts shall accrue interest from the date of the applicable invoice at a monthly rate equal to the lower of **[*]** percent (**[*]**%) or the highest rate permitted by law, and (b) ICOS may terminate this Agreement as set forth in Section 14.2A upon written notice to PDL (unless PDL's failure to pay is due to its rejection of Product pursuant to Section 6.2A and the parties are within the dispute resolution procedures set forth in Section 6.2B) provided that such termination will not forgive PDL's obligation to pay all amounts owing to ICOS.

8. Raw Materials

ICOS will be responsible for procuring, testing, releasing and maintaining sufficient inventory of all raw materials necessary to Process the Product in accordance with this Agreement and the applicable Work and Quality Statements; provided, however, that PDL shall reimburse ICOS for the purchase of unusual or special raw materials, which are to be identified on the applicable Work Statement as the "PDL Raw Materials," in such amount and in the manner as described in such Work Statement.

9. Confidentiality

9.1 Non-disclosure

Each party agrees (a) to take all reasonable precautions and to use its commercially reasonable efforts (provided such efforts shall be no less than what such party uses to protect its own confidential information, but in no event less than reasonable care) to maintain the confidentiality of all Confidential Information that such party (the "Recipient") obtains in respect to the other party (the "Disclosing Party") and (b) not to use or disclose to any third

parties Confidential Information of the Disclosing Party other than as permitted by Section 9.2. The Disclosing Party's disclosure of Confidential Information to the Recipient shall not constitute a grant of any license or any other rights or generate any business arrangements unless specifically set forth herein or in another written agreement between the parties.

9.2 Permitted Disclosures

A Recipient may disclose Confidential Information of the Disclosing Party only (a) to its employees solely for purposes of performing the Services, (b) with the prior written consent of the Disclosing Party and subject to any non-disclosure agreement that the Disclosing Party wishes to execute with the third party recipient of the Confidential Information, or (c) to appropriate regulatory authorities, attorneys and accountants and pursuant to any order of a court, administrative agency or other governmental authority, provided that the Disclosing Party has been provided with reasonable prior notice so that the Disclosing Party can take actions to prevent such disclosure or mitigate the effect of such disclosure on the Disclosing Party, and (d) to its attorneys, advisors, investors, prospective acquirors and investors, lenders and other financing sources, and to strategic partners or licensees of the Products, provided that such disclosure shall be made under terms of confidentiality at least as protective as those herein.

9.3 Terms of This Agreement

Except as required by law and disclosure to each party's respective accountants and legal counsel, neither party shall disclose to any third party any information about this Agreement other than the existence of this Agreement, without the other party's prior written consent. Each party shall give the other at least ten (10) business days advance written notice, unless such number of days must be shortened to comply with a legal request, of a disclosure required by applicable law and will cooperate with the other party to minimize the scope and content of such disclosure.

9.4 Press Release

The text and timing of any press release or other communication to be published publicly in any manner by either party concerning the subject matter of this Agreement shall require the prior written approval of the other party, which shall not be unreasonably withheld.

10. Representations and Warranties; Disclaimers

10.1 ICOS

ICOS represents and warrants to PDL the following:

A. As of the date of this Agreement, ICOS has all requisite corporate power and authority to enter into and perform all of its obligations under this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action in respect thereof on the part of ICOS. As of the date of this Agreement, neither the execution and

delivery of this Agreement nor the performance of the transactions contemplated hereby, nor compliance by ICOS with the provisions hereof, shall (i) conflict with or result in a breach of any provision of the certificate of incorporation or by-laws of ICOS, (ii) violate any order, writ, injunction, decree, statute, rule or regulation applicable to ICOS, or (iii) conflict with any obligations or agreements of ICOS to any person, contractual or otherwise;

B. The Product will have been manufactured in all material respects with the Manufacturing and Release Requirements and cGMP; **[*]** this **[*]** is **[*]** upon **[*]** giving **[*]** of **[*]** within **[*]** and **[*]** returning all **[*]** to **[*]** (at **[*]** cost) as soon as **[*]**; provided, however, that **[*]** may retain only **[*]** of the **[*]** that is then being used **[*]**, and may use such **[*]** solely to **[*]**, but in no event may **[*]** use any of the **[*]** for **[*]** after it becomes aware of **[*]** (and **[*]** shall indemnify **[*]** for all liabilities, costs and damages incurred by **[*]** resulting from **[*]** of this **[*]**). Without limitation to the foregoing **[*]**, the parties agree that **[*]** may not **[*]** based on **[*]** of this **[*]** unless such **[*]** results directly in **[*]** being imposed on **[*]** by a **[*]** and

C. ICOS is not debarred and has not and, in providing the Services, will not knowingly use in any capacity the services of any person debarred under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992 or any comparable law of any foreign jurisdiction, as each may be amended from time to time;

D. EXCEPT AS EXPRESSLY WARRANTED IN THIS SECTION 10.1, ICOS MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE SERVICES OR PRODUCT, EXPRESS OR IMPLIED, IN ANY MANNER AND EITHER IN FACT OR BY OPERATION OF LAW, AND SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR NONINFRINGEMENT. Without limiting the foregoing, PDL acknowledges that it has not and is not relying upon any implied warranty of any kind or upon any representation or warranty whatsoever by ICOS as to the commercial exploitability of the Product, the prospects (financial, regulatory or otherwise) or likelihood of commercial success of the Product after the date of this Agreement, or the need for third party licenses to commercialize the Product.

10.2 PDL

PDL represents and warrants to ICOS the following:

A. As of the date of this Agreement, PDL has all requisite power and authority to enter into and perform all of its obligations under this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action in respect thereof on the part of PDL. Neither the execution and delivery of this Agreement nor the performance of the transactions contemplated hereby, nor compliance by PDL with the provisions hereof, shall (i) conflict with or result in a breach of any provision of the certificate of incorporation or by-laws of PDL, (ii) violate any order, writ, injunction, decree, statute, rule or regulation applicable to

PDL, or (iii) conflict with any obligations or agreements of PDL to any person, contractual or otherwise;

B. PDL is entitled to supply the applicable PDL Patent Rights, PDL Trade-Secrets and PDL Materials to ICOS for the performance of the related Services;

C. PDL shall use all Product supplied by ICOS pursuant to this Agreement solely for conducting clinical trials (and research and development activities related thereto) for the purpose of collecting clinical data necessary to meet North American and European regulatory filing requirements; and

D. EXCEPT AS EXPRESSLY WARRANTED IN THIS SECTION 10.2, PDL MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PDL PATENT RIGHTS, PDL TRADE-SECRETS, PDL MATERIALS OR THE PRODUCT, EXPRESS OR IMPLIED, IN ANY MANNER AND EITHER IN FACT OR BY OPERATION OF LAW, AND SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR NONINFRINGEMENT.

11. Limitation on Liability

A. EXCEPT FOR BREACHES OF SECTION 9, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL (INCLUDING, WITHOUT LIMITATION, LOST PROFITS) OR SPECIAL DAMAGES OF ANY TYPE OR AMOUNT ARISING OUT OF ITS BREACH OF ANY PROVISION IN THIS AGREEMENT (INCLUDING WITHOUT LIMITATION, THE PERFORMANCE OR FAILURE TO PERFORM HEREUNDER) EVEN IF SUCH DAMAGES WERE FORESEEABLE AND WHETHER SUCH DAMAGES ARISE IN TORT, IN CONTRACT OR OTHERWISE.

B. ICOS's sole liability to PDL for delivering Product that PDL is entitled to reject pursuant to Section 6.2 or breaching its warranty made in Section 10.1B, is to perform the obligations in accordance with Section 6.2.

C. Without expanding (i) PDL's liability as described in Section 7.2 for the failure to make timely payments as described therein or (ii) ICOSs' liability as described in Section 11.B for the happening of the events described therein, each party's liability to the other for any loss suffered by such other party arising as a direct result of a breach of this Agreement or of any other liability of any kind or nature, including without limitation, misrepresentation and negligence, arising out of this Agreement shall be limited to the payment of damages which shall not exceed in US Dollars an amount equal to **[*]**; provided, however, if and only to the extent that such damages are caused by the party's willful or intentional misconduct, then **[*]**.

12. Indemnification

12.1 Indemnification of ICOS

Except to the extent any of the following Liabilities (defined as follows) are as a result of ICOS's negligence or willful misconduct, PDL shall defend, indemnify and hold harmless ICOS, its officers, agents, employees and Affiliates from and against any liabilities, damages, losses, expenses and costs (including reasonable attorneys' fees) (collectively "Liabilities") as a result of any third party claims or actions arising out of (a) PDL's breach, violation or nonfulfillment of any of its covenant, agreements, representations or warranties under this Agreement, (b) PDL's gross negligence or willful misconduct, (c) the handling, possession, marketing and distribution, sale or use of the Product following delivery by ICOS to PDL, including without limitation any claim alleging breach of warranty or product liability, (d) any claims alleging ICOS's use of the PDL Patent Rights, PDL Trade-Secrets and PDL Materials infringes any third party's rights, or (e) any claim of infringement arising out of the composition of matter of the Product, Processing of the Product or use of the Product.

12.2 Indemnification of PDL

Except to the extent any of the following Liabilities are as a result of PDL's negligence or willful misconduct, ICOS shall defend, indemnify and hold harmless PDL, its officers, agents, employees and Affiliates from and against any Liabilities (as defined in Section 12.1) as a result of any third party claims or actions arising out of (a) ICOS's breach, violation or nonfulfillment of any of its covenant, agreements, representations or warranties under this Agreement, (b) ICOS's gross negligence or willful misconduct, (c) ICOS's handling, possession, or use of the Product and PDL Materials (except for claims of infringement based on ICOS's Processing the Product) in ICOS's possession and prior to delivery by ICOS to PDL, and (d) claims alleging that ICOS's operations constitute an infringement of third-party proprietary rights, if infringement arises from technical information and know-how provided by ICOS, unless developed by ICOS on PDL's behalf.

12.3 Indemnification Procedures

Each party agrees it shall give to the party that is obligated to indemnify such party (a) prompt notice of any claim coming within the purview of the indemnities contained in this Section 12, (b) all relevant facts in its possession or control, (c) the right to exclusive control of the defense of any action unless a conflict of interest exists with respect to defending such action, and (d) its cooperation in the defense of any such action. In addition, each party agrees that the indemnified party will not settle any Liabilities without the prior written consent of the indemnifying party, not to be unreasonably withheld.

12.4 Product Liability and Worker's Compensation Insurance

Each Party shall maintain, during the term of this Agreement and for a period of one (1) year thereafter, product liability in an amount not less than **[*]** per occurrence and aggregate and shall maintain worker's compensation insurance as required under applicable laws.

13. Term and Termination

13.1 Term

Unless terminated early according to this Agreement (a) this Agreement shall continue for a period of five (5) years from the date hereof and may be extended by the parties' mutual written agreement and (b) each Work or Quality Statement shall commence on the date of execution by the parties and shall terminate on the completion of the Services described therein. The termination of this Agreement for any reason shall automatically terminate any and all Work and Quality Statements, unless the parties otherwise agree in writing. In any event, each Work or Quality Statement is and shall remain subject to the terms and conditions of this Agreement.

13.2 Termination

PDL is entitled to terminate this Agreement at any time and for any reason on sixty (60) days prior written notice to ICOS, subject to the Effects of Termination as described in Section 13.3 including, without limitation, the obligation to make such payments to ICOS as described in Section 13.3C.

In addition to the termination rights stated in foregoing paragraph and in Section 7.2, either party may terminate this Agreement by written notice to the other party on the occurrence of any of the following events:

A. if the other commits a material breach of this Agreement which (in the case of a breach capable of remedy) is not remedied within sixty (60) days of the receipt by the other of written notice identifying the breach with specificity and requiring its remedy; provided, however, if the breach is as a result of non-payment of any amounts owed, following the expiration of any applicable grace period, the breaching party must remedy the breach within ten (10) days after receiving such written notice; or

B. a petition is filed against the other party for an involuntary proceeding under any applicable bankruptcy or other similar law, and (i) such petition has not been dismissed within sixty (60) days of filing; or (ii) a court having jurisdiction has appointed a receiver, liquidator, trustee or similar official of such other party for any substantial portion of its property, or ordered the winding up or liquidation of its affairs; or

C. the other party commences a voluntary proceeding under applicable bankruptcy or other similar law, has made any general assignment for the benefit of creditors, or has failed generally to pay its debts as they become due.

D. ICOS may terminate this Agreement by providing written notice to PDL if (i) PDL or ICOS is unable to perform or is substantially impaired from performing its respective obligations in a timely manner under this Agreement and the Work and Quality Statements due to court rulings related to third-party claims of intellectual property infringement against PDL covered under Section 12.1(d) and (ii) the parties cannot reach agreement about how to proceed within twenty (20) days of ICOS's written notice to PDL.

E. PDL may terminate this Agreement by providing written notice to ICOS if (i) PDL or ICOS is unable to perform or is substantially impaired from performing its respective obligations in a timely manner under this Agreement and the Work and Quality Statements due to court rulings related to third-party claims of intellectual property infringement against ICOS described under Section 12.2(d) and (ii) the parties cannot reach agreement about how to proceed within twenty (20) days of PDL's written notice to ICOS.

13.3 Effect of Termination

A. On termination of this Agreement for any reason (whether due to breach of either party or otherwise), ICOS will furnish to PDL a complete inventory of all work in progress and an inventory of all Processed Product.

B. By no later than the date on which the termination of this Agreement becomes effective, each party will return to the other all Confidential Information that it possesses or controls that belongs to the other, except that each may retain a copy in its law department or with its outside counsel for record-keeping purposes. Notwithstanding the foregoing, the license rights granted to PDL under Sections 3.6 and 3.7 shall survive the termination of this Agreement unless this Agreement is terminated pursuant to the events described in Section 13.3C.

C. In the event this Agreement is terminated (i) by PDL for any reason other than pursuant to Section 13.2.A, B, C or E, or Section 15 or (ii) by ICOS pursuant to Section 13.2.A, B, C or D, PDL will pay ICOS a sum equal to one hundred percent (100%) of the full Price of all stage(s) of the scheduled Services less all amounts already paid to ICOS for such Services, the payment for which shall be due to ICOS on or before the date of termination of this Agreement. With respect to the manufacturing capacity that would have otherwise been used to perform the Services, in the event ICOS (i) resells any such capacity to any third party and/or (ii) uses any such capacity for any internal manufacturing projects, ICOS and PDL shall negotiate in good faith a reasonable refund to PDL.

D. If this Agreement is terminated pursuant to Section 13.2.E, ICOS shall **[*]**.

E. On termination of this Agreement, neither party shall use or exploit in any manner whatsoever any Intellectual Property Rights of any kind or nature of the other party, except for the express rights granted in other Agreements between the parties and in Section 3.6 of this Agreement. Without limitation to the foregoing, on termination of this Agreement, ICOS shall not use or exploit the PDL Patent Rights, PDL Trade-Secrets, PDL Confidential Information or PDL Materials in any way.

F. Termination of this Agreement for any reason will not relieve the parties of any obligation accruing prior thereto.

G. The following Sections will survive the termination of this Agreement for whatever reason: 3.6, 3.7, 6.2, 7, 8, 9 through 13, and 17 through 24.

14. Facility Inspection

PDL has the right on **[*]** days' notice and during business hours to visit ICOS (i.e., person in the plant) to observe the Process and the progress of the work and to inspect related records and data for the purpose of making quality control inspections so as to assure compliance with the applicable Work and Quality Statements; provided, however, that if another party's product is being manufactured during the time that PDL intends to visit, such visit, as mutually agreed, (i) may be reasonably delayed until only PDL's Product is being manufactured or (ii) take place subject to the provision that PDL's representatives will not enter areas of any ICOS facility at times when third parties' products are being manufactured. The form, participants and procedures of all such inspections shall be subject to ICOS's reasonable approval. PDL representatives will follow such security and facility access procedures as are reasonably designated by ICOS. During all such inspections, PDL shall use good faith efforts to avoid disrupting ICOS's operations.

On no less than **[*]** days' notice to ICOS, PDL shall also be entitled to conduct a reasonable annual multi-day quality assurance site audit, the form, participants and procedure of which shall be subject to ICOS's reasonable approval. When conducting an inspection or audit as described, each of PDL's representatives will (a) be subject to a nondisclosure obligation comparable in scope to Section 9, (b) follow such security and facility access procedures as are reasonably designated by ICOS, (c) be accompanied by an ICOS representative, and (d) not enter areas of any ICOS facility at times when third parties' products are being manufactured to assure protection of ICOS's or a third party's Confidential Information.

15. Force Majeure

Neither party hereto shall be liable to the other party for any delay or default in such party's performance hereunder if such delay or default is caused by conditions beyond such party's reasonable control including, but not limited to, delays by the FDA or other governmental agency which are not due to serious violations of law by ICOS, acts of God, war, insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances including strikes or lockouts or epidemic ("Force Majeure"). Each party hereto agrees to promptly notify the other party of any event of Force Majeure and to employ all reasonable efforts toward prompt resumption of its performance hereunder when possible if such performance is delayed or interrupted by reason of such event. If an event of Force Majeure affecting ICOS continues for a period of sixty (60) days, ICOS shall notify PDL as to how long ICOS expects the Force Majeure delay will last. If ICOS expects that the Force Majeure delay will last six (6) months or more, PDL shall have the right to terminate this Agreement. If ICOS expects that the Force Majeure delay will last less than six (6) months, and after such six (6) month period ICOS can still not perform under this Agreement, ICOS shall be in material breach of this Agreement and PDL shall have the right to terminate this Agreement.

16. Assignment

This Agreement will be binding on and will inure to the benefit of the parties hereto and their respective successors and assigns; provided, however, that neither party may assign any of its rights or obligations under this Agreement or the Work and Quality Statements to any third party without the other party's prior written consent, which consent will not be unreasonably withheld; provided, however, that either party may assign its rights and obligations hereunder without the other party's consent to a third party that is acquiring or merging with such party or that is purchasing all or substantially all of such party's assets that are the subject matter of this Agreement, provided that the assignee assumes all of such party's rights and obligations under this Agreement.

17. Use of Intellectual Property Rights

Except as expressly stated in this Agreement, no Intellectual Property Rights of any kind or nature are conveyed by this Agreement and neither party shall have any right, title or interest in or to the other party's Intellectual Property Rights for any purpose whatsoever without such other party's prior written consent. Neither party shall use or disclose the name of the other in any advertising, sales, marketing or other promotional material, without the prior written consent of the other.

18. Entire Agreement; Amendments

Unless otherwise agreed to in a writing signed by both parties, this Agreement and the applicable Work and Quality Statements represent the entire understanding of the parties. There are no promises, terms or conditions, oral or written, expressed or implied, other than those contained in this Agreement and/or in a Work or Quality Statement. The terms of this Agreement shall supersede all previous and contemporaneous agreements between ICOS and PDL relating to the subject matter contained herein. To the extent any terms of a Work or Quality Statement (or any Appendices attached thereto) conflict with the terms of this Agreement, the terms of this Agreement shall control unless the parties expressly state in the Work or Quality Statement (or in the Appendices) that specific terms contained therein control over the applicable conflicting terms in this Agreement. If PDL chooses to issue a purchase order ("PO") for the delivery of Product, such PO should reference this Agreement and the specific Work and Quality Statements and shall be issued solely for the convenience of PDL and to provide subject matter description. Except as expressly provided in this Agreement, this Agreement and each Work or Quality Statement may be modified or amended only by the parties' written agreement.

19. Waiver; Severability

No delay or waiver (or single or partial exercise) on the part of either party on any one or more occasions in exercising any right, power or privilege hereunder will operate as a waiver thereof or of any other right, power or privilege hereunder. Any such waiver must be made in writing. If any provision of this Agreement or any Work or Quality Statement is held to be illegal, invalid, or unenforceable under present or future laws effective while this Agreement

remains in effect, the legality, validity and enforceability of the remaining provisions will not be affected thereby.

20. Construction; Headings

This Agreement and all Work and Quality Statements will be deemed to have been drafted by both PDL and ICOS and will not be construed against either party as the draftsperson hereof. All section titles or headings contained in this Agreement and any Work and Quality Statements are for convenience only, will not be deemed a part hereof or thereof and will not affect the meaning or interpretation of this Agreement or the Work and Quality Statements.

21. Attorneys' Fees

If either party is reasonably required to initiate legal action to enforce its rights and the other party's obligations under this Agreement, the prevailing party in such action shall be entitled to recover its reasonably attorneys' fees and costs.

22. Notices

Any notices, demand, invoices, payments or statements required or permitted to be given pursuant to this Agreement shall be in writing and shall be deemed to have been delivered when personally delivered, when sent by fax or email (with confirmation of delivery), or on the third business day following its mailing by registered or certified mail (return receipt requested), to the parties at their respective addresses stated in the opening paragraph of this Agreement, or to such other address as designated in writing.

23. Independent Contractor

The parties hereto are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venturer. The parties agree that neither shall have power or right to bind or obligate the other, nor shall either hold itself out as having such authority.

24. Counterparts

This Agreement and any Work or Quality Statements may be executed in counterparts, each of which will be deemed an original but all of which together will constitute a single instrument.

[signatures on following page]

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

PROTEIN DESIGN LABS, INC.	**ICOS CORPORATION**
By _____	By _____
Name: _____	Name: _____
Title _____	Title _____

EXHIBIT

WORK STATEMENT
TO MANUFACTURING AGREEMENT
BETWEEN
ICOS CORPORATION AND PROTEIN DESIGN LABS, INC.
DATED

Date of Work Statement:

I. Product

"Product" means M200.

II. Scope of Services

Attached as Appendix A

III. PDL Materials

IV. Manufacture and Release Requirements

A. Manufacturing Procedure and Requirements

B. QA/QC Tests

C. Handling and Storage Requirements

D. Packaging Requirements

E. Record Keeping Requirements

V. Acceptance Criteria

Attached as Appendix B.

VI. Estimated Timeline

Attached as Appendix C.

VII. Price and Payment Terms

Attached as Appendix D.

VIII. Quality Statement

Attached as Appendix E.

PROTEIN DESIGN LABS, INC.	**ICOS CORPORATION**
By _____	By _____
Name: _____	Name: _____
Title _____	Title _____
Dated: _____	Dated: _____

APPENDIX A
SCOPE OF SERVICE

Manufacture of M200, a Recombinant Antibody

Scope of Services

A. Assumptions

1. ICOS has maintained a Master Cell Bank (MCB), produced under prior contract, suitable for manufacturing clinical trial lots of the M200 Product.
2. The cell line will be grown in **[*]**
3. Six (6) cGMP clinical lots will be manufactured that are suitable for regulatory filings and human clinical trials.
4. ICOS will provide (bulk) Formulated Drug Substance to PDL or designee.
5. ICOS will provide **[*]**

B. Services

Manufacturing of Clinical (cGMP) Batches

Objectives

Perform six (6) cGMP production runs (six cell culture and six purification runs). Each run is also referred to as a "lot" herein.

Carry out in-process and Drug Substance testing to confirm that the process is in control and that the Product from each lot meets Product Specifications.

1. Carry out six cGMP (clinical) production runs based on the process developed previously by ICOS for this product.
2. Revise master documents to include process corrections and improvements identified during the previous clinical production lot.
3. Carry out manufacturing processes and testing according to approved, written procedures. Master documents will be reviewed and approved by ICOS and PDL according to the Quality Statement.
4. Store solutions, process intermediates, and Formulated Drug Substance in controlled access locations under appropriate conditions as specified in the Work Statement.

5. Test each lot of Drug Substance by the methods described in Section D and as specified in the Material Specifications.
6. Save a sample of EOP cells from each cGMP run.
7. Perform Lot Disposition according to the Quality Statement.
8. Prepare for PDL a summary of the results, including items such as key in-process control data, production titers, process step yields, for the cGMP runs.

9. Within **[*]**of delivery of Product, deliver Product-related Records and Documentation described in Section E needed to support the CMC section for PDL's regulatory filings. Additional detailed data will be provided on specific request from PDL.

C. Deliverables

The following items will be delivered from ICOS Corporation to PDL.
1. Six (6) lots of (bulk) Formulated Drug Substance prepared from six cGMP clinical production runs using the 3000L ICOS bioreactor.
2. Certificates of Analysis that include all ICOS release testing results and a notice of disposition from ICOS Quality Assurance, delivered within **[*]** following the date of product lot formulation.
3. Documentation as described in Section E and in the Quality Statement.
4. The pre-bank and Master Cell Bank(1).
5. EOP cell samples, if requested by PDL.

(1) If desired, ICOS will retain a number of vials in the event that at some future date PDL would like to request additional clinical production runs.

D. In-Process and Drug Substance Testing

The test methods in the table below will be performed at the indicated process stages.
The development or performance of any other assays is out-of-scope work.

	Production Scale (Clinical)		
Method	**Harvest fluid**	**Purification In-Process**	**Formulated Drug Substance**
Mycoplasma(1)	X (EOP)		
Sterility(1)	X (EOP)		
MMV(1)	X (EOP)		
In-vitro viral – 14 day(1)	X (EOP)		
Product Titer (Protein A)	X		
Bioburden	X		X
Endotoxin	X	X	X
Product concentration (A_{280})		X	X
Size Exclusion HPLC		X	X
SDS-PAGE, unreduced		X	X
SDS-PAGE, reduced		X	X
Isoelectric Focusing			X
MALDI-MS			X
Silver stain, unreduced			X
Silver stain, reduced			X
Appearance			X
Osmolality			X
PH			X
Insulin			X
Residual Protein A EIA			X
Residual Host Cell DNA Content			X
Residual Host protein Content			X
Binding assay			X
Potency assay			X
Bovine IgG			X
Polysorbate 80 concentration(2)			X

(1) Contracted to an outside vendor
(2) Protocol and necessary reagents to be transferred from PDL to ICOS

E. Product-related Records and Documentation Provided to PDL

Drug History Record – provided for each clinical lot

- **[*]**
- Lot disposition notice **[*]**
- Certificate of Analysis **[*]**
- Certificate of Compliance
- Indented bill of materials **[*]**
- Process flowchart

Satellite Files

Informational copies (on request) of:

- Product specific master manufacturing batch records
- Product specific test methods
- Product specific material specifications

APPENDIX B
ACCEPTANCE CRITERIA

[*]

APPENDIX C
ESTIMATED TIMELINE

[*]

APPENDIX D
PRICE AND PAYMENT TERMS

Stage	Terms	Estimated Date of Payment(1)	[*]
Reservation Fee	**[*]**	9/1/03	**[*]**
Run Initiation Fee	**[*]**	1/15/04	**[*]**
Per Lot Fee(2),(3)	**[*]**	TBD	**[*]**
Additional Services(5)			**[*]**

(1) The dates listed are estimates only. The actual payment date is the date on which the applicable event occurs as stated in the "Terms" column.

[*]

[*]

[*]

(5) Determined by written agreement of the Project Leaders.

APPENDIX E
QUALITY STATEMENT

1. Purpose

This Quality Statement has been developed to define the regulatory compliance roles and responsibilities of PDL and ICOS Corporation (ICOS, "Manufacturer"). The Quality Statement shall constitute part of the agreement between PDL and ICOS and may be revised from time to time when mutually agreed in writing by the Quality Assurance contacts listed in Section 2 or their designees. In the event of a conflict between the provisions of the Manufacturing Agreement and Quality Statement, the provisions of the Manufacturing Agreement shall prevail.

2. Quality Assurance Contacts

Emergency Quality Assurance contact names and numbers during and outside working hours at each company:

PDL Quality Assurance:
[*]

ICOS Quality Assurance:
[*]

The PDL and ICOS Quality Departments will jointly establish a list of Quality contacts in order to conduct their business.

3. Definitions

"Agreement" shall mean the Manufacturing Agreement executed between PDL and ICOS on **[*]**

"cGMP" shall mean Current Good Manufacturing Practices as promulgated under the US Federal Food Drug and Cosmetic Act and 21 CFR Sections 210, 211, 600 and 610 and ICH Q7A, cGMPs for APIs

"Critical Deviation" shall mean deviations where (i) **[*]**

"Party" means either PDL or ICOS

"Parties" means both PDL and ICOS

"Products" shall mean PDL drug products and all intermediate precursors

4. Regulatory Activities

4.1 Roles of the parties

PDL will be the holder the IND or equivalent and the holder of the registration submission and subsequent license. ICOS will support these submissions as a contract manufacturer under the direction of PDL.

4.2 Regulatory submissions

PDL will be responsible for the submission of documentation to regulatory authorities in support of the Products. ICOS will provide PDL with the information necessary to complete regulatory submissions in a timely and effective manner.

ICOS and PDL will mutually agree on responses to questions regarding PDL submissions, which PDL will make, to FDA questions and requests regarding facilities, production processes and Product testing relevant to ICOS.

4.3 Inspections

PDL will inform ICOS in a timely fashion when regulatory agencies are seeking to schedule inspections concerning the Product at ICOS' facilities.

PDL will be permitted to have **[*]**on site for consultation during a PDL Product inspection but will not participate during the inspection unless requested by ICOS or a regulatory representative.

ICOS will **[*]**PDL will **[*]**

ICOS will hold daily wrap-up discussions with PDL to discuss any potential issues identified and corrective action plans.

[*]addressing manufacturing, facility, and compliance observations. PDL will receive one copy of any FDA 483 appropriately purged.

For regulatory observations (e.g. FDA 483 observations) that specifically involve the Product, **[*]**

For regulatory observations (e.g. FDA483 observations) that involve facility and system-related cGMP issues**[*]**

5. Compliance

5.1 Roles of the parties

ICOS, in its activities under the Agreement, is responsible for compliance with cGMP, other applicable guidelines and ICOS SOPs.

PDL, in its activities under the Agreement, is responsible for compliance with cGMP and applicable guidelines and for confirming ICOS' compliance with cGMP, other applicable guidelines and ICOS SOPs.

5.2 Audits

Upon no less than **[*]**notice to ICOS, PDL shall be entitled to perform one audit of ICOS facilities, laboratories and warehouses each year for the purposes of confirming ICOS compliance with cGMP, applicable guidelines and ICOS SOPs in the manufacture, testing and validation of the Product. The audit will be limited to **[*]**to occur on mutually agreed dates.

[*]

[*]

At the conclusion of each audit, PDL will hold a wrap-up meeting with ICOS and/or its subcontractors to review all significant audit observations.

Within**[*]**of each audit that it performs at ICOS and its subcontractors, PDL will provide ICOS with a written report of its observations and recommendations. Within **[*]**of receipt of PDL's audit report, ICOS and/or its subcontractors will provide a written response to PDL including a response to all PDL observations and details regarding corrective actions.

5.3 Documentation

ICOS is responsible for generating and maintaining records of equipment usage, calibration, cleaning and maintenance.

ICOS is responsible for developing documentation to support the manufacturing, testing and validation of the Product as defined by the Scope of Services.

PDL-QA must approve documents and procedures specific to the Product prior to implementation as listed below:

- Master Batch Records specific for the production of the Product.
- Test Methods specific for the production and testing of the Product.
- Product specific Material Specifications for materials produced during the manufacture of the Product, including the Product.

ICOS will provide PDL with copies of all Product-specific documents used in the production, testing and validation of the Product, upon request. Documents that are not specific to the Product are available for onsite review.

Changes to documentation will be implemented according to the Change Control section of this document.

ICOS is responsible for maintaining Product batch production and testing records for the period of **[*]**. Written authorization from PDL-QA is required before the destruction of Product records. When ICOS is no longer willing or able to store Product records, PDL may have the records destroyed, or transferred to an alternate storage location at PDL's expense.

5.4 Product Release

ICOS and PDL will each identify a Quality Assurance representative who will function as the points of contact between the companies for the purposes of communication regarding Product release and regulatory compliance activities.

ICOS will source raw materials and components to be used in the manufacture of the Product and will ensure that approved specifications are in place.

PDL will determine in-process, release and stability specifications for the Product. ICOS and PDL will mutually agree on these testing specifications for the Product. The parties will mutually agree in writing to all changes to specification before implementation. ICOS may subcontract some or all of the Product testing, subject to prior written approval by PDL.

ICOS is responsible for control and monitoring of the Product manufacturing process and production facility.

ICOS is responsible for reviewing Product lot records, test results against specifications and determining whether to reject the lot or issue a manufacturer's release to PDL-QA. PDL-QA is responsible for the final release of each Product lot.

ICOS will issue a Certificate of Analysis and Certification of Compliance to PDL for each lot that receives a manufacturer's release. The Certificate of Analysis will contain a summary of the Product test results, specifications, and date of manufacture. The Certificate of Compliance will contain a statement signed by ICOS' QA representative stating that the lot has been manufactured and tested in compliance with cGMPs, ICOS procedures and applicable guidelines.

PDL may request additional documentation to support its review and release of Product lots, including but not limited to copies of Batch Production Records, raw data from Product testing and in-process test results. Environmental monitoring data is available for on site review.

PDL will make reasonable efforts to release each lot within **[*]** of receipt of the Certificate of Analysis, Certificate of Compliance and documents listed in the scope of services.

ICOS will store and ship the Product according to written PDL instructions and in compliance with cGMP. ICOS will ship Product only upon PDL's approval.

PDL is responsible for retaining samples from each lot for testing in accordance with cGMP. ICOS will provide retain samples to PDL as identified in the production batch records.

5.5 Product Complaints and Adverse Drug Events

PDL shall notify ICOS of all complaints related to the Products that occur after release and transportation if the complaint is deemed to be directly related to the manufacture of the Product including, but not limited to, Product testing, batch record review, procedure assessment or examination of retention samples. ICOS shall provide the necessary information to assist any investigations required by PDL as a result of a Product complaint or adverse event.

5.6 Product Recall

PDL is responsible for instituting and facilitating a Product recall.

PDL will notify ICOS in a timely fashion when a Product recall may be due to manufacturing of the Products.

In the event that a Product recall may be due to manufacture of the Products, ICOS will provide PDL **[*]**ICOS will provide this information to PDL within **[*]**of receipt of the request from PDL.

At PDL's request and under PDL's direction, ICOS will support communication with regulatory authorities.

5.7 Change Control

ICOS and PDL must mutually approve changes to documents and procedures listed as requiring PDL approval in Section 5.3, prior to implementation. Administrative changes (i.e. correcting typographical errors) do not require PDL approval.

5.8 Validation

All validation specific to the Product (as specified in the Scope of Services) must be executed according to protocols approved before execution by PDL.

ICOS will provide PDL with copies of all Product specific validation reports. Validation reports which are Product related but not Product specific are available for on site review.

5.9 Investigations

ICOS will notify PDL of all excursions, critical deviations, observations and investigations that could impact past, current or future lots of the Product.

Laboratory investigations will be performed when an out of specification (OOS) result is obtained during Product testing. Resampling and/or retests may be authorized by the ICOS Laboratory Manager during the laboratory investigation phase of an OOS investigation as described in ICOS standard operating procedures. ICOS will notify PDL of all Product testing failures within **[*]**, and before initiating retesting and/or resampling of any sample where the laboratory investigation did not show laboratory error to be the cause of the OOS result.

All critical deviation investigations concerning the Product and conducted at ICOS will be reviewed and approved by ICOS and reviewed by PDL after completion.

6. Product Supply

6.1 Roles of the parties

ICOS will perform manufacture, testing and validation of the Products in its facilities as defined in the Scope of Services.

PDL is authorized to have **[*]** present at ICOS' manufacturing facilities during Product manufacture, testing and/or validation. Additional PDL representatives may be permitted when mutually agreed with ICOS.

7. Authorization of production

Manufacture of the Product at ICOS will be authorized in accordance with the Agreement.

7.1 Lot numbers

ICOS is responsible for assigning and tracking unique identifier numbers to each lot of raw material, component, product intermediate and Product. From this information ICOS will develop a trace tree for each lot of Product; ICOS will send to PDL the trace tree for any and all Product lots upon request by PDL.

7.2 Dates of production and expiration

The dates of manufacture will be determined by the date of sterile filtration, and documented in the Batch Production Records. PDL will determine the expiration date of the Product.

8. Dispute Resolution

Disputes concerning the acceptability of Product lots or general compliance issues will be resolved by the Quality Assurance representatives of the Parties. If the dispute is not resolved after **[*]**, either Party may upon written notification to the other request that the dispute be resolved according to the provisions of the Agreement.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-36708) of Protein Design Labs, Inc.,
(2) Registration Statement (Form S-3 No. 333-108701) of Protein Design Labs, Inc.,
(3) Registration Statement (Form S-3 No. 333-122760) of Protein Design Labs, Inc.,
(4) Registration Statement (Form S-8 No. 333-44762) pertaining to the 1993 Employee Stock Purchase Plan of Protein Design Labs, Inc.,
(5) Registration Statement (Form S-8 No. 333-87957) pertaining to the 1999 Stock Option Plan and 1999 Nonstatutory Stock Option Plan of Protein Design Labs, Inc.,
(6) Registration Statement (Form S-8 No. 33-65224) pertaining to the 1993 Employee Stock Purchase Plan of Protein Design Labs, Inc.,
(7) Registration Statement (Form S-8 No. 33-50116) pertaining to the Outside Directors Stock Option Plan of Protein Design Labs, Inc.,
(8) Registration Statement (Form S-8 No. 33-50114) pertaining to the 1991 Stock Option Plan of Protein Design Labs, Inc.,
(9) Registration Statement (Form S-8 No. 33-96318) pertaining to the 1991 Stock Option Plan of Protein Design Labs, Inc.,
(10) Registration Statement (Form S-8 No. 33-68314) pertaining to the 1999 Stock Option Plan and 1999 Nonstatutory Stock Option Plan of Protein Design Labs, Inc., and
(11) Registration Statement (Form S-8 No. 333-104170) pertaining to the 1999 Nonstatutory Stock Option Plan and 2002 Outside Directors Stock Option Plan of Protein Design Labs, Inc.;

of our reports dated March 11, 2005, with respect to the consolidated financial statements of Protein Design Labs, Inc., Protein Design Labs, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Protein Design Labs, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Palo Alto, California
March 11, 2005

EXHIBIT 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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 14, 2005

/s/ MARK MCDADE

Mark McDade
Chief Executive Officer
(Principal Executive Officer

EXHIBIT 31.2

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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 14, 2005

/s/ GLEN SATO

Glen Sato
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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 14, 2005

By:

/s/ MARK MCDADE
Mark McDade
Chief Executive Officer

/s/ GLEN SATO
Glen Sato
Chief Financial Officer