

**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, 2005**

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-19756

**PDL BIOPHARMA, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

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

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

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

**Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, Par value \$.01**  
*(Title of Class)*

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the average bid and ask price of the common stock on June 30, 2005, as reported on the NASDAQ National Market System, was approximately \$1,587,481,697.

As of March 13, 2006, the registrant had outstanding 114,182,089 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Part III - Portions of the definitive proxy statement with respect to the 2006 Annual Meeting of Stockholders to be filed subsequently by PDL BioPharma, Inc. with the U.S. Securities and Exchange Commission (hereinafter referred to as the "Proxy Statement").



## PART I

This Annual Report (including all of its Parts) for PDL BioPharma, 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 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 PDL BioPharma, Inc. and its subsidiaries (unless the context indicates a different meaning).

PDL BioPharma, the PDL logo, *HuZAF*<sup>™</sup> and *Zamyf*<sup>™</sup> are considered trademarks and *Retavase*<sup>®</sup>, *Busulfex*<sup>®</sup>, and *Nuvion*<sup>®</sup> are registered trademarks of PDL. *Cardene*<sup>®</sup> and *Zenapax*<sup>®</sup> are registered trademarks of Hoffmann-La Roche (Roche). All other company names and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

## ITEM 1. BUSINESS

### OVERVIEW

We are a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life-threatening illnesses. We are a fully integrated, commercial biopharmaceutical company with proprietary marketed products, a growing and diverse operating revenue base and a broad, proprietary pipeline. We market and sell products in the acute-care hospital setting in the United States and Canada and receive royalties through licensing agreements with numerous biotechnology and pharmaceutical companies based on our antibody humanization technology platform. Our product development pipeline includes six investigational compounds in Phase 2 or Phase 3 clinical development for hepatorenal syndrome, inflammation and autoimmune diseases, cardiovascular disorders and cancer.

Our products are sold through our hospital-focused sales force which focuses on the cardiac, neurological and intensive care unit sections. *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. *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. 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 anti-tumor 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.

Nearly half of our revenues generated in 2005 were from royalties paid for use of our patented antibody humanization technology as applied to 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 widely validated in our industry, based on the existence of multiple approved and licensed antibodies.

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We have licensed and will continue to offer to 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 generated royalties to PDL in 2005: Genentech Inc.'s (Genentech) *Avastin*<sup>™</sup>, *Herceptin*<sup>®</sup>, *Xolair*<sup>®</sup> and *Raptiva*<sup>®</sup>; MedImmune, Inc.'s (MedImmune) *Synagis*<sup>®</sup>; Wyeth's *Mylotarg*<sup>®</sup>; Elan Corporation, Plc's (Elan) *Tysabri*<sup>®</sup> and Roche's *Zenapax*<sup>®</sup>. Combined annual worldwide sales of these products exceeded \$4.0 billion in 2005. We are aware of more than 90 humanized antibodies in development worldwide by various pharmaceutical and biotechnology companies, and we have entered into patent agreements which may cover many of these products.

While we currently market drugs and continue to pursue humanization licenses, we are making significant investments in our future product pipeline, both alone and with our co-development partners. We believe these investments in research and clinical development activities may lead to an expanded product portfolio, and make a significant contribution to the company's future revenue and growth potential.

2005 was a year of significant growth for PDL. During the year, we acquired ESP Pharma Holding Company, Inc. (ESP Pharma) a privately held, hospital-focused pharmaceutical company, and we acquired from Centocor, Inc. (Centocor) the right to manufacture, develop, market and distribute *Retavase* in the United States and Canada. The acquisitions of ESP Pharma and *Retavase* enabled us to be a fully integrated, hospital-focused biopharmaceutical company. Consistent with our strategy of entering into development and commercialization partnerships for those pipeline programs which would be commercialized largely outside the hospital setting, in August 2005, we entered into a collaboration agreement with Biogen Idec, Inc. (Biogen Idec), a global biotechnology leader with products and capabilities in oncology, neurology and immunology, for the joint development, manufacture and commercialization of three of our Phase 2 antibody products. In October 2005, we expanded our existing relationship with Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer-term maintenance therapy (transplant maintenance). The addition of marketed products resulting from the ESP Pharma and *Retavase* acquisitions, as well as the financial effects of the Biogen Idec and Roche collaborations, contributed to the achievement of positive cash flows from operations in the fourth quarter of 2005.

In order to better reflect our status as a commercial biopharmaceutical company, on January 9, 2006, we changed our name from Protein Design Labs, Inc. to PDL BioPharma, Inc. This change coincided with the merger of ESP Pharma into PDL to create a single organization and operating structure. ESP Pharma had been operating as a wholly-owned subsidiary since the acquisition in the first quarter of 2005.

### **OUR BUSINESS AND COMMERCIALIZATION STRATEGY**

Our business and commercialization strategy is to continue our evolution 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 proprietary products. Key elements of our strategy include the following:

- *Fully-integrated commercial organization.* Our hospital sales force is dedicated to the acute-care setting. In the hospital setting, our sales force focuses on decision making in the cardiac, neurological and intensive care units and in emergency departments. We have expanded the sales force from 68 field representatives as of the date of the ESP Pharma acquisition in March 2005 to 118 field representatives as of December 31, 2005. The expanded sales force markets our three biopharmaceutical products, *Cardene IV*, *Retavase* and *IV Busulfex*, to nearly 1,600 hospitals in the United States, an increase from approximately 800 hospitals at the time of the acquisition.

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- *Development of proprietary drugs.* Our aim is to develop antibody- or other protein-based products from our internal discovery efforts, as well as to selectively and opportunistically in-license proprietary therapeutic candidates. Our current stated aim is to derive on average one new U.S. investigational new drug (IND) candidate per calendar year, and augment this pipeline generation through additional in-licensing at various stages of development. Our most advanced clinical-stage program is the Phase 3 program for terlipressin, conducted by our partner Orphan Therapeutics, LLC (Orphan Therapeutics) for the treatment of type 1 hepatorenal syndrome. If the development program for terlipressin is successful and terlipressin subsequently gains regulatory approval for therapeutic use in the United States and Canada, our goal is to expand our North American hospital-focused sales and marketing operation. The additional field representatives would focus on the marketing of terlipressin and IV *Busulfex*. If we have success in the development program for *Nuvion* for the treatment of intravenous steroid-refractory ulcerative colitis, and *Nuvion* subsequently gains regulatory approval for therapeutic use in the United States and Canada, such infrastructure also would be complementary to our potential marketing needs for a *Nuvion* launch.
- *Shared Development and Commercialization arrangements.* Our goal is to market our hospital-focused products in North America. However, three of our products in development address indications that require specific expertise or large development and marketing efforts, such as multiple sclerosis (MS), respiratory diseases and some oncology indications, and our stated strategy for those products is to seek large partners with global development, manufacturing and commercialization capabilities. Therefore, we have partnered with Biogen Idec for the joint development and commercialization of three Phase 2 antibodies – daclizumab in MS and all indications not covered under the Roche agreements, M200 in all indications and *HuZAF* in all indications. In addition, we have partnered with Roche for the joint development and commercialization of daclizumab in asthma and related respiratory diseases, as well as chronic organ transplant maintenance. In each of these collaborative alliances, we have received upfront licensing payments, and may receive milestone payments related to successful development and commercialization. We share with these partners the cost of clinical development and will share operating profits on any future product sales, or in certain markets, receive royalties. With respect to each of the other products we are currently developing, we may in the future consider partnering arrangements for these compounds if partnering would be consistent with our current objectives.

## OUR MARKETED PRODUCTS

**Marketed Products.** Our portfolio of actively marketed products currently consists of three biopharmaceutical products:

- ***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 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. The primary driver in future growth of *Cardene IV* will be the effective marketing by the expanded sales force to hospitals in the United States plus potential new specialty dosing formulations and indications.
- ***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. AMI is the leading cause of death in the United States. We re-launched *Retavase* in late April 2005 after acquiring it in March 2005.
- ***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 anti-tumor 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*.

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IV *Busulfex* was launched in Europe by Pierre Fabre Medicament S.A. (Pierre Fabre) and in several Asian countries by Kirin Brewery Company, Limited (Kirin) and is expected to be launched in Japan in 2006. Both Pierre Fabre and Kirin are our exclusive distributors in their territories.

**Sales Force.** Our biopharmaceutical products are sold through wholesale distributors to nearly 1,600 hospitals in the United States. Our hospital-focused sales force is committed to the acute-care setting and has grown from 68 field representatives as of the date of the ESP Pharma acquisition to 118 field representatives as of December 31, 2005. In the hospital setting, our sales force focuses on the cardiac, neurological and intensive care unit sections.

**Manufacturing and Logistics.** We outsource the manufacturing of *Cardene IV*, *Retavase* and IV *Busulfex* to third-party contract manufacturers located in the U.S. Specialty Pharmaceutical Services (SPS), a subsidiary of Cardinal Health 105, Inc., handles a number of distribution and trade functions for us including: warehousing, distribution, receiving orders from customers, invoicing and collection of receivables. All of our finished product inventory is shipped directly from SPS's third-party warehouse. Warehousing of active pharmaceutical ingredients and the overall management of our product supply chain are the responsibilities of our Minnesota-based manufacturing operations.

**Divestiture of Off-Patent Brands.** In March 2005, we acquired both branded and off-patent branded products through the acquisition of ESP Pharma. Our net sales of the off-patent branded products in 2005 were \$9.8 million during the nine months of 2005 in which we marketed these products. As we are committed to the development, manufacture and commercialization of proprietary biopharmaceutical products, marketing the off-patent branded products was inconsistent with our strategy. Accordingly, during the first quarter of 2006, we obtained consent from Wyeth necessary to transfer all rights to *Declomycin* and our other three off-patent branded products. The transfer of rights to *Declomycin* to Glades for total cash proceeds of \$8.3 million was completed in February 2006, and we sold the rights to *Sectral*, *Tenex* and *Ismo* to Dr. Reddy's Laboratories Limited for total cash proceeds of \$2.7 million in March 2006. Currently, we do not expect to recognize any material gain or loss from the sale. We are now entitled to royalty payments from Glades on sales of *Declomycin*.

## OUR PRODUCTS IN CLINICAL DEVELOPMENT

We are engaged in the discovery and development of protein-based therapeutic products, with the majority of our emphasis based upon deriving humanized antibody product candidates employing our proprietary platform. We currently have six product candidates in clinical development for various disease indications. Four of these are antibodies and are in clinical development with a near-term emphasis on autoimmune and inflammatory diseases and cancer, specifically inflammatory bowel disease, asthma, MS and solid tumors. The remaining two product candidates, ularitide and terlipressin, were added to the portfolio through our acquisition of ESP Pharma.

The following table summarizes the potential therapeutic applications and development status under various 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."

<u>Product Candidate</u>	<u>Indication(s)</u>	<u>Status</u>
Terlipressin (synthetic peptide)	Type 1 hepatorenal syndrome	Phase 3 (conducted by a partner)
<i>Nuvion</i> (visilizumab, anti-CD3)	Intravenous steroid-refractory ulcerative colitis	Phase 2 / 3
	Crohn's disease	Phase 2
Ularitide (synthetic peptide)	Acute decompensated heart failure	Phase 2
Daclizumab (anti-IL-2 receptor)	Asthma	Phase 2
	Multiple sclerosis	Phase 2
	Solid organ transplant maintenance	Phase 2
M200 (volociximab, anti- $\alpha$ 5 $\beta$ 1 integrin)	Advanced solid tumors	Phase 2
<i>HuZAF</i> (fontolizumab, anti-gamma-interferon)	Crohn's disease	Phase 2
	Rheumatoid arthritis	Phase 2

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**Terlipressin.** Terlipressin is a synthetic, 12-amino acid peptide (1-triglycyl-8-lysine-vasopressin) derived from the natural hormone lysine-vasopressin. Due to its constrictive activity on vascular and extra-vascular smooth muscle cells (V-1 agonist), it reduces blood flow in the splanchnic area, and thereby lowers portal blood pressure.

Terlipressin is in Phase 3 clinical development for the treatment of type 1 hepatorenal syndrome. Hepatorenal syndrome is the development of a functional renal failure in patients with end-stage liver disease in the absence of any other cause of renal pathology. Type 1 hepatorenal syndrome is characterized by rapid deterioration of renal function, with a median survival time of less than two weeks, unless liver transplantation is performed. The treatment of choice is liver transplantation, if the patient is suitable for transplantation and survives until a transplant is available. Terlipressin currently is not available in the United States or Canada, but has been marketed for more than 20 years outside the United States and Canada and is considered a standard of care for the treatment of esophageal variceal hemorrhage.

Under an agreement with Orphan Therapeutics, we hold exclusive marketing, sales and distribution rights for terlipressin in the United States and Canada. Orphan Therapeutics holds the IND application for terlipressin and is conducting the Phase 3 clinical trial in the United States and Europe. The ongoing clinical study, conducted by Orphan Therapeutics, is a double-blind, placebo-controlled Phase 3 trial of terlipressin in patients with type 1 hepatorenal syndrome. In this study, patients receive terlipressin, or placebo, given intravenously at 1-2 mg every six hours. Therapy is continued until creatinine decreases to less than or equal to 1.5 mg/dl for at least 48 hours, or for a total of 14 days, unless treatment fails or the patient undergoes liver transplantation.

In April 2005, the FDA granted “fast track” status to the development of terlipressin for the treatment of patients with type 1 hepatorenal syndrome. The FDA grants fast track status under the Food and Drug Administration Modernization Act of 1997 to facilitate the development and to 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 to be considered for the submission of a New Drug Application serially in sections rather than submitting all components simultaneously, and the potential to be considered for priority review and/or accelerated approval. Fast track designation does not mean that the FDA will expedite approval of the product nor does it increase the likelihood of approval of the product. Terlipressin previously had been granted Orphan Drug status, a designation from the FDA that a drug in development addresses a rare disease or condition and that, if approved for marketing in the United States, will receive seven years of marketing exclusivity.

**Nuvion (visilizumab, anti-CD3).** Nuvion is a humanized monoclonal antibody that 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 in a Phase 2/3 clinical study in patients with IVSR-UC. This refractory patient population has no approved medical alternatives and generally requires surgery.

We have conducted a Phase 1/2 trial of Nuvion in this patient population. In the Phase 1 dose-ranging portion of this study, we explored 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 enrolled patients with Epstein-Barr virus levels up to 5,000 copies/ml and had an exploratory provision for re-treatment of patients who have an initial response, but relapse within one year. Following the completion of the study, the 5 µg/kg dose was selected as the optimal dose for use in subsequent studies.

In each of the ulcerative colitis studies of Nuvion reported to date, the most common adverse events have been associated with 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 lymphoproliferative 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.

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We conducted a *Nuvion* end-of-Phase 1 meeting with the FDA in the first quarter of 2005. As a result of these discussions, we plan to conduct two pivotal clinical trials and a retreatment study of *Nuvion* in the setting of intravenous steroid-refractory ulcerative colitis (IVSR-UC). The first pivotal study is a Phase 2/3 clinical trial, which was initiated in the first quarter of 2006. A total of up to 150 patients will be randomized to receive visilizumab 5 µg/kg given IV on days one and two, or placebo, using a 2:1 randomization scheme. The primary endpoint is the assessment of response using the Mayo Clinic score at day 45. The Mayo Clinic score includes an assessment of the colon by endoscopy. An independent Data and Safety Monitoring Committee (DSMB) will review the data after 60 patients have been enrolled. If the DSMB determines it is appropriate for the trial to continue, the Phase 3 component of the study with an additional 90 patients will be initiated, and a second Phase 3 trial also will begin. This second trial also is expected to have a sample size of 150, with the same visilizumab regimen as the Phase 2/3 study. It will not be necessary to use EBV status as criteria for enrollment in either of these trials. Both trials will be performed as multinational studies and each is expected to have a total of 60 sites in North America and Europe. The FDA reviewed the study protocols before the initial pivotal study was initiated. A retreatment study is being initiated in the first half of 2006.

The Phase 1/2 clinical trial included an exploratory option to retreat patients. Patients were eligible for retreatment if they received visilizumab previously, had a response to their initial treatment and then had worsening of their symptoms within a year of the initial treatment. As of February 2006, 17 patients have been retreated in this ongoing study. The safety profile for retreated patients is very similar to the initial treatment, except for an apparent decrease in the symptoms of cytokine release syndrome. In this relatively small group of retreated patients, the clinical response to therapy has been similar to the initial treatment. None of the patients had positive titers of anti-visilizumab antibodies at the time of retreatment. There have been no apparent infusion reactions associated with retreatment. The visilizumab pharmacokinetics in these patients are very similar to the initial treatment course.

We have received fast track status from the FDA for the investigation of *Nuvion* in patients with IVSR-UC. 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.

*Nuvion* additionally is being evaluated in two small open-label Phase 2 studies for the potential treatment of severe Crohn's disease. Data from the first of these studies is expected to be presented at or around the time of the Digestive Disease Week conference held in the United States in May 2006. We also are evaluating the potential for pursuing other clinical indications for *Nuvion*, although our near-term focus continues to be in the area of severe inflammatory bowel disease.

**Ularitide.** Ularitide is a synthetic form of a naturally occurring human protein which is produced in the kidney, where it regulates levels of fluid and sodium. When injected into the blood stream, ularitide causes relaxation of blood vessels, specifically in the arteries that feed the kidneys, lungs and heart, and stimulates natriuresis (excretion of abnormal amounts of sodium into the urine) and diuresis (increase in urination). Ularitide currently is in development for the treatment of acute decompensated heart failure (ADHF). CardioPep Pharma, GmbH (CardioPep Pharma), a biotechnology company based in Germany, has conducted clinical development of ularitide in ADHF including the SIRIUS II Phase 2 clinical trial. PDL has obtained from CardioPep Pharma worldwide rights for the subsequent development and marketing of ularitide in all disease settings.

The SIRIUS II trial was a randomized, double-blind, placebo-controlled clinical trial conducted at 19 centers across Europe. A total of 221 patients were randomized equally to receive ularitide 7.5, 15, or 30 ng/kg/min given intravenously as a 24-hour infusion, or placebo. The two primary endpoints in the study were change in pulmonary capillary wedge pressure (PCWP), a measurement of lung vessel pressure, and change in dyspnea (shortness of breath) score, at six hours. Secondary endpoints included serum creatinine levels (a standard measure of kidney function) and mortality.

The findings demonstrated a significant decrease in pulmonary pressure ( $p < 0.05$ ) as measured by PCWP at six hours. Ularitide treatment also was associated with a significantly improved dyspnea score ( $p < 0.05$ ) in all three dosing groups compared to placebo. Dyspnea was assessed using a standard dyspnea scale, which measures a patient's perception of their change in shortness of breath.

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Serum creatinine levels were unchanged in patients treated with ularitide compared to placebo through 72 hours. This finding suggests that ularitide may not negatively affect kidney function in study patients. There was no increase in mortality in the ularitide treatment groups compared to placebo. The mortality rate through day 30 was higher in the placebo group compared to the three ularitide groups: 13.2% in the placebo group and 3.3% (p=0.080, compared to placebo), 3.8% (p=0.16), and 1.8% (p=0.029) in the 7.5, 15 and 30 ng/kg/min groups, respectively.

Ularitide was well tolerated by patients in the study. The most frequent adverse event was hypotension, which occurred in 1.9% of placebo patients and in 8.3%, 11.3%, and 16.4% of patients in the 7.5, 15, and 30 ng/kg/min groups, respectively.

The studies of ularitide for the treatment of acute decompensated congestive heart failure have been conducted in Europe by CardioPep Pharma. We filed an IND application in the United States in the fourth quarter of 2005 and plan to subsequently initiate a U.S.-based Phase 2b clinical trial during the first quarter of 2006, in which we expect to enroll patients from centers in the United States, Europe, Israel and Australia. This study is evaluating the 15 ng/kg/min dose and uses a composite endpoint, including a physician's global assessment, patient-assessed dyspnea and a need for co-intervention. Mortality is a secondary endpoint. Patients will be followed for six months. Separately, we are discussing with the European Medicines Agency (EMA), using the Scientific Advice procedure, the possibility of using data from a single Phase 3 study as the basis for a marketing approval application in the European Union. There can be no assurance that the discussions with the EMA will permit us to receive marketing approval using data from a single Phase 3 study.

**Daclizumab (Zenapax, anti-IL-2 receptor).** 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.

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. Daclizumab is currently marketed by our licensee, Roche, under the brand name *Zenapax* in the United States, Europe and other territories for acute kidney transplant indication. We have completed Phase 1 trials in healthy volunteers to support asthma and transplant maintenance indications and we are currently conducting a Phase 2 trial for MS.

In September 2004, we and Roche announced the co-development of the subcutaneous formulation of daclizumab (daclizumab s.c.) in asthma and related respiratory disorders. In November 2005, we announced a further expansion of our partnership with Roche to co-develop and commercialize daclizumab for organ transplant patients on long-term, maintenance therapy. Our agreement with Roche provides for sharing of expenses and responsibilities, and collaborative decision making on development programs and other matters. See "Collaboration Agreements and Strategic Transactions" below for a more detailed description of our arrangement with Roche on daclizumab. The use of daclizumab s.c. as an element of maintenance treatment may allow for the reduction, and potential elimination, of more toxic drugs from transplant patient maintenance regimens. During 2005, we conducted a single-dose and a multiple-dose Phase 1 clinical trials of daclizumab s.c. in healthy volunteers, intended to gather additional experience with the PDL-manufactured subcutaneous formulation. We and Roche intend to initiate a subsequent Phase 2b clinical trial in patients with moderate-to-severe persistent asthma.

Effective as of September 2005, we entered into a collaboration agreement with Biogen Idec, a global leader in MS, for the joint development, manufacture and commercialization of three Phase 2 antibody products, including shared development and commercialization of daclizumab in MS and other indications not covered under our Roche agreements. Our agreement with Biogen Idec provides for shared responsibilities, expenses and profits, as well as joint decision making on development plans and other commitment such as manufacturing. See "Collaboration Agreements and Strategic Transactions" below for a more detailed description of our partnering agreement.

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 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.

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A Phase 2 clinical trial of daclizumab, combined with beta interferon, in relapsing-remitting MS patients was initiated in the second quarter of 2005. We and Biogen Idec plan a second Phase 2 study using daclizumab as monotherapy, compared with placebo, in relapsing-remitting MS patients.

**M200 (volociximab, anti-a5b1 integrin antibody).** 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 a5b1 integrin receptors, angiogenesis is inhibited. *In vitro* studies have shown that the antibody inhibits angiogenesis, including vessel formation induced by vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF), as well as other pro-angiogenic growth factors. As a result, the antibody may prove effective in treating tumors in which one or more growth factors contribute to angiogenesis.

Our anti-a5b1 integrin chimeric antibody program, M200, is in Phase 2 clinical studies for advanced solid tumors. We have previously reported interim clinical data from a Phase 1 study of M200. In the Phase 1 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, 15 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 1 extension study. Three of these patients maintained stable disease for greater than 16 weeks over the two studies.

In 2005, we initiated a series of three open-label, Phase 2 clinical trials to study M200 in the treatment of renal, melanoma and pancreatic cancers. The renal cell carcinoma study is a single-agent trial, while the studies in the other malignancies are combination studies with standard therapy. We expect to present the first data from one or more of these M200 studies, at or during the American Society of Clinical Oncology meetings to be held in May 2006 in the United States.

For M200, development and commercialization in all disease settings is included under our Biogen Idec collaboration.

**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.

We conducted two Phase 2 studies of *HuZAF* in a total of approximately 329 patients with Crohn's disease, a form of inflammatory bowel disease. In March 2004, we reported that *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.

A Phase 2 clinical trial of *HuZAF* in patients with rheumatoid arthritis was initiated in the first quarter of 2006. As with M200, we are collaborating with Biogen Idec in the further development and commercialization of *HuZAF*.

## **OUR PRODUCTS IN RESEARCH OR PRECLINICAL STAGE DEVELOPMENT**

Based on our proprietary and focused antibody discovery capabilities, 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. This effort is consistent with our stated aim of entering a proprietary candidate into clinical studies each calendar year beginning in 2006.

We anticipate that the next antibody to advance from our preclinical research pipeline to the clinical development stage will be a humanized antibody directed to an undisclosed target that is highly expressed in patients with multiple myeloma. In addition, we have several humanized antibody candidates in earlier research stages, the most-advanced of which could enter clinical trial studies over the next several years if ongoing preclinical development is successful.

## 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 60 humanized antibodies in clinical trials, including several antibodies addressing large markets.

### 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. Our researchers are continuously searching for new technologies and approaches to build upon our strong antibody know-how.

## OUR RESEARCH

Our research efforts are focused on creating and developing humanized antibodies for the treatment of autoimmune diseases, inflammatory conditions and cancer. 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. We also have in-licensed targets or antibodies, through collaborative research agreements, from academic institutions or other biotechnology or pharmaceutical companies and expect to in-license additional rights in the future in order to develop additional antibody-based products.

We validate targets that result from our own discovery efforts, our collaborations and in-licensing, by evaluating antibodies against these targets in a number of different *in vitro* and *in vivo* assays. Our validation activities help 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 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.

M200 is currently supplied by ICOS Corporation (ICOS) as part of a manufacturing agreement related to our 2003 acquisition of Eos Biotechnology, Inc. (Eos). We have initiated efforts to transfer manufacturing from ICOS to supply materials under the terms of our collaboration with Biogen Idec as soon as is reasonably practicable, subject to regulatory and physical constraints.

We intend to continue to manufacture potential antibody products for use in preclinical and clinical trials, and to manufacture products for commercial use once these products are approved for manufacture, sale and use. 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 in mid-2006.

## COLLABORATION AND STRATEGIC AGREEMENTS

**Roche Collaboration.** Effective October 2003, we entered into an Amended and Restated Worldwide Agreement with Roche under which we paid \$80 million for the acquisition of exclusive rights to daclizumab in all indications other than transplantation. Under the terms of this arrangement, Roche and PDL each held certain rights which entitled PDL to acquire all rights to the transplantation indications for an additional exercise fee to Roche.

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 (in transplantation, marketed as *Zenapax*®) for the treatment of asthma and other 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. Under the terms of the Collaboration Agreement, we and Roche will globally co-develop daclizumab in asthma, share equally in development expenses and co-promote the product in the United States. Outside the United States, we would receive royalties on net sales of the product in asthma and related respiratory diseases.

In October 2005, we executed an Amended and Restated Co-Development and Commercialization Agreement and a Second Amended and Restated Worldwide Agreement (collectively, the Amended Agreements) with Roche, which amended our existing agreements with Roche.

The Amended Agreements expand our relationship with Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer-term maintenance therapy (transplant maintenance). Under the terms of the Amended Agreements, we received a \$10 million upfront payment and may receive up to \$145 million in development and commercialization milestone payments if the development of daclizumab in transplant maintenance is successful. We will share global development costs equally with Roche. In addition, we will have the option to co-promote daclizumab for transplant maintenance and will share in the profits in the United States, and we will receive royalties on net sales of the product in transplant maintenance outside the United States.

The Amended Agreements also provide that we will not exercise our option to acquire rights to promote and sell *Zenapax* for the prevention of acute kidney transplant rejection and eliminated our obligation to make a payment for such right, which would have otherwise been due in 2006. The Amended Agreements also limited the royalty obligations of Roche to PDL with respect to future sales of *Zenapax* in the existing transplant indication to revenues above those currently achieved by Roche. Based on our current expectations of *Zenapax* product sales, we do not expect to receive royalties from Roche under the Amended Agreements.

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**Biogen Idec Collaboration.** In September 2005, we entered into a collaboration with Biogen Idec for the joint development, manufacture and commercialization of three Phase 2 antibody products. We also entered into a stock purchase agreement with Biogen Idec. The collaboration agreement provides for shared development and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and for shared development and commercialization of M200 (volociximab) and *HuZAF* (fontolizumab) in all indications.

On effectiveness of the agreements, we received an upfront license fee payment of \$40.0 million, and Biogen Idec purchased approximately 4.1 million shares of our common stock, at \$24.637 per share, which represents the then fair market value of the stock, for approximately \$100.0 million in cash. These shares are subject to a lock-up provision, which expires as to half the shares in April 2006 and expires as to the remainder of the shares in September 2006. Biogen Idec also agreed to a standstill period of one year during which it is restricted from acquiring or soliciting other parties to acquire our voting securities.

Under our collaboration agreement, we and Biogen Idec will share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies will jointly oversee development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. We will be eligible to receive development and commercialization milestones based on the further successful development of these molecules. Each party will have co-promotion rights in the United States and Europe. Outside the United States and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to PDL on sales of collaboration products.

Our collaborations with Roche and Biogen Idec require each party to undertake extensive efforts in support of the collaboration, and require the performance of both parties to be successful. In general the collaborations are operated through joint steering and other committees. Each party has rights under certain conditions or at certain times to terminate the ongoing collaboration, in whole or as to a particular program, and to terminate the agreement in certain events.

**ESP Pharma and Retavase Acquisitions.** On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma Holding Company, Inc. (ESP Pharma), a privately held hospital-focused company. The aggregate purchase price was approximately \$435.2 million, including the cash paid to ESP Pharma stockholders of \$325.0 million, the fair value of 7,330,182 shares of PDL's common stock issued to ESP Pharma stockholders and direct transaction costs of approximately \$5.4 million. Concurrently, we acquired from Centocor, Inc. (Centocor) the right to manufacture, develop, market and distribute *Retavase* in the United States and Canada. The purchase price for the acquisition of *Retavase* was \$110.5 million, consisting of \$110.0 million paid to Centocor and \$0.5 million of transaction costs. Additionally, we may be required to pay Centocor certain milestone payments of up to \$45 million if additional conditions relating to ongoing clinical trials and manufacturing arrangements for *Retavase* are satisfied. The acquisitions of ESP Pharma and *Retavase* enabled us to be a fully integrated, hospital-focused biopharmaceutical company.

## **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 (Abbott), Biogen Idec, Human Genome Sciences, Inc. (Human Genome Sciences), Chugai Pharmaceutical Company, Ltd. (Chugai), Elan, Genentech, GLYCART Biotechnology AG (GLYCART), Medarex, Inc. (Medarex), MedImmune, Inc. (MedImmune), Merck & Co., Merck KGaA, Millennium Pharmaceuticals, Inc. (Millennium Pharmaceuticals), Morphotek, Inc. (Morphotek), Sankyo Co., Ltd. (Sankyo), Seattle Genetics, Inc. (Seattle Genetics), UCB Group (formerly Celltech Therapeutics Limited) 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 Genentech, GlaxoSmithKline, MedImmune, Millennium Pharmaceuticals, Tanox, Inc. (Tanox) and UCB Group. 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 UCB Group, 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 Co., Inc. (Ajinomoto), Eli Lilly and Company (Eli Lilly), InterMune Pharmaceuticals, Inc. (InterMune), Mochida Pharmaceutical Co., Ltd. (Mochida Pharmaceutical), Progenics Pharmaceuticals, Inc. (Progenics Pharmaceuticals), Teijin Limited (Teijin), Wyeth and Astellas Pharma Inc. (Astellas Pharma, formerly Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd.). 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. For example, in 2005, we outlicensed PR-1, a prostate cancer antibody, to Genentech and we outlicensed *Zamyl*, an antibody targeting certain hematologic malignancies, to Seattle Genetics, a biotechnology company focused on the development of monoclonal antibody-based therapies for the treatment of cancer and immunologic diseases.

## **OUR 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 (entitlement to priority, 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. In February 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to take place on July 10, 2006 through July 13, 2006. Due to a schedule conflict we have requested that the oral proceeding take place later in 2006. We are awaiting response from the European Patent Office to our request. 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.

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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, Minnesota facility, we must meet the FDA guidelines. 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 also are governed by FDA regulations and guidelines.

Both before and after approval is obtained, a pharmaceutical product, its manufacturer and the holder of the Biologics License Application (BLA) or New Drug Application (NDA) for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA or NDA 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 or NDA, 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 or NDA holder.

The marketing and sale of approved pharmaceutical product is subject to strict regulation. 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, there may be a similar risk with respect to *Cardene IV*, *Retavase* and *IV Busulfex*.

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Additional information regarding the regulatory matters that affect our business is contained under the headings “We are subject to extensive government regulation, which requires us to invest significant resources in development, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize our products” in Item 1A Risk Factors below.

### **COMPETITION**

Competitors and potential competitors relative to our marketed products in the United States and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Our competitors include Baxter International Inc., Bedford Laboratories, Hospira, Inc., Genentech, GlaxoSmithKline and Scios Inc. (Scios), a Johnson & Johnson Company.

In addition, our product sales may face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of our products. We face competition in our 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 our marketed products, or that would render our products obsolete or noncompetitive.

Potential antibody-based 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 success in marketing.

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 of competitors’ products;
- patent protection of our products; and
- the ability to hire qualified personnel, specifically in California.

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### HUMAN RESOURCES

As of December 31, 2005, we had 977 full-time employees. Of the total, 204 employees were engaged in research and process development, 142 in clinical and regulatory, 207 in manufacturing, 133 in quality assurance and compliance, and 291 in selling, general and administrative functions. Our scientific staff members have diversified experience and expertise in molecular and cell biology, biochemistry, immunology, protein chemistry, computational chemistry and computer modeling. Our success will depend in large part on our ability to attract and retain skilled and experienced employees. None of our employees is 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.

### EXECUTIVE OFFICERS OF THE REGISTRANT

Certain information with respect to our executive officers as of December 31, 2005, except as otherwise noted, is set forth below. Each of our executive officers serves at the discretion of our Board. See "DIRECTORS" under Part III, Item 10 of this Annual Report on Form 10-K for information regarding Mr. McDade, our chief executive officer.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steven E. Benner, M.D., M.H.S.	46	Senior Vice President and Chief Medical Officer
Peter Calcott, D.Phil.	57	Vice President, Quality and Compliance
David Iwanicki	39	Vice President, Sales and Sales Operations
George T. Jue	54	Vice President, Finance and Corporate Controller
Richard Murray, Ph.D.	47	Senior Vice President and Chief Scientific and Technical Officer
Jaisim Shah	45	Vice President, Marketing and Business Affairs
Laurie Torres	45	Vice President, Human Resources

**Steven E. Benner, M.D., M.H.S.**, has been Senior Vice President and Chief Medical Officer at the Company since November 2002. He joined the Company from the Pharmaceutical Research Institute of Bristol-Myers Squibb, where he started 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. In 2000 he was named Vice President, Licensing and Alliances in the Worldwide Medicines Group at Bristol-Myers Squibb, and assumed responsibilities as Global Development Champion and Vice President for Garenoxacin in 2002. Previously, Dr. Benner was Associate Professor of Medicine in the Division of Hematology/Oncology at The University of North Carolina at Chapel Hill, and 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 earned a bachelor's degree in Biological Sciences from The College of the University of Chicago and an M.H.S. degree in Clinical Epidemiology from The Johns Hopkins School of Hygiene and Public Health. He received his M.D. from the University of Missouri-Columbia School of Medicine.

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**Peter Calcott, D.Phil.**, joined the Company as Vice President, Quality and Compliance in October 2005. Prior to this appointment, he served as Corporate Vice President of Quality and Chief Quality Officer at Chiron Corporation from November 2001 to September 2005. He also served as Vice President of Quality for Immunex Corporation, and held positions in R&D, Manufacturing, Process Development, and Business Development at companies including Monsanto Company, SmithKline Beecham and Bayer AG. A native of the United Kingdom, he holds a B.Sc. (hons) in biology from the University of East Anglia and a D.Phil. from the University of Sussex.

**David Iwanicki** joined the Company as Vice President, Sales and Sales Operations in March 2005 at the completion of the Company's acquisition of ESP Pharma, Inc., having served in the same capacity at ESP Pharma. He also serves as site manager of the Company's Edison, New Jersey facility. Mr. Iwanicki was part of the initial management team that commercialized ESP Pharma and was responsible for creating the nearly 70-person specialized hospital sales force. Prior to joining ESP Pharma, Mr. Iwanicki held various sales, marketing and sales management positions at Eli Lilly and Company from 1988 until May 2002. Mr. Iwanicki was involved with the creation of Eli Lilly's cardiology business unit and cardiology specialty sales force. He later helped create a diabetes specialty sales force of more than 510 sales representatives that launched three new products in three years. He also assisted in creating a critical care sales force of 210 representatives. Mr. Iwanicki earned a bachelor's degree in Marketing from Western New England College at Springfield, Massachusetts in 1988.

**George T. Jue** has been the Company's Vice President, Finance and Corporate Controller since May 9, 2005. In June 2005, the Board appointed Mr. Jue as the Company's Principal Accounting Officer. From 2000 to 2005, Mr. Jue served as Corporate Controller at Scios Inc., a biopharmaceutical company affiliated with Johnson & Johnson. Prior to Scios, he served as Director of Finance at Roche Bioscience, a biopharmaceutical company, in the Urology and CNS Division from 1999 to 2000. Before Roche, he was Senior Group Controller at Genentech, Inc., a biotechnology company, from 1997 to 1999. Prior to Genentech, he served as Assistant CFO at Lawrence Berkeley National Laboratories from 1995 to 1997. From 1982 to 1995, Mr. Jue held various management responsibilities at Syntex Laboratories, the U.S. sales and marketing division of Syntex Corporation, a pharmaceutical company, in commercial planning, corporate finance, and product launches. His most recent position at Syntex was Director of Financial Planning and Analysis. He received a B.S. in Accounting from Bentley College and an MBA from Golden Gate University.

**Richard Murray, Ph.D.**, has served as the Company's Vice President, Research since April 2003 and was made to Senior Vice President, Chief Scientific and Technical Officer in September 2005. Prior to the Company, Dr. Murray co-founded Eos where he served as Vice President, Research from February 1998 to April 2003 before joining the Company's management team through the Company's acquisition of Eos. Dr. Murray 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, where he established the transgenic and knock-out mouse program. Dr. Murray received a Ph.D. from the University of North Carolina in Chapel Hill, with his work in the area of immuno-genetics.

**Jaisim Shah** was named Senior Vice President, Marketing and Business Affairs at the Company in March 2005 after serving as our Vice President, Marketing and Medical Affairs since August 2000. Prior to joining the Company, he served in various marketing management positions at Bristol Myers Squibb, most recently as Vice President, Marketing, for U.S. Pharmaceutical Group, Infectious Diseases. Mr. Shah joined Roche Laboratories in 1991 as Product Director for biotech oncology products for the U.S. market. He then became Global Business Leader for oncology and virology for Roche in 1993 based in Basel, Switzerland. Mr. Shah 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 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 for the treatment of cancer, from 2000 to 2003. From 1998 to 2000, Ms. Torres was Senior Director of Human Resources for Heartport, Inc., a medical devices company specializing in minimally invasive cardiac surgery, 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 a bachelor's degree in Personnel Administration/Industrial Relations at California State University, Hayward.

As a recent development, on March 7, 2006, we entered into an offer letter with Andrew L. Guggenhime, pursuant to which Mr. Guggenhime has agreed to serve as the Company's Senior Vice President and Chief Financial Officer (principal financial officer), effective as of April 3, 2006.

## AVAILABLE INFORMATION

For a report of our fiscal year 2005 profit/loss, total assets, the amount we spent on research and development activities, and our revenues from external customers, including a geographic breakdown of such revenues, see the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

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 and Investor Relations Department at our corporate offices by calling (510) 574-1400.

## ITEM 1A. 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, as well as other risks and uncertainties, 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. Additional risks not currently known to us also may harm our business.

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

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

In general, our expenses have exceeded revenues. As of December 31, 2005, we had an accumulated deficit of approximately \$440.1 million. We expect our expenses to increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for our portfolio of existing products and potential products. For example, over the next several years, we will incur substantial additional expenses as we continue to invest in life cycle management of our existing products, 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 not achieve sustained positive cash flow from operations that we have currently projected. We may also incur acquisition-related charges relating to our ESP or Retavase transactions, which would adversely affect our operating results. The amount of net losses and the time required to reach sustained profitability from our proprietary products 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:

- many of our earlier stage potential products move into later stage clinical development;

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- 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 life cycle management initiatives for our existing products;
- we invest in staffing and operations to meet our manufacturing requirements;
- we expand our commercial infrastructure to market and sell our products;
- 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 additional sales of existing or newly approved products, new agreements with third-party collaborators, significant royalties on sales of products licensed under our intellectual property rights or other uncertain sources of revenue, we will continue to incur operating losses and may require additional capital to fully execute our business strategy.

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

*Cardene IV* has accounted for a significant portion of the operating income and growth in our sales since we acquired it in our acquisition of ESP Pharma in March 2005. *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 recent rate of growth. While we expect to increase committed sales and marketing resources in an effort to ensure the continued growth of *Cardene IV*, there can be no assurance that we can continue the rapid growth rate that ESP Pharma achieved. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive and other related 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 sold 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 from product sales and potential growth in cash flow from operations. *Retavase* is sold into a thrombolytic market that has recently been declining due to the more widespread use of stents and gpIIb/IIIa inhibitor products. Moreover, *Retavase* competes for use in the management of acute myocardial infarction with *TNKase*<sup>TM</sup> and *Activase*® from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we possess. While we believe that our planned investment in additional 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 was previously marketed on behalf of Centocor by Scios, a Johnson & Johnson company. We recently completed the transfer of the product from these companies but will require the continued cooperation of Centocor and Scios to successfully transfer the manufacturing of the product to our operations, and there can be no assurance that we will be successful in achieving this transition or our projected sales levels.

### **We are 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*.**

We will be required to manufacture *Retavase* 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 RTP Inc. and Roche. While the rights to *Retavase* included the acquisition in March 2005 of at least 12 months of inventory, the manufacturing of this product for use as a therapeutic in compliance with regulatory requirements will be complex, time-consuming and expensive. We are required to effect the transfer of manufacturing from Centocor in a timely manner. 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.

**We rely on third-party suppliers to provide our products for sale and certain clinical candidates for trials. 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 acquired ESP Pharma products and have only recently become familiar with the manufacturing process for these products. We assumed from ESP Pharma long-term agreements with various third parties to supply the products under our label. If there are supply problems with the third party manufacturers, in particular with respect to *Cardene IV* and *Retavase*, there may not be sufficient supplies of *Cardene IV* or *Retavase* to meet commercial demand, in which case our future results could suffer. In addition, we rely upon third parties for the supply of ularitide and terlipressin for clinical trials, and in the case of terlipressin, supply is managed by our partner, Orphan Therapeutics. The manufacturing of terlipressin is complex and time consuming. If there are supply problems with the third party manufacturers, or if Orphan Therapeutics is not successful in managing the suppliers for terlipressin, our clinical trials or the potential commercialization of these products could be substantially delayed and our financial results would be adversely affected.

In addition, our 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 (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.

**Achieving future profitability or sustaining cash flow positive results of operations will depend in significant part upon the continuing success of the products we acquired in our acquisitions of ESP Pharma and *Retavase*.**

PDL has incurred losses since inception. In order for us to achieve our goal to be sustainably cash flow positive in 2006 and thereafter, as currently projected, we will need to achieve continued growth from *Cardene IV*, *Retavase* and *IV Busulfex* as well as continued growth in royalties from products licensed under our intellectual property rights.

**Our product 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 and return patterns of these wholesalers and distribution partners.**

We sell our 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, 2005, revenues from the sales of our products to our three largest U.S. wholesalers totaled approximately 88% of our net product sales. Our reliance on a small number of wholesalers and distribution partners could cause revenues to fluctuate from quarter to quarter based on the buying, return and payment patterns of these wholesalers and distribution partners. In addition, as of December 31, 2005, these three U.S. wholesalers represented approximately 75% of our outstanding accounts receivable. We recently had significant adjustments to returns of off-patent branded products acquired in our acquisition of ESP Pharma. These adjustments were due primarily to unexpected returns from wholesalers. We believe these unexpected returns resulted from overstocking of inventory by wholesalers in anticipation of future price increases that did not occur, and therefore have affected the rate of returns. We continue to monitor current levels of inventory at the wholesalers consistent with our forecasts of end user demand. Nevertheless, in the absence of a written agreement with a wholesaler or distribution partner, there can be no assurance that our wholesalers and distribution partners will maintain inventory levels consistent with our forecast of end user demand. Due to enhanced inventory management and enforcement of product return policy, we do not believe that we will experience the same level of returns for products sold subsequent to the acquisition date and we have established reserves based on these expectations. If returns exceed our expectations, revenues would be adversely affected. In addition, if any of these wholesalers fails to pay on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

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

At December 31, 2005, we had approximately \$508.0 million of outstanding debt, including without limitation \$250.0 million in principal that remains outstanding under our 2.00% Convertible Senior Notes due February 15, 2012 (the 2005 Notes). In addition to the 2005 Notes, approximately \$250.0 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2023 (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;

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- 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.

### **We may not successfully continue to integrate the ESP Pharma business and may not realize the anticipated benefits of the merger.**

In March 2005, we completed our acquisition of ESP Pharma, a privately owned company. Achieving the benefits of the merger will depend in substantial part on the successful integration of the two companies' operations and personnel. Prior to the merger, PDL and ESP Pharma operated independently, each with its own operations, corporate culture, locations, employees and systems. PDL and ESP Pharma are now operating as a combined organization and began utilizing common business, information and communication systems, operating procedures, financial controls, compensation practices, training and professional development programs. However, additional activities in many areas are required to achieve full integration and we will continue to face significant challenges in integrating the organizations and operations in a timely and efficient manner. Some of the challenges and difficulties involved in this integration include:

- demonstrating to our customers 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 as a combined company;
- retaining key sales-related employees;
- coordinating and rationalizing commercialization and development activities to enhance life cycle management and development programs;
- continuing the establishment of new trade practices and relationships with wholesalers;
- management distraction from the business of the combined company;
- consolidating and rationalizing corporate and administrative infrastructures, including establishment of appropriate internal control and staffing levels to manage a much larger business enterprise;

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- integrating and documenting ESP Pharma-related 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 United States.

Any one or all of these factors, many of which are outside our control, may increase operating costs or lower anticipated financial performance. In addition, the combined company may lose distributors, suppliers, manufacturers and employees. Continuing to achieve the potential benefits of the merger will depend on the continued successful integration of the two companies. While we have achieved a significant level of integration, it is not certain that we will achieve all aspects of integration successfully, or that all 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.

### **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 from the merger.**

We continue to market and sell the two key products acquired in our acquisition of ESP Pharma: *Cardene IV* and *IV Busulfex*. Although we have retained and increased the size of the hospital-focused sales and sales-related infrastructure, prior to the merger we had never sold, marketed or distributed products, and we may encounter challenges in the continuing integration of such capabilities.

We cannot assure you that our customers will continue their current buying patterns. Any delay or deferral in purchasing decisions by such customers due to our marketing and sales efforts could have a material adverse effect on the business or operating results. In addition, as part of the integration of ESP Pharma, we have changed certain trade practices and more effectively enforced trade policies to be more consistent with what we believe to be industry standards and the natural demand for our products. This has resulted in adjustments to reserves and declining or holding orders to align selling patterns with our estimate of the end user demand for our products.

### **As a result of the ESP Pharma merger, the combined company is 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.**

As a result of the merger with ESP Pharma, we 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 and the inability to retain or replace key employees could have a material adverse effect on the operating results of the combined company and, as a result, on the market price of PDL's common stock.

### **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 and essential components for those products, to design and 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. In addition, the design of the clinical studies may not be sufficient or appropriate for regulatory review and approval and we may have to conduct further studies in order to facilitate approval.

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Our collaboration arrangements with Roche and with Biogen Idec are particularly important to us. Effective in September 2005 we and Biogen Idec entered into a long-term agreement under which Biogen Idec became our partner on three of our most advanced antibody clinical programs, M200 and *HuZAF* in all indications and daclizumab in certain indications including MS. In October 2005, we expanded our existing relationship with Roche and our collaboration now includes the co-development and commercialization of daclizumab for asthma and for organ transplant patients on longer-term maintenance therapy (transplant maintenance). These collaboration agreements provide for the development, manufacture and potential commercialization of products. PDL and each of our partners assume certain responsibilities and share expenses. Because of the broad scope of the collaborations, we are particularly dependent upon the performance by Roche and by Biogen Idec, respectively, of their obligations under the agreements. The failure of these partners to perform their obligations, our failure to perform our obligations under either agreement, our failure to effectively manage the relationship, or a material contractual dispute between us and either Biogen Idec or Roche would have a material adverse effect on our prospects or financial results. Moreover, our financial results are dependent in substantial part upon our efforts and related expenses for these programs. Our revenues and expenses recognized under the collaborations, and particularly our collaboration with Biogen Idec will vary depending on the work performed by us and our partners in any particular reporting period.

We rely on other collaborators, such as CardioPep Pharma with respect to ularitide and Orphan Therapeutics with respect to terlipressin, as well as other third parties, such as clinical research organizations, medical institutions and clinical investigators, including physician sponsors, to conduct nearly all of our clinical trials, including recruiting and enrolling patients in the trials. If these 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 clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by third party contractors 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 collaborative agreements can generally be terminated by our partners under certain conditions, and in some cases 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 continued 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 capabilities and priorities. These 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.

**If we are unable to favorably assess the effectiveness of internal control 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 (Section 404), our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. The rules governing the standards that must be met for management to assess the effectiveness of our internal control over financial reporting are new and complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal control over financial reporting successfully in 2004 and 2005.

In 2005, we moved several key finance controls at ESP Pharma under our corporate process at PDL. As a result, we were permitted and elected to exclude certain of the ESP Pharma operations from the Section 404 compliance requirements for the year ended December 31, 2005. However, there can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting as of the end of 2006. The Section 404 compliance process has resulted, and will continue to result, in increased expenses and the devotion of significant management resources. For example, during our review of the results of operation for the quarter ended September 30, 2005, we identified a material weakness in the operations of our internal control over financial reporting as defined in Public Company Accounting Oversight Board Standard No. 2 related to the failure of an existing internal control to operate effectively. Specifically, with respect to the third quarter of 2005 we did not complete an impairment review with regard to the net carrying value of certain of the intangible assets and inventory acquired in the business combination with ESP Pharma. During the third quarter of 2005, we decided to sell four generic products acquired from ESP Pharma. Also during September 2005 there was an indication of impairment as the proceeds likely to be received in such a sale would be materially less than the net carrying value of the related intangible assets and inventory as of September 30, 2005. We remediated this material weakness through the addition of staff and consulting resources during the fourth quarter of 2005.

**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. In particular, our product sales and royalty revenues may be unpredictable and may fluctuate since they depend upon:

- the seasonality and rate of growth of sales of existing and licensed products;
- the existence of competing products;
- our ability to market and sell recently acquired products;
- the response of wholesalers at announced or anticipated price changes for our products;
- uncertainty resulting from the purchase practices of wholesalers and inventory levels at wholesalers;
- product returns, reimbursements and rebates which could differ from our estimates and accruals;
- the continued safety of approved products;
- the marketing and promotional efforts of our licensees from whom we receive royalty payments;
- the timing of royalty reports;
- our ability to successfully defend and enforce our patents;
- the effect of taxes and estimates or adjustments to estimates for federal and state taxes that may impact our reported net income in any particular quarter; and
- the effect of new accounting, pronouncements or interpretations of existing guidance, in particular as they may affect the accounting treatment of reimbursement of research and development expenses under collaborative arrangements.

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We receive royalty revenues on sales of *Synagis*, which is marketed by MedImmune. This product has significantly 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 is expected to continue 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. In addition, based on current accounting principles and guidance, we currently recognize reimbursement of expenses under our existing collaborative arrangements as revenue at the time the work is performed under the collaboration. In the event that there is a change in the accounting principles or guidance that would result in a “netting” of revenues and expenses during the period in which the work is performed, our revenues would be reduced and netted with related expenses, although our net loss would not change. Nevertheless, a change to this effect would likely reduce our reported rate of growth in licensed and other and total revenues from historical periods due to this change in accounting. In addition, 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 and the unpredictable nature of clinical trial and related 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 will begin recognizing expense for outstanding employee stock options beginning in 2006, and as a result, we will incur significantly higher losses. In addition, we hold a \$30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. (Exelixis) that matures in May 2006. 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.**

Our revenues include revenues 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.

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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 (entitlement to priority, 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. In February 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to take place on July 10, 2006 through July 13, 2006. Due to a schedule conflict we have requested that the oral proceeding take place later in 2006. We are awaiting response from the European Patent Office to our request. 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 United States 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 have appealed the decision to the Technical Board of Appeal at the European Patent Office in July 2005. 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 interleukin-2 (IL-2) receptor and the composition of matter directed to the *Zenapax* (daclizumab) antibody product. 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.

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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, paying royalties under existing patent licenses with us and not terminating those existing licenses with us. To date, we have been successful in obtaining and maintaining such licensing arrangements, and in receiving royalties on product sales, from parties whose products may be covered by our patents. However, there can be no assurance that we will continue to be successful in our licensing efforts in the future. In the past we have experienced challenges in our licensing efforts, such as the disagreement we had with Genentech in 2003 over whether its *Xolair* antibody product was covered under our humanization patents. Although we have reached an amicable settlement with Genentech that is intended to resolve such disagreements, Genentech or other companies may, in the future, terminate their licensing agreements with us, or 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.

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Celltech Therapeutics Limited (Celltech) which has been acquired by UCB Group, 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 an 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, which rights may be exercised under the agreement through 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 products 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; or

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- we may be unable to successfully integrate the research, development and commercialization capabilities necessary to bring these products to market.

### **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 drugs. 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 potentially new drugs 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 sufficient supply of materials to enroll and complete clinical studies according to planned timelines;
- 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, proprietary and intended use of the product candidate and is difficult to predict. Further, we, the FDA, EMEA, 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 invest significant resources in development, 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. 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.

Early clinical trials such as Phase 1 and 2 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 potential drug product where a change in the manufacturing process or manufacturing site 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.

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 any of our products may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood the product 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 and our partner Orphan Therapeutics has received fast track designation from the FDA for terlipressin for Hepato-Renal Syndrome, Type 1, receipt of fast track designation may not result in 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* or terlipressin 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. 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 royalty 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 and Elan announced that they had voluntarily suspended supplying, marketing and the sale of *Tysabri*, a drug approved to treat MS 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*. Although data in support of the product has been resubmitted for FDA approval, 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 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, commercial, scientific and management personnel. To achieve our objectives, we expect to expand our operations and increase the number of our employees significantly. If we are unsuccessful in attracting and retaining qualified personnel, particularly at the management level, our business could be impaired. We have been successful in hiring and retaining key personnel in the past; however, we face significant competition for experienced, management level personnel. For example, our CFO resigned in October 2005, and we only recently announced the retention of a new CFO. If other positions in finance remain or become vacant, our ability to operate effectively, including our ability to report on and attest to, the effectiveness of our internal control over financial reporting, could be adversely affected.

**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;

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- 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, our collaborations with Roche and Biogen Idec involving daclizumab may be significantly negatively impacted by our failure to successfully operate and receive regulatory approval of our Brooklyn Park, Minnesota manufacturing facility.

Moreover, 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 from 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, Minnesota manufacturing facility from our Plymouth, Minnesota 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 has manufactured all of the drug material contemplated for use in our current Phase 2 clinical studies. We and Biogen Idec will need to demonstrate that the M200 drug material produced will be sufficiently bioequivalent 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.

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. In addition, 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.

**We may be unable to obtain or maintain regulatory approval for our products and the marketing and sale of our products could result in violations of law or regulations.**

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 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.

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.

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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, there may be a similar risk with respect to *Cardene IV*, *IV Busulfex* and *Retavase*.

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 payers 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;

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- their potential advantage over alternative treatment methods;
- reimbursement policies of government and third-party payers; 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 products and product candidates. Once a supplier's materials have been selected for use in the 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 products sold by us or the use of products during research and development efforts or after commercialization results in adverse effects. This risk exists even with respect to any products that receive regulatory approval for commercial sale. While we maintain liability insurance for our products, it may not be sufficient to satisfy any or all liabilities 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 payers 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.

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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, 2005 to March 13, 2006, our common stock closed as high as \$32.77 per share and as low as \$13.85 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 our marketed products;
- approval or introduction of competing products and technologies;
- disappointing sales of products from which we receive royalties;
- withdrawal from the market of an approved product from which we receive royalties;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including without limitation the obtaining of regulatory approvals;
- 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;

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- 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 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. For example, SFAS 123R requires us to adopt a method of determining the compensation expense of our employee stock options and report them in the captions of our financial statements. The compensation expense reported under SFAS 123R will have a significant adverse effect on our reported financial condition beginning in 2006 and may impact the way we conduct our business.

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.

### **We may not have the ability to raise the funds to repurchase the 2003 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 the 2003 Notes may require us to repurchase all or a portion of their 2003 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 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 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 2003 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 2003 Notes or make our repurchase of 2003 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 repurchase the 2003 Notes. Our failure to repurchase tendered 2003 Notes would constitute an event of default under the indenture for the 2003 Notes, which might also constitute a default under the terms of our other debt, including the 2005 Notes. 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 their 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 National 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 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 2003 Notes or 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 2003 Notes or 2005 Notes, respectively, then outstanding. Any such payment would have a material adverse effect on our cash position.

**Charges to earnings and related amortization of assets resulting from our acquisitions may adversely affect the market value of PDL's common stock following the merger.**

In accordance with U.S. generally accepted accounting principles, we accounted for the acquisition of ESP Pharma, our acquisition of *Retavase* and our acquisition of certain rights with respect to daclizumab using the purchase method of accounting, which resulted in charges to earnings in the year of acquisition and which will result in ongoing expenses due to the amortization and depreciation of certain assets acquired in those transactions. Under the purchase method of accounting, we allocated 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 recorded the excess of the purchase price over those fair values as goodwill. The portion of the purchase price of ESP Pharma allocated to in-process research and development in the amount of \$79.4 million was expensed by the combined company in the first quarter of 2005. We 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 acquisition transactions. In addition, to the extent the value of goodwill becomes impaired in the future, as experienced with the review for impairment of the off-patent branded products in the third quarter of 2005, we 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 and the market value of our common stock.

**Failure to achieve revenue targets or raise additional funds in the future may require us to reduce the scope of or eliminate one or more of our planned activities.**

The acquisition of ESP Pharma and certain rights to *Retavase* required cash payments of approximately \$435.5 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 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;

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- the extent to which *Retavase* sales can be maintained or increased from recent historical levels;
- the progress, level and timing of research and development activities related to clinical trials we are conducting or that are being conducting in collaboration with our partners, including clinical trials with respect to daclizumab, *Nuvion*, ularitide 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.

### **We face 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 our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions.

In addition, our products face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of its products. Many of the marketed products are generic versions of brand-name products with declining total sales levels. Additionally, some of our brand-name products are subject to competition from generic products. As a result, we face competition for our 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 our products, or that would render our products obsolete or noncompetitive.

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 historically accounted for a majority of the cash flow from operations of ESP Pharma. We do not consider these products as strategic assets and made the decision to sell the related intangible assets and inventory for these products in the third quarter of 2005. The related intangible assets and inventory were classified as held for sale since September 30, 2005. Because the fair market value of the related intangible assets was lower than the carrying value, an impairment loss of approximately \$15.2 million was recognized in the third quarter 2005 and an additional \$0.3 million impairment loss was recognized in the fourth quarter of 2005 (see Note 4 to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K). We completed the sale of *Declomycin* in February 2006, and the remaining three off-patent branded products in March 2006.

### **Our 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, our combined portfolio of product candidates. We cannot be sure that reimbursement in the United States 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 products, and may not be able to obtain a satisfactory financial return on products.

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Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States 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 our products. 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 and approved. 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 our business.

**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 1B. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 2. PROPERTIES**

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 \$7.4 million mortgage on these facilities. In addition, we lease approximately 160,000 square feet of adjacent research and development and general office space in Fremont, California. Our leases for these facilities will expire in December 2006 and March 2008.

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We lease approximately 75,000 square feet of manufacturing, laboratory and office space in three separate buildings in Plymouth, Minnesota. The leases will expire in February 2009, subject to our option to extend the leases for an additional five-year term.

We purchased approximately 29 acres in Brooklyn Park, Minnesota in March 2002 and have built a new commercial manufacturing plant of approximately 214,000 square feet on this property that is currently being validated. In January 2005, we purchased 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.

We lease offices consisting of approximately 21,000 square feet for sales management and administrative purpose in Edison, New Jersey. The lease will expire in January 2008. In addition, in Paris, France, we lease approximately 1,900 square feet of general office space. The lease will expire in August 2013.

We anticipate that we will need additional space for our facilities and we are considering various opportunities for meeting those needs. As such, in December 2005, we entered into option agreements to lease certain facilities, which will expire in July 2006. We have not decided to exercise these options and we are still in the process of evaluating other opportunities.

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

We own substantially all of the equipment used in our facilities. (See Note 13 to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.)

### **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 (entitlement to priority, 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. In February 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to take place on July 10, 2006 through July 13, 2006. Due to a schedule conflict we have requested that the oral proceeding take place later in 2006. We are awaiting response from the European Patent Office to our request. 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 will suspend the legal effect of the decision of the Opposition Division during the appeal process, which is likely to take several years.

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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.

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**PART II**

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

	High	Low
<b>2005</b>		
First Quarter	\$21.36	\$13.79
Second Quarter	20.56	14.84
Third Quarter	30.79	20.12
Fourth Quarter	30.50	24.76
<b>2004</b>		
First Quarter	\$25.07	\$17.12
Second Quarter	27.58	16.28
Third Quarter	21.67	14.62
Fourth Quarter	20.94	17.18

Our common stock trades on the Nasdaq National Market under the symbol "PDLI." Prices indicated above are the high and low 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 March 13, 2006, we had approximately 303 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 400 holders.

**ITEM 6. SELECTED FINANCIAL DATA**

**CONSOLIDATED STATEMENTS OF OPERATIONS DATA:**

(In thousands, except per share data)	Years ended December 31,				
	2005	2004	2003	2002	2001
<b>Revenues:</b>					
Product sales	\$ 121,191	\$ —	\$ —	\$ —	\$ —
Royalties	130,068	83,807	52,704	40,421	30,604
License and other	28,395	12,217	13,982	5,952	13,796
<b>Total revenues</b>	<b>279,654</b>	<b>96,024</b>	<b>66,686</b>	<b>46,373</b>	<b>44,400</b>
<b>Costs and expenses:</b>					
Cost of product sales	60,257	—	—	—	—
Research and development	172,039	122,563	82,732	57,978	52,163
Selling, general and administrative	82,386	31,806	27,613	18,373	15,004
Acquired in-process research and development <sup>(1)</sup>	79,417	—	85,993	—	—
Other acquisition-related charges <sup>(2)</sup>	19,434	—	—	—	—
Asset impairment charge <sup>(3)</sup>	31,269	—	—	—	—
<b>Total costs and expenses</b>	<b>444,802</b>	<b>154,369</b>	<b>196,338</b>	<b>76,351</b>	<b>67,167</b>
<b>Operating loss</b>	<b>(165,148)</b>	<b>(58,345)</b>	<b>(129,652)</b>	<b>(29,978)</b>	<b>(22,767)</b>
Interest and other income, net <sup>(4)</sup>	9,616	10,212	9,831	25,978	35,135
Interest expense	(10,177)	(5,028)	(9,770)	(9,146)	(9,709)
Impairment loss on investment <sup>(5)</sup>	—	—	(150)	(1,366)	—
<b>Income (loss) before income taxes</b>	<b>(165,709)</b>	<b>(53,161)</b>	<b>(129,741)</b>	<b>(14,512)</b>	<b>2,659</b>
<b>Income tax expense</b>	<b>(868)</b>	<b>(80)</b>	<b>(73)</b>	<b>(42)</b>	<b>(12)</b>
<b>Net income (loss)</b>	<b>\$(166,577)</b>	<b>\$(53,241)</b>	<b>\$(129,814)</b>	<b>\$(14,554)</b>	<b>\$ 2,647</b>
<b>Basic and diluted net income (loss) per share:</b>	<b>\$ (1.60)</b>	<b>\$ (0.56)</b>	<b>\$ (1.40)</b>	<b>\$ (0.16)</b>	<b>\$ 0.03</b>
<b>Shares used in computation of net income (loss) per share:</b>					
Basic	104,326	94,982	92,478	88,865	87,624
Diluted	104,326	94,982	92,478	88,865	92,889

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### CONSOLIDATED BALANCE SHEET DATA:

	2005	2004	2003	2002	2001
Cash, cash equivalents, marketable securities and restricted investments	\$ 333,922	\$ 397,080	\$ 504,993	\$606,410	\$650,315
Working capital	307,302	356,660	467,248	599,215	641,896
Total assets	1,166,001	713,732	742,030	717,818	729,898
Long-term obligations, less current portion	507,294	257,768	258,627	158,426	158,892
Accumulated deficit	(440,109)	(273,532)	(220,291)	(90,477)	(75,923)
Total stockholders' equity	526,065	412,510	448,331	544,766	558,443

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 years ended December 31, 2003, 2004 and 2005.

- (1) Represents acquired in-process research and development. The amount for 2003 relates to the Eos acquisition and the purchase of certain technology from Roche that had not yet achieved technological feasibility. The amount for 2005 relates to the ESP Pharma acquisition. For a description of these charges, see Notes 1, 4 and 6 to the Consolidated Financial Statements.
- (2) Represents product sales returns, accounts receivable allowances and other liabilities related to ESP Pharma operations prior to our acquisition of the business. See Note 1 to the Consolidated Financial Statements.
- (3) Represents non-cash charges related to the impairment of off-patent branded products and termination of reversion right. For a description of these charges, see Note 4 to the Consolidated Financial Statements.
- (4) Includes charges associated with the early extinguishment of certain of our debt.
- (5) Represents non-cash charges related to the impairment of an equity investment.

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

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this report 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.

#### Revisions to ESP Pharma Purchase Accounting

During the preparation of PDL's consolidated financial statements for the year ended December 31, 2005, and subsequent to the issuance of our earnings press release on February 27, 2006, management revised the purchase accounting and certain related account balances previously reported in the each of the Company's 2005 Form 10-Q filings with respect to the acquisition of ESP Pharma which was completed on March 23, 2005. This acquisition was accounted for pursuant to Statement of Financial Accounting Standards No. 141, "Business Combinations" (FAS 141). Pursuant to FAS 141, the allocation period during which we were able to make adjustments to the purchase price and allocation thereof ended on March 31, 2005. As a result, revisions to our previously reported balances have been included in "Other acquisition-related charges" in our consolidated statement of operations.

Please refer to page 100 in this report on Form 10-K for the detail of the affected quarterly balances, as previously reported and as subsequently revised. A summary of the more significant revisions is as follows:

On the acquisition date in March 2005, we believed beyond a reasonable doubt that the 2,523,588 shares placed into escrow (the escrow shares) would ultimately be issued to former ESP Pharma shareholders and, therefore, we included the value of such shares, which approximated \$36.1 million, in the calculation of the purchase price due to various liabilities identified subsequently. We have since determined that the value of these shares should not have been included in purchase consideration until the underlying contingencies are resolved and they are released from the escrow in favor of the former ESP Pharma shareholders. This revision reduced the originally recorded goodwill and stockholders' equity by approximately \$36.1 million at March 31, 2005. During September 2005, approximately one-half of the escrow shares were released to the former ESP shareholders. As such, the fair value of such shares at that time of \$35.3 million was added to the revised purchase price as contingent consideration and reflected as an increase to goodwill and stockholders' equity at that date.

During the second, third and fourth quarters of 2005, we incurred various costs and liabilities that related to ESP Pharma operations prior to our acquisition of the business. Specifically, we experienced a significant volume of product returns related to products sold by ESP Pharma prior to our acquisition of the business (pre-acquisition sales). Charges associated with returns of pre-acquisition sales totaled approximately \$17.2 million. Further, certain acquired accounts receivable were subsequently identified as being uncollectible and resulted in additional charges of \$1.4 million. Other pre-acquisition liabilities identified during 2005 and charged to operations approximated \$0.8 million. All charges described above have been included in other acquisition-related charges in our consolidated statement of operations.

During the third and fourth quarters, we initially accounted for most of the items outlined above as a reduction to stockholders' equity rather than as a charge to results of operations, inasmuch as we expected to reduce the amount of purchase consideration originally reported by claiming certain shares from the escrow. As noted above, however, based upon subsequent events we have determined not to include the escrow shares should in the initial purchase price. Accordingly, these amounts have now been included in other acquisition related charges.

Although we have made our best estimates of other acquisition-related charges as of the filing of this Annual Report on Form 10-K, during 2006 we may identify additional other acquisition-related charges that could affect our results of operations.

Under the terms of the Amended and Restated Agreement and Plan of Merger, we have the right to claim escrow shares if product returns related to pre-acquisition sales exceed a specific threshold. Due to the large volume of product returns, tax-related items and certain other liabilities incurred by us we have filed claims to recover 388,807 escrow shares and expect to file claims to recover a significant number of additional shares.

**Revision to Previously Reported Fourth Quarter 2005 Results of Operations**

We revised the number of shares used in the calculation of basic and diluted net loss per share calculation for the quarter and year ended December 31, 2005. This increase of approximately 4.0 million and 1.0 million shares for the quarter and year ended December 31, 2005, respectively, related to share of common stock we issued in connection with a collaboration.

## OVERVIEW

We are a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life-threatening illnesses. We are a fully integrated, commercial biopharmaceutical company with proprietary marketed products, a growing and diverse operating revenue base and a broad, proprietary pipeline. We currently market and sell three products in the acute-care hospital setting in the United States and Canada and receive royalties through licensing agreements with numerous biotechnology and pharmaceutical companies based on our antibody humanization technology platform. We have six investigational compounds in Phase 2 or Phase 3 clinical development for hepatorenal syndrome, inflammation and autoimmune diseases, cardiovascular disorders and cancer.

Our products are sold through our hospital-focused sales force which focuses on the cardiac, neurological and intensive care unit sections. *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. 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 anti-tumor 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. *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.

Almost half of our revenues generated in 2005 were from royalties paid for use of our patented antibody humanization technology as applied to 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 widely validated in our industry, based on the existence of multiple approved and licensed antibodies.

We have licensed and will continue to offer to 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 generated royalties to PDL in 2005: Genentech Inc.'s (Genentech) *Avastin*<sup>™</sup>, *Herceptin*<sup>®</sup>, *Xolair*<sup>®</sup> and *Raptiva*<sup>®</sup>; MedImmune, Inc.'s (MedImmune) *Synagis*<sup>®</sup>; Wyeth's *Mylotarg*<sup>®</sup>; Elan Corporation, Plc's (Elan) *Tysabri*<sup>®</sup> and Hoffmann-La Roche's (Roche) *Zenapax*<sup>®</sup>. Combined annual worldwide sales of these products exceeded \$4.0 billion in 2005. We are aware of more than 90 humanized antibodies in development worldwide by various pharmaceutical and biotechnology companies, and we have entered into patent agreements which may cover many of these products.

2005 was a year of significant growth for PDL. During the year, we acquired ESP Pharma Holding Company, Inc. (ESP Pharma) a privately held, hospital-focused pharmaceutical company. Consistent with our strategy of entering into development and commercialization partnerships for those pipeline programs which would be commercialized largely outside the hospital setting, in August 2005, we entered into a collaboration agreement with Biogen Idec, Inc. (Biogen Idec), a global biotechnology leader with products and capabilities in oncology, neurology and immunology, for the joint development, manufacture and commercialization of three of our Phase 2 antibody products. In October 2005, we expanded our existing relationship with Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer-term maintenance therapy (transplant maintenance). The addition of marketed products resulting from the ESP Pharma and *Retavase* acquisitions, as well as the financial effects of the Biogen Idec and Roche collaborations, contributed to the achievement of positive cash flows from operations in the fourth quarter of 2005.

In order to better reflect our status as a commercial biopharmaceutical company, on January 9, 2006, we changed our name from Protein Design Labs, Inc. to PDL BioPharma, Inc. This change coincided with the merger of ESP Pharma into PDL to create a single organization and operating structure. ESP Pharma had been operating as a wholly-owned subsidiary since the acquisition in the first quarter of 2005.

### **Roche Collaboration**

Effective October 2003, we entered into an Amended and Restated Worldwide Agreement with Roche under which we paid \$80 million for the acquisition of exclusive rights to daclizumab in all indications other than transplantation. Under the terms of this arrangement, Roche and PDL each held certain rights to cause PDL to acquire all rights to the transplantation indications for an additional exercise fee to Roche.

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 (in transplantation, marketed as *Zenapax*) for the treatment of asthma and other 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. We and Roche will globally co-develop daclizumab in asthma, share equally in development expenses and co-promote the product in the United States. Outside the United States, we would receive royalties on net sales of the product in asthma and related respiratory diseases.

In October 2005, we executed an Amended and Restated Co-Development and Commercialization Agreement and a Second Amended and Restated Worldwide Agreement (collectively, the Amended Agreements) with Roche, which amended our existing agreements with Roche. These Amended Agreements expand our relationship with Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer-term maintenance therapy (transplant maintenance). Under the terms of the Amended Agreements, we received a \$10 million upfront payment and may receive up to \$145 million in development and commercialization milestone payments if the development of daclizumab in transplant maintenance is successful. We will share global development costs equally with Roche. In addition, we will have the option to co-promote daclizumab for transplant maintenance and will share profits in the United States, and we will receive royalties on net sales of the product in transplant maintenance outside the United States. During 2005, we recognized \$0.2 million of upfront license fee and \$0.2 million for the reimbursement of certain research and development expense under the Agreements as revenue.

The Amended Agreements also provide that we will not exercise our option to acquire rights to promote and sell *Zenapax* for the prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2006. As a result, during the fourth quarter of 2005 we recorded a charge in asset impairment in the consolidated statements of operations to expense the carrying value of the reversion right of \$15.8 million acquired under the October 2003 agreement. The Amended Agreements also limited the royalty obligations of Roche to PDL with respect to future sales of *Zenapax* in the existing transplant indication to revenues above those currently achieved by Roche. Based on our current expectations of *Zenapax* product sales, we do not expect to receive royalties from Roche under the Amended Agreements.

### **Biogen Idec Collaboration**

In September 2005, we entered into a collaboration with Biogen Idec for the joint development, manufacture and commercialization of three Phase 2 antibody products. We also entered into a stock purchase agreement with Biogen Idec. The collaboration agreement provides for shared development and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and for shared development and commercialization of M200 (volociximab) and *HuZAF* (fontolizumab) in all indications.

Upon effecting the agreement, we received an upfront license fee payment of \$40.0 million, and Biogen Idec purchased approximately 4.1 million shares of our common stock, at \$24.637 per share, which represents the then fair market value of the stock, for approximately \$100.0 million in cash. These shares are subject to a lock-up provision, which expires as to half the shares in April 2006 and expires as to the remainder of the shares in September 2006. Biogen Idec also agreed to a standstill period of one year during which it is restricted from acquiring or soliciting other parties to acquire our voting securities.

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Under our collaboration agreement, we and Biogen Idec will share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies will jointly oversee development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. We will be eligible to receive development and commercialization milestones based on the further successful development of these molecules. Each party will have co-promotion rights in the United States and Europe. Outside the United States and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to PDL on sales of collaboration products. If multiple products are developed successfully in multiple indications and all milestones are achieved, PDL could receive certain development and commercialization milestone payments totaling up to \$660 million. Of these, \$560 million are related to development and \$100 million are related to commercialization of collaboration products.

Our collaborations with Roche and Biogen Idec require each party to undertake extensive efforts in support of the collaboration, and require the performance of both parties to be successful. In general the collaborations are operated through joint steering and other committees. Each party has rights under certain conditions or at certain times to terminate the ongoing collaboration, in whole or as to a particular program, and to terminate the agreement in certain events.

### **ESP Pharma and Retavase Acquisitions**

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma Holding Company, Inc. (ESP Pharma), a privately held hospital-focused company. The aggregate purchase price was approximately \$435.2 million, including the cash paid to ESP Pharma stockholders of \$325.0 million, the fair value of 7,330,182 shares of PDL's common stock issued to ESP Pharma stockholders and direct transaction costs of approximately \$5.4 million. In addition, during 2005 we recognized approximately \$19.4 million in other acquisition-related charges. During September 2005, we released 1,260,842 shares from escrow to the ESP Pharma shareholders and recorded an additional \$35.3 million of goodwill, which increased the purchase price to \$470.5 million. In September 2005, prior to the release of the 1,260,842 shares from the escrow, we delivered a claim against 952 shares held in escrow based on ESP Pharma's breaches of certain representations and warranties under the Amended and Restated Agreement and Plan of Merger. As the agent representing the former ESP Pharma stockholders did not respond to this claim within 60 days from the date of the claim, the 952 shares were released to us and cancelled. In December 2005, we delivered another claim against 387,855 shares held in escrow primarily as a result of higher sales returns than allowable under the acquisition agreement and tax related items. The ESP Pharma stockholders have disputed the claim and we have initiated the process to resolve the dispute. We believe all current claims against the escrow shares will be resolved in PDL's favor and will be collected. As of December 31, 2005, the remaining number of shares in the escrow account was 1,262,746.

Simultaneous with the acquisition, ESP Pharma acquired the rights to manufacture, develop, market and distribute *Retavase* (reteplase) from Centocor, a biopharmaceutical operating company of Johnson & Johnson. The purchase price for the acquisition of *Retavase* was \$110.5 million, consisting of \$110.0 million paid to Centocor and \$0.5 million of transaction costs. Additionally, we may be required to pay Centocor certain milestone payments of up to \$45 million if additional conditions relating to ongoing clinical trials and manufacturing arrangements for *Retavase* are satisfied.

### **Significant Risks**

In general, we have a history of operating losses and may not achieve sustained profitability. As of December 31, 2005, we had an accumulated deficit of approximately \$440.1 million. Our expenses will continue to increase over the next several years because of the extensive resource commitments required to identify and develop product 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, marketing and manufacturing capabilities.

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Our operating expenses may also increase if 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.

We acquired ESP Pharma in the first quarter of 2005. The integration of the two companies' product rights, technologies, operations and personnel is a complex, time consuming and expensive process and requires 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 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 meet our objective of sustaining cash flow positive results on an annual basis beginning in 2006, we will have to continue to increase sales levels for our existing products, *Cardene IV*, *Retavase* and *IV Busulfex*. We have a limited history of product marketing and sales and the markets for *Cardene IV* and *Retavase* are highly competitive. Our competitors include pharmaceutical, biopharmaceutical and specialty pharmaceutical companies with substantially greater revenues and experience in marketing products than we have. If we do not achieve our near term objectives we may continue to incur substantial operating losses.

We are dependent to a significant extent on third parties, and our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost, in a timely manner and with appropriate quality, or successfully market our proprietary products or maintain desired margins for products sold, we may not achieve sustained cash flow positive results and may never achieve sustained profitable operations.

In addition, we have approximately \$500.0 million in convertible debt outstanding, approximately \$250.0 million of which are callable by PDL in each of 2008 and 2010, and due in 2023 and 2012, respectively. 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 recognize revenues from product sales, net of estimated allowances for cash discounts, product returns and rebates. We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated discounts, product returns, bad debts, and rebates. 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.

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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 Co-Development and Commercialization Agreement with Roche (the Roche Collaboration Agreement), including milestones and the reimbursement of research and development expenses, the \$17.5 million upfront license fee that we received from Roche will be recognized over the term of the Roche Collaboration Agreement as services are provided. Similarly, we did not establish fair value for all undelivered elements of the multiple products of the Collaboration Agreement with Biogen Idec (the Biogen Idec Collaboration Agreement). The \$40.0 million upfront license fee, milestones and the reimbursement of research and development expenses that we received from Biogen Idec will be recognized over the term of the Biogen Idec Collaboration Agreement as services are provided with respect to the specific products under development to which the upfront license fees, if any, and reimbursement relate. As we share research and development expenses equally under this arrangement, we recognize expense incurred as research and development expenses and recognize reimbursement as other revenue.

In addition, we enter into non-monetary 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 non-monetary 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.

### **Sales Allowances and Rebate Accruals**

We record estimated reductions to product sales for expected returns of products under our current policies, chargebacks, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are based on contractual terms, historical utilization rates and expectations regarding future utilization rates for these programs. Estimates for product returns, including new products, are calculated based on the inventory data available to us in monitoring channel inventory levels, the purchase of third-party data to monitor prescriptions as well as, for new products, a review of our products we have sold through the same or similar channels. In addition, our estimates are based on the historical chargeback data we receive from wholesalers and the applicable customer chargeback rates, returns and rebate thresholds we have from Wyeth and Centocor with respect to *Cardene IV* and *Retavase*, respectively. Further, we monitor the activities and clinical trials of our key competitors and assess the potential impact on our future sales and return expectations where necessary.

If conditions become more competitive for any of the markets served by our drugs or if other circumstances change, we may take actions to increase our product return estimates or we may offer additional customer incentives. This would result in an incremental reduction of future revenue at the time the return estimate is changed or new incentives are offered. Product sales' allowances for chargebacks, returns and rebates require substantial judgment. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made, based on actual results.

During the second half of 2005, we experienced a significant volume of product returns from products sold by ESP Pharma prior to our acquisition of ESP Pharma (pre-acquisition sales). These returned products were either expired or would have been expired before they could be sold to the hospitals and administered to the patients. When we began experiencing higher than expected returns from pre-acquisition sales, we met with all of our large wholesalers to enforce the terms and conditions of the original product sales in order to minimize the credits we issued to the wholesalers. We also put inventory management arrangements in place with our three largest wholesalers during the third and fourth quarters of 2005, which will reduce the risk of product returns on our current period sales to such wholesalers. As discussed in Note 1 of our Consolidated Financial Statements, we recognized the expenses related to pre-acquisition product sales as other acquisition-related charges in the Consolidated Statements of Operations.

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We also maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is based on our analysis of several factors including, but not limited to, contractual payment terms, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region, and a review of the local economic environment and its potential impact on government funding and reimbursement practices. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an inability to make payments, additional allowances may be required. We believe that the allowance for doubtful accounts is adequate to cover anticipated losses under current conditions; however, significant deterioration in any of the above factors could materially change these expectations and result in an increase to our allowance for doubtful accounts.

### **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.

### **Goodwill and Other Intangible Assets**

The valuation in connection with the initial purchase and the ongoing evaluation for impairment of goodwill and other 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 the 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. For example, we recorded an impairment charge of \$15.5 million in 2005 to reduce the net carrying values of the intangible assets related to our off-patent branded product rights to fair value (see Note 4 to the Financial Statements in Part II, Item 8 of this Annual Report).

**RESULTS OF OPERATIONS**

Years ended December 31, 2005, 2004 and 2003

(In thousands)	Years Ended December 31,			Annual Percent Change	
	2005	2004	2003	2005 / 2004	2004 / 2003
<b>Revenues</b>					
Product sales, net	\$ 121,191 <sup>(1)</sup>	\$ —	\$ —	100%	—
Royalties	130,068	83,807	52,704	55%	59%
License and other	28,395	12,217	13,982	132%	(13)%
<b>Total Revenues</b>	<b>\$ 279,654</b>	<b>\$ 96,024</b>	<b>\$ 66,686</b>	<b>191%</b>	<b>44%</b>

(1) Represents net product sales generated during the nine-month period since our acquisition of ESP Pharma on March 23, 2005.

Our total revenues increased in 2005, primarily due to product sales resulting from our acquisition of ESP Pharma and *Retavase*. The increase in total revenues in 2004 was primarily due to higher royalties and license fees compared to 2003. These revenue changes are further discussed below.

**Product sales, net**

We acquired marketed products from the acquisitions of ESP Pharma and *Retavase*, both of which closed on March 23, 2005. Total net product sales in the approximate nine-month period of 2005 (i.e., from March 23, the date of acquisition, through December 31) were \$121.2 million. Net product sales of *Cardene IV*, *Retavase* and *IV Busulfex* totaled \$111.4 million for the period, or approximately 92% of net product sales. Off-patent branded product sales for the period totaled \$9.8 million. We expect that sales of *Cardene IV*, *Retavase* and *IV Busulfex* will increase in 2006 and sales generated from off-patent branded products will be minimal as we completed the sale of *Declomycin* in February 2006 and the sale of *Sectral*, *Tenex* and *Ismo* in March 2006.

During 2005, we experienced significant fluctuations in our distribution channel inventory levels which we believe was the result of overstocking of product by our major wholesalers prior to our acquisition of ESP Pharma. As a result, during the year we experienced a significant level of product returns related to expired products. In order to help alleviate these fluctuations and in conjunction with the integration of ESP Pharma operations into PDL's, during the third and fourth quarters of 2005, we significantly improved our customer relations and supply chain management by allocating more resources to these areas. In addition, we implemented controls that will effectively reduce the risk of product returns in the future. Such controls include management's assessment of customer demand by way of reviewing channel inventory and pull-through data obtained from third party sources, and the approval of all sales orders in line with customer demand.

Further, understanding the importance of having a clear view of our wholesalers' channel inventory, during the first quarter of 2006 but effective during the fourth quarter of 2005, we entered into inventory management arrangements with three major pharmaceutical wholesalers that distribute more than 90 percent of our product sales for our three major products (*Cardene IV*, *IV Busulfex*, and *Retavase*). We implemented these agreements to limit speculative buying and to help ensure that wholesaler purchasing is more consistent with customer demand. Under these agreements, we agreed to pay the wholesalers a fee in exchange for product distribution and inventory management information and services. Such fees are recorded as a reduction to product sales in the consolidated statements of operations in accordance with Emerging Issues Task Force Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)" (EITF 01-9). Additionally, under the terms of the agreements, each wholesaler has agreed not to exceed specified maximum levels of inventory on hand. As of the end of December 2005, we believe that these three major wholesalers have inventories on-hand for all PDL products of less than two month's supply, which is in compliance with the contractually specified levels.

During 2005, we recognized approximately \$24.8 million in product returns for expired product associated with sales made prior to our acquisition of ESP Pharma. Of these returns, we expect to recover approximately \$14.6 million from our claims to the escrow account from the ESP Pharma acquisition. As a result of the improved processes surrounding channel inventory management, we expect a minimal level of product returns related to products sold after our acquisition of ESP Pharma. Accordingly, we reduced our product returns allowance during the fourth quarter to appropriately reflect our revised estimate of future product returns.

## Royalties

Total royalty revenues recognized under separate agreements with Roche, Genentech, MedImmune and Wyeth have been steadily increasing year-over-year. In 2005, the increase was primarily due to a 53% increase in combined *Herceptin* and *Avastin* sales reported by Genentech and *Synagis* sales reported by MedImmune. 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 Genentech and MedImmune accounted for 67% and 25%, respectively, of our royalty revenues during 2005 compared to 57% and 34%, respectively during 2004 and 46% and 47%, respectively, during 2003.

We expect that in 2006, with the exception of *Zenapax* royalties from Roche, we will continue to experience royalty revenue growth based on the assumed continued growth in product sales underlying our royalty revenues. As per the terms of our Second Amended and Restated Worldwide Agreement with Roche signed in October 2005, Roche will pay us royalties at a reduced rate only once *Zenapax* product sales have reached a certain threshold. As such, we expect to receive trivial to no royalty revenue from Roche's sale of *Zenapax* going forward. We also continue to expect quarterly fluctuations in royalty revenues due to the seasonality of sales of *Synagis*. In addition, we received a small amount of royalty revenue related to *Tysabri* sales in early 2005 and future royalty revenues from that product will not occur unless it is successfully re-introduced.

## License and Other Revenues

(in thousands)	Years Ended December 31,		
	2005	2004	2003
<b>License and Other Revenues</b>			
Patent rights and licensing	\$ 3,757	\$ 5,126	\$ 8,450
Humanization and other	<u>24,638</u>	<u>7,091</u>	<u>5,532</u>
Total License and Other Revenues	<u>\$28,395</u>	<u>\$12,217</u>	<u>\$13,982</u>

License and other revenues recognized in 2005, 2004 and 2003 consisted of upfront licensing and patent rights fees, milestone payments related to licensed technology and license maintenance fees. Also included in license and other revenues in 2005 and 2004 were revenues recognized under our collaborations with Roche and Biogen Idec.

License and other revenues increased in 2005 from 2004 primarily due to the revenue recognized under our collaborations with Biogen Idec and Roche and timing of milestone achievement from our licensees, which is recognized when earned, partially offset by lower revenues generated from fewer patent licensing agreements in 2005 compared to 2004. We recognized a total of \$20.0 million from Biogen Idec and Roche in 2005 compared to only \$3.7 million in 2004 from Roche. We recognized \$1.8 million in milestone revenues in 2005 compared to \$0.5 million in 2004.

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.

We continuously review opportunities to seek to out-license marketing rights for certain antibodies, 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. 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 2006 due to a full year of revenue under our Biogen Idec Collaboration Agreement and the amended Roche Collaboration Agreement. A portion of the license and other revenue we expect to recognize in 2006 and future years will be based upon recognition over time of upfront license fees which were paid to us in 2005.

## Costs and Expenses

(In thousands)	Years Ended December 31			Annual Percent Change	
	2005	2004	2003	2005 / 2004	2004 / 2003
<b>Costs and Expenses</b>					
Cost of product sales	\$ 60,257	\$ —	\$ —	100%	—
Research and development	172,039	122,563	82,732	40%	48%
Selling, general and administrative	82,386	31,806	27,613	159%	15%
Acquired in-process research and development	79,417	—	85,993	100%	(100)%
Other acquisition-related charges	19,434	—	—	100%	—
Asset impairment charges	31,269	—	—	100%	—
Total costs and expenses	<u>\$444,802</u>	<u>\$154,369</u>	<u>\$196,338</u>	188%	(21)%

### Cost of Product Sales

Cost of product sales (COS) as a percentage of product sales was 50% in 2005. We did not sell products prior to 2005. COS largely reflects cost of goods sold, amortization of product rights from the purchase of *Retavase* and the other products acquired from ESP Pharma, royalty expenses, and certain start-up production costs related to the transition of sales to us from Centocor for *Retavase*. Amortization of product rights was \$35.4 million or 59% of COS in 2005 compared to no such costs incurred in 2004 and 2003.

### 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 research and development costs in 2005 compared to 2004 was primarily due to increases in personnel costs of \$19.4 million, clinical development expenses for our major research and development projects of \$14.8 million, facility-related costs of \$9.2 million, information technology-related costs of \$8.0 million, production material costs of \$4.4 million, outside services costs of \$1.5 million and research and development licensing costs of \$0.5 million. These increases were related to the hiring of additional employees to pursue our expanding research and development programs, partially offset by decreases in contract manufacturing services of \$6.8 million and other miscellaneous items of \$1.5 million.

The increase in 2004 compared to 2003 was primarily due to an increase in personnel costs of approximately \$16.1 million. Also contributing to the increase were contract manufacturing costs of \$8.9 million, an increase in facility-related expenses of \$7.5 million, in-licensing of research and development technology of \$3.9 million, outside services of \$2.1 million, and 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, Inc. (Eos) and technology rights from Roche in 2003. These increases related to the hiring of additional employees to pursue our expanding research and development programs, which were partially offset by lower direct clinical and preclinical studies' costs for our major research and development projects of approximately \$2.0 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 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.

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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 Years Ended December 31,		
					2005	2004 (In thousands)	2003
Daclizumab	Healthy Volunteer	Phase 1	Roche	2006	\$ 37,908	\$ 30,444	\$ 17,737
	Asthma	Phase 2a	Roche	Completed			
	Multiple Sclerosis	Phase 2	Biogen Idec	2007			
	Solid organ transplant maintenance	Phase 2	Roche	2008			
Ularitide <sup>(1)</sup>	Acute Decompensated Heart Failure	Phase 2	CardioPep Pharma	Completed	11,170	N/A	N/A
Terlipressin <sup>(2)</sup>	Type 1 Hepatorenal Syndrome	Phase 3	Orphan Therapeutics	2006	2,930	N/A	N/A
HuZAF	Crohn's disease	Phase 2	—	Completed	4,055	7,266	22,888
Nuvion	Severe steroid-refractory ulcerative colitis	Phase 1/2	—	2005	28,209	21,407	9,134
M200	Solid tumors	Phase 2	Biogen Idec	2006	27,588	20,574	3,528
Other <sup>(3)</sup>			—		60,179	42,872	29,445
Total Research and Development Expenses					<u>\$ 172,039</u>	<u>\$ 122,563</u>	<u>\$ 82,732</u>

- (1) We assumed development responsibility in Q1 2005. The Phase 2 study was completed by CardioPep Pharma in Europe. PDL has worldwide development and commercialization rights to this product.
- (2) Orphan Therapeutics has development responsibility for this molecule; PDL has exclusive marketing rights in the United States and Canada.
- (3) No other clinical product included in "other" constitutes more than 5% of the total research and development expenses for the period presented. Also includes expenses for terminated and out-licensed product candidates.

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 invest significant amounts of resources in development, 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," "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 and the marketing and sale of our products could result in violations of law or regulations" sections of our Risk Factors.

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### **Selling, General and Administrative Expenses**

Selling, 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 2005 as compared to 2004 was primarily due to increased personnel-related expenses of approximately \$28.9 million resulting from the addition of sales force through the ESP Pharma acquisition, outside services expenses of approximately \$25.9 million for advertising, market research and promotion materials, facility-related expenses of \$2.9 million, and miscellaneous expenses of \$0.9 million, which were partially offset by information technology-related costs allocation out to research and development expenses of \$8.0 million. We expect that selling, general and administrative expenses will continue to increase in 2006, as compared to 2005, as we operate our expanded sales force and support staff and initiate or continue promotional programs for our products. We expanded our sales force by 80% since our acquisition of ESP Pharma.

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.

### **Acquired In-Process Research and Development**

#### **ESP Pharma Acquisition**

In connection with the March 2005 acquisition of ESP Pharma, we recorded charges for acquired in-process research and development of \$79.4 million due to ESP Pharma's incomplete research and development programs that had not yet reached technological feasibility as of March 23, 2005 and had no alternative future use as of that date. A summary and the status of these programs at December 31, 2005 follows:

<u>Program</u>	<u>Description</u>	<u>Status of Development</u>	<u>Value Assigned</u> <u>(in thousands)</u>
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for hepatorenal syndrome	Our third-party licensor, Orphan Therapeutics holds the IND and is conducting a Phase 3 trial in patients with type I hepatorenal syndrome in the United States.	\$ 23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	Our third-party licensor, CardioPep Pharma, has completed SIRIUS II, a double-blind, placebo-controlled Phase 2 study	55,652
			<u>\$ 79,417</u>

The value of the acquired in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 14%, which at the time of our acquisition was determined to be our cost of capital. 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 the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the 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 in-process research and development, the assumed commercialization dates for these potential products begins in 2007, specifically for terlipressin.

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### ***Eos Acquisition***

In connection with the April 2003 acquisition of Eos Biotechnology, Inc. (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, 2005 follows:

<b>Program</b>	<b>Description</b>	<b>Status of Development</b>	<b>Value Assigned (in thousands)</b>
Anti-angiogenesis (M200, Anti-a5β1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including melanoma, pancreatic, and renal cell cancers	Phase 2 clinical trials initiated in December 2004	\$ 24,067
Ocular Neovascularization (F200, Anti-a5β1 Integrin Antibody)	Fab fragment of Anti-a5β1 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 Daclizumab 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 daclizumab (*Zenapax*) 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.

- In September 2004, we and Roche announced the co-development of the subcutaneous formulation of daclizumab (daclizumab s.c.) in asthma and related respiratory disorders. During 2005, we conducted a single-dose and a multiple-dose Phase 1 clinical trials of daclizumab s.c. in healthy volunteers, intended to gather additional experience with the PDL-manufactured subcutaneous formulation. We and Roche intend to initiate a subsequent Phase 2b clinical trial in patients with moderate-to-severe persistent asthma in the second half 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 the ESP Pharma acquisition, 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 14% for the ESP Pharma acquisition and 15% for both the Eos acquisition and the Roche arrangement. 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 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 related to the ESP Pharma acquisition and the Roche arrangement and 2008 to 2009 related to the Eos acquisition.

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.

**Other Acquisition-related Charges**

Other acquisition-related charges represent costs incurred during 2005 that relate to ESP Pharma operations prior to our acquisition of the business. Such charges include \$18.6 million for product sales returns and accounts receivable allowances related to pre-acquisition sales and \$0.8 million for other liabilities. As such charges directly related to ESP Pharma operations prior to our acquisition of the business, we recognized them as operating expenses rather than as a reduction to current year product sales. Although we have made our best estimates of other acquisition-related charges as of the filing of this Annual Report on Form 10-K, during 2006 we may identify additional other acquisition-related charges that could affect our results of operations.

**Asset Impairment Charges**

In 2005, we recognized an asset impairment charge of \$15.5 million to write down the carrying amounts of the product rights and related inventory of our four off-patent branded products to their fair values based on a revaluation completed in September 2005. We acquired these product rights as part of the acquisition of ESP Pharma, however, as we are committed to the development, manufacture and commercialization of proprietary biopharmaceutical products, marketing the off-patent branded products was inconsistent with our strategy. Accordingly, during third quarter of 2005, we made a decision to market the assets relating to these products to potential acquirers, and we engaged a financial advisor to assist us in this effort. At September 30, 2005, the fair value of these product rights and related inventory was estimated by management based on the indications of interests that we had received from potential buyers. We classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights in accordance with Financial Accounting Standards Board Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." In addition, we reserved \$1.1 million of this off-patent branded product inventory on hand as of December 31, 2005 based on its expected realizable amount.

In addition, pursuant to the terms of the Amended Agreements with Roche in October 2005, we agreed not to exercise the reversion right under the Prior Agreements to promote and sell *Zenapax* for prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2006. As a result, during the fourth quarter of 2005 we wrote off the carrying value of the reversion right of \$15.8 million acquired under the Amended and Restated Worldwide Agreement with Roche in October 2003. The Amended Agreements also amended the royalty obligations of Roche with respect to future sales of *Zenapax* in the existing transplant indication by including a revenue threshold below which royalties are not due.

**Interest and Other Income, net and Interest Expense**

(In thousands)	Years Ended December 31			Annual Percent Change	
	2005	2004	2003	2005 / 2004	2004 / 2003
<b>Interest and Other Income, net and Interest Expense</b>					
Interest and other income, net	\$ 9,616	\$10,212	\$ 9,681	(6)%	5%
Interest expense	(10,177)	(5,028)	(9,770)	102%	(49)%

Interest and other income, net in 2005 decreased from 2004 primarily due to losses on investments in available-for-sale securities of \$0.3 million realized in 2005 compared to realized gains on investments of \$0.3 million in 2004. Interest and other income, net in each of 2005 and 2004 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.

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Interest expense in 2005, net of amounts capitalized, related to a 2.00%, \$250.0 million Convertible Senior Notes (2005 Notes), a 2.75%, \$250.0 million Convertible Subordinated Notes (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 2004, net of amounts capitalized, related to the 2003 Notes, the 7.64% term loan and the notes payable acquired in the Eos acquisition. Interest expense in 2003, net of amounts capitalized, related to our 5.50% Convertible Subordinated Notes that were redeemed in November 2003, the 2003 Notes, the 7.64% term loan and the notes payable acquired in the Eos acquisition.

Interest expense for 2005 increased from 2004 as a result of both our 2005 Notes and 2003 Notes being outstanding during 2005, compared to only our 2003 Notes being outstanding in 2004. The decrease in interest expense in 2004 compared 2003 was due primarily to the redemption of our 5.50% convertible subordinated notes in November 2003.

We expect that full-year interest expense in 2006 will increase slightly from 2005 since the 2005 Notes will be outstanding for the full year in 2006 compared to only a partial year in 2005. The 2005 Notes were issued in February 2005.

### **Income Taxes**

We recorded a tax expense of approximately \$0.9 million and \$0.1 million for the years ended December 31, 2005 and 2004, respectively. Taxes during the year ended December 31, 2005 are primarily related to state income taxes on income earned by ESP Pharma and foreign taxes on income earned by our foreign operations. Taxes during the year ended December 31, 2004 are primarily related to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee. We recorded a tax provision benefit of approximately \$0.9 million during the fourth quarter of 2005 primarily related to a change in estimates for our annual tax provision for the year ended December 31, 2005. We recorded a \$10.1 million federal deferred tax asset related to the carry back of ESP Pharma's tax loss for the period from January 1, 2005 through March 23, 2005 partially offset by a net \$0.4 million state deferred tax liability related to future amortization expense for intangible assets from the acquisition of ESP Pharma that are not deductible for tax purposes. This \$9.7 million net deferred tax asset was recorded as a reduction of goodwill from the ESP Pharma acquisition.

### **LIQUIDITY AND CAPITAL RESOURCES**

To date, we have financed our operations primarily through product sales, public and private placements of equity and debt securities, revenue under agreements with third parties and interest income on invested capital. At December 31, 2005, we had cash and cash equivalents and marketable securities and restricted investments in the aggregate of \$333.9 million, compared to \$397.1 million at December 31, 2004.

Net cash provided by our operating activities in 2005 was \$31.6 million compared with net cash used in operating activities of \$27.2 million and \$23.6 million in 2004 and 2003, respectively. The \$31.6 million net cash provided by operating activities in 2005 was primarily attributable to our product sales and increased revenues from royalties, which is offset partially by the increase in spending for advancing clinical programs and our expansion into sales and marketing activities as well as headcount. In 2004 and 2003, the changes 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 and increases in other current assets and other assets resulting from the transaction costs associated with the issuance of our 2003 Notes in 2003, which was partially offset by an increase in accounts payable and accrued liabilities resulting from the construction of our new commercial manufacturing facility in Brooklyn Park, Minnesota.

Net cash used in investing activities in 2005 was \$320.8 million compared to \$240.2 million and \$20.9 million in 2004 and 2003, respectively. The \$320.8 million net cash used for investing activities in 2005 was primarily attributable to \$432.6 million in cash payments (net of cash received) related to the ESP Pharma and *Retavase* acquisitions in March 2005 and \$41.3 million in capital expenditures, which were partially offset by \$154.5 million in sales and maturities of our marketable securities and maturities of restricted investments. The changes in 2004 and 2003 were primarily the result of the timing of purchases of marketable securities, as well as the purchase of intangible assets and increase in capital expenditures. The purchase of intangible assets in 2003 primarily related to an amendment to our collaboration agreement with Roche. The capital expenditures in 2005, 2004 and 2003 were primarily related to the development, construction and validation activities for our manufacturing facility in Brooklyn Park, Minnesota.

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Net cash provided by financing activities in 2005 was \$381.2 million compared to \$17.0 million and \$98.5 million in 2004 and 2003, respectively. The \$381.2 million net cash provided by financing activities in 2005 was primarily due to the issuance of our 2005 Notes in February 2005, the issuance of common stock to Biogen Idec for \$100 million, and employee stock purchase plan and stock option exercises totaling \$39.9 million, which was partially offset by \$0.7 million for payments of debts during 2005. Net cash provided by financing activities in 2004 and 2003 primarily related to the proceeds from the exercise of stock options, and additionally in 2003, from the issuance of our 2003 Notes, which was 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 used the proceeds from the 2005 Notes to help fund the acquisitions of ESP Pharma and *Retavase*.

We estimate that our existing capital resources will be sufficient to fund our operations through 2006 and the foreseeable future. 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*, *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 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, 2005, the remaining portion of the \$6.8 million balance will be paid off in 2006 and is reflected on the Consolidated Balance Sheet within marketable securities.

In May 2001, we signed a collaboration agreement with Exelixis, Inc. relates to the discovery of potential antibody targeting in the field of cancer. As part of this agreement, we purchased a \$30.0 million five-year note, convertible at our option after the first year of the collaboration into Exelixis common stock. We anticipate collecting principle and interest owed from Exelixis on a timely basis in May 2006.

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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, with a \$7.4 million outstanding balance as of December 31, 2005. 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.

Our contractual obligations under lease, debt, contract manufacturing, and construction agreements for the next five years and thereafter as of December 31, 2005 are as follows:

(In thousands)	Payments Due By Period				Total
	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years	
<b>Contractual Obligations<sup>(1)</sup></b>					
Operating leases	\$ 4,323	\$ 4,847	\$ 404	\$ 365	\$ 9,939
Long-term debt	1,227	2,278	2,278	4,587	10,370
Convertible notes	11,875	23,750	273,748	257,500	566,873
Contract manufacturing	1,659	—	—	—	1,659
Construction contracts	3,269	—	—	—	3,269
<b>Total contractual cash obligations</b>	<b>\$ 22,353</b>	<b>\$ 30,875</b>	<b>\$ 276,430</b>	<b>\$ 262,452</b>	<b>\$ 592,110</b>

<sup>(1)</sup> 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.

### Off-Balance Sheet Arrangements

None.

### 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 and restricted stock, to be recognized in the financial statements based on their fair values, beginning with the first interim or annual period after June 15, 2005. The pro forma disclosures previously permitted under FAS 123, will no longer be an alternative to financial statement recognition. We are required to adopt FAS 123R on January 1, 2006. 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. The adoption of FAS 123R will have a material impact on our consolidated results of operations. We will adopt FAS 123R using the prospective method and the Black Scholes valuation model to calculate stock-based compensation expense. Based on this approach, we expect that the total stock-based compensation expense for 2006 will be in the range of \$32 million to \$38 million. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors. Actual results may differ materially from our estimates as a result of these factors, and we disclaim any obligation to update or revise this or any other forward-looking statements in this Form 10-K.

**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. due in May 2006. 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 debt 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, 2005 levels, the fair value of the portfolio would decline by approximately \$1.2 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, 2005, the aggregate fair values of our long-term debt and convertible subordinated notes were approximately \$7.9 million and \$706.3 million, respectively, based on available pricing information. The long-term debt bears interest at a fixed rate of 7.64%, the convertible subordinated notes issued in 2003 bear interest at a fixed rate of 2.75% and the convertible senior notes issued in 2005 bear interest at a fixed rate of 2.00%. 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.

Liabilities (000's)	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>Thereafter</u>	<u>Total</u>	<u>Fair Value</u>
<b>Long-term debt, including current portion</b>								
Fixed Rate	\$ 588	\$ 635	\$ 685	\$ 741	\$ 800	\$ 3,931	\$ 7,380	\$ 7,864 <sup>(1)</sup>
Avg. Interest Rate	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%
<b>Convertible subordinated notes</b>								
Fixed Rate	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 499,998	\$ 499,998	\$ 706,250 <sup>(2)</sup>
Avg. Interest Rate	2.38%	2.38%	2.38%	2.38%	2.38%	2.38%	2.38%	2.38%

<sup>(1)</sup> 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.

<sup>(2)</sup> The fair value of the remaining payments under our convertible subordinated notes is based on the market price of similar instruments with similar convertible features.

**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 considered minimal.

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

**Consolidated Balance Sheets**

(In thousands, except per share data)	December 31,	
	2005	2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 183,377	\$ 91,395
Marketable securities, including \$6.8 million and \$6.9 million of restricted investments at December 31, 2005 and 2004, respectively	101,617	140,579
Accounts receivable, net of allowances of \$10.0 million at December 31, 2005	21,963	—
Inventories	17,728	—
Deferred tax assets	9,244	—
Prepaid and other current assets	18,272	9,750
Short-term note receivable	30,000	—
Total current assets	<u>382,201</u>	<u>241,724</u>
Long-term marketable securities, including zero and \$6.7 million of restricted investments at December 31, 2005 and 2004, respectively	48,928	165,106
Land, property and equipment, net	266,053	238,077
Goodwill	57,783	—
Other intangible assets, net	397,266	31,309
Other assets	13,770	7,516
Convertible note receivable	—	30,000
Total assets	<u>\$1,166,001</u>	<u>\$ 713,732</u>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 2,728	\$ 4,921
Accrued compensation	16,401	6,977
Royalties payable	3,295	—
Other accrued liabilities	40,509	13,244
Deferred revenue	11,290	17,389
Current portion of notes payable	—	379
Current portion of other long-term debt	676	544
Total current liabilities	<u>74,899</u>	<u>43,454</u>
Convertible notes	499,998	249,998
Notes payable	—	7,469
Long-term deferred revenue	57,743	—
Other long-term debt	7,296	301
Total liabilities	<u>639,936</u>	<u>301,222</u>
Commitments and contingencies (Notes 14 and 15)		
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; 112,062 and 95,857 shares issued and outstanding at December 31, 2005 and 2004 respectively	1,121	959
Additional paid-in capital	969,118	686,302
Deferred stock-based compensation	(1,998)	—
Accumulated deficit	(440,109)	(273,532)
Accumulated other comprehensive loss	(2,067)	(1,219)
Total stockholders' equity	<u>526,065</u>	<u>412,510</u>
Total liabilities and stockholders' equity	<u>\$1,166,001</u>	<u>\$ 713,732</u>

See accompanying notes.

[Table of Contents](#)**Consolidated Statements of Operations**

(In thousands, except per share data)	Years ended December 31,		
	2005	2004	2003
<b>Revenues:</b>			
Product sales, net	\$ 121,191	\$ —	\$ —
Royalties	130,068	83,807	52,704
License and other	28,395	12,217	13,982
Total revenues	279,654	96,024	66,686
<b>Costs and expenses:</b>			
Cost of product sales	60,257	—	—
Research and development	172,039	122,563	82,732
Selling, general and administrative	82,386	31,806	27,613
Acquired in-process research and development	79,417	—	85,993
Other acquisition-related charges	19,434	—	—
Asset impairment charges	31,269	—	—
Total costs and expenses	444,802	154,369	196,338
Operating loss	(165,148)	(58,345)	(129,652)
Interest and other income, net	9,616	10,212	9,681
Interest expense	(10,177)	(5,028)	(9,770)
Loss before income taxes	(165,709)	(53,161)	(129,741)
Income tax expense	868	80	73
<b>Net loss</b>	<b>\$(166,577)</b>	<b>\$(53,241)</b>	<b>\$(129,814)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (1.60)</b>	<b>\$ (0.56)</b>	<b>\$ (1.40)</b>
<b>Shares used in the computation of basic and diluted net loss per share</b>	<b>104,326</b>	<b>94,982</b>	<b>92,478</b>

See accompanying notes.

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**Consolidated Statements of Cash Flows**

(in thousands)	Years Ended December 31,		
	2005	2004	2003
<b>Cash flows from operating activities:</b>			
Net loss	\$(166,577)	\$ (53,241)	\$(129,814)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	79,417	—	85,993
Asset impairment charges	31,269	—	—
Depreciation and amortization	15,126	11,361	8,407
Amortization of convertible notes offering costs	2,214	1,205	1,147
Amortization of intangible assets	37,557	2,502	941
Stock-based compensation expense	970	1,214	276
Loss on investment in marketable securities	302	—	—
Impairment loss on investment	—	—	150
Loss on early extinguishment of debt	—	—	6,538
Loss on disposal of fixed assets	7	741	455
Other non-cash research and development expenses	1,500	3,000	—
Non-cash license revenue	—	(4,000)	—
Changes in assets and liabilities:			
Accounts receivable	(24,473)	—	—
Interest receivable	323	340	2,975
Inventories	923		
Other current assets	(6,618)	939	(3,286)
Other assets	(124)	405	(8,941)
Accounts payable	(4,029)	1,277	1,064
Accrued liabilities	13,619	(9,627)	10,407
Deferred revenue	50,144	16,728	123
Total adjustments	198,127	26,085	106,249
Net cash provided by (used in) operating activities	31,550	(27,156)	(23,565)
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(600)	(291,271)	(110,049)
Sales and Maturities of marketable securities	147,660	139,290	278,000
Maturities (purchases) of restricted securities	6,876	7,487	(20,822)
Adjustment to goodwill related to ESP Pharma acquisition	(873)	—	—
Cash paid for ESP Pharma acquisition, net of cash acquired	(322,558)	—	—
Cash paid for <i>Retavase</i> acquisition	(110,000)	—	—
Cash obtained from Eos	—	—	2,453
Purchase of intangible assets	—	—	(80,000)
Purchase of land, property and equipment	(41,268)	(95,683)	(90,518)
Net cash used in investing activities	(320,763)	(240,177)	(20,936)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock	139,868	18,313	4,110
Proceeds from issuance of convertible notes	242,048	—	250,000
Extinguishment of long-term convertible debentures	—	—	(154,125)
Payments on other long-term obligations	(721)	(1,353)	(1,446)
Net cash provided by financing activities	381,195	16,960	98,539
Net increase (decrease) in cash and cash equivalents	91,982	(250,373)	54,038
Cash and cash equivalents at beginning of year	91,395	341,768	287,730
Cash and cash equivalents at end of year	<u>\$ 183,377</u>	<u>\$ 91,395</u>	<u>\$ 341,768</u>
<b>Cash Flow for Acquisition of ESP Pharma, Retavase and Eos:</b>			
Cash and cash equivalents	\$ 2,442	—	—
Inventories	19,712	—	—
Other current assets	1,904	—	691
Acquired in-process research and development	—	—	37,834
Property and equipment	2,208	—	2,274
Intangible assets	432,700	—	1,410
Accounts payable	(1,836)	—	—
Accrued compensation	(1,803)	—	—
Other liabilities	(20,767)	—	(5,848)
Acquisition and transaction costs incurred	(5,388)	—	(4,652)
Common stock issued	(104,851)	—	(34,162)
<b>Supplemental Disclosure of Cash Flow Information</b>			
Cash paid during the year for interest (net of amount capitalized)	\$ 6,083	8,220	10,736
Cash paid during the year for income taxes	\$ 365	—	—

See accompanying notes.

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**Consolidated Statements of Stockholders' Equity**

(In thousands, except shares of common stock data)	Common Stock		Additional
	Shares	Amount	Paid-In Capital
<b>Balance at December 31, 2002</b>	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
<b>Balance at December 31, 2003</b>	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			1,214
Issuance of common stock upon conversion of convertible notes	99		2
<b>Balance at December 31, 2004</b>	95,857,236	959	686,302
Issuance of common stock under employee benefit plans	3,451,678	34	39,834
Issuance of common stock in connection with ESP Pharma acquisition	7,330,182	73	104,778
Issuance of common stock in connection with Biogen Idec collaboration agreement	4,058,935	41	99,959
Issuance of common stock options to consultants for services			710
Issuance of restricted stock to employees	103,200	1	2,257
Issuance of common stock in connection with release of escrow shares from ESP Pharma acquisition	1,260,842	13	35,278
<b>Balance at December 31, 2005</b>	<b>112,062,073</b>	<b>\$ 1,121</b>	<b>\$ 969,118</b>

	Deferred Stock-based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stock- Holders' Equity
<b>Balance at December 31, 2002</b>	\$ —	\$ (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 for consultants				276
Comprehensive loss:				
Net loss		(129,814)		(129,814)
Change in unrealized gains and losses on investments in available-for-sale securities			(5,169)	(5,169)
Total comprehensive loss				(134,983)
<b>Balance at December 31, 2003</b>	—	(220,291)	890	448,331
Issuance of common stock under employee benefit plans				18,313
Stock-based compensation expense for consultants				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 investments in available-for-sale securities			(2,109)	(2,109)
Total comprehensive loss				(55,350)
<b>Balance at December 31, 2004</b>	—	(273,532)	(1,219)	412,510
Issuance of common stock under employee benefit plans				39,868
Issuance of common stock in connection with ESP Pharma acquisition				104,851
Issuance of common stock in connection with Biogen Idec collaboration agreement				100,000
Issuance of restricted stock to employees	(2,258)			—
Stock-based compensation expense for employees	260			260
Stock-based compensation expense for consultants				710
Issuance of common stock in connection with release of escrow shares from ESP Pharma acquisition				35,291
Comprehensive loss:				
Net loss		(166,577)		(166,577)
Change in unrealized gains and losses on investments in available-for-sale securities			(848)	(848)
Total comprehensive loss				(167,425)
<b>Balance at December 31, 2005</b>	<b>\$ (1,998)</b>	<b>\$ (440,109)</b>	<b>\$ (2,067)</b>	<b>\$ 526,065</b>

See accompanying notes.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2005

### 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Organization and Business

We are a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life-threatening illnesses. We market and sell a portfolio of products in the acute-care hospital setting in the United States and Canada and generate royalties through licensing agreements with numerous biotechnology and pharmaceutical companies based on our antibody humanization technology platform. Our product development pipeline includes six investigational compounds in Phase 2 or Phase 3 clinical development for hepatorenal syndrome, inflammation and autoimmune diseases, cardiovascular disorders and cancer.

On January 9, 2006, subsequent to our stockholders' approval in June 2005, we changed our corporate name to PDL BioPharma, Inc. from Protein Design Labs, Inc.

#### Principles of Consolidation

The consolidated financial statements include the accounts of PDL BioPharma, 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.

#### 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. Actual results could differ from those estimates.

#### Revisions to ESP Pharma Purchase Accounting

During the preparation of PDL's consolidated financial statements for the year ended December 31, 2005, management revised the purchase accounting and certain related account balances with respect to the acquisition of ESP Pharma which was completed on March 23, 2005. This acquisition was accounted for pursuant to Statement of Financial Accounting Standards No. 141, "Business Combinations" (FAS 141). Pursuant to FAS 141, the allocation period during which we were able to make adjustments to the purchase price and allocation thereof ended on March 31, 2005. As a result, substantially all of the revisions to our previously reported balances have been included in "Other acquisition-related charges" in our consolidated statement of operations.

Please refer to page 100 in this report on Form 10-K for the detail of the affected quarterly balances, as previously reported and as subsequently revised. A summary of the more significant revisions is as follows:

On the acquisition date in March 2005, we believed beyond a reasonable doubt that the 2,523,588 shares placed into escrow (the escrow shares) would ultimately be issued to former ESP Pharma shareholders and, therefore, we included value of such shares, which approximated \$36.1 million, in the calculation of the purchase price due to various liabilities identified subsequently. We have since determined that the value of these shares should not have been included in purchase consideration until the underlying contingencies are resolved and they are released from the escrow in favor of the former ESP Pharma shareholders. This revision reduced the original recorded goodwill and stockholders' equity by approximately \$36.1 million at March 31, 2005. During September 2005, approximately one-half of the escrow shares were released to the former ESP shareholders. As such, the fair value of such shares at that time of \$35.3 million was added to the revised purchase price as contingent consideration and reflected as an increase to goodwill and stockholders' equity at that date.

During the second, third and fourth quarters of 2005, we incurred various costs and liabilities that related to ESP Pharma operations prior to our acquisition of the business. Specifically, we experienced a significant volume of product returns related to products sold by ESP Pharma prior to our acquisition of the business (pre-acquisition sales). Charges associated with returns of pre-acquisition sales totaled approximately \$17.2 million. Further, certain acquired accounts receivable were subsequently identified as being uncollectible and resulted in additional charges of \$1.4 million. Other pre-acquisition liabilities identified during 2005 and charged to operations approximated \$0.8 million. All charges described above have been included in other acquisition-related charges in our consolidated statement of operations.

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During the third and fourth quarters, we initially accounted for most of the items outlined above as a reduction to stockholders' equity rather than as a charge to results of operations, inasmuch as we expected to reduce the amount of purchase consideration originally reported by claiming certain shares from the escrow. As noted above, however, based upon subsequent events we have determined not to include the escrow shares in the initial purchase price. Accordingly, these amounts have now been included in other acquisition-related charges.

Although we have made our best estimates of other acquisition-related charges as of the filing of this Annual Report on Form 10-K, during 2006 we may identify additional other acquisition-related charges that could affect our results of operations.

Under the terms of the Amended and Restated Agreement and Plan of Merger, we have the right to claim escrow shares if product returns related to pre-acquisition sales exceed a specific threshold. Due to the large volume of product returns, tax-related items and certain other liabilities incurred by us, we have filed claims to recover 388,807 escrow shares and expect to file claims to recover a significant number of additional shares.

### **Revision to Previously Reported Fourth Quarter 2005 Results of Operations**

We revised the number of shares used in the calculation of basic and diluted net loss per share calculation for the quarter and year ended December 31, 2005. This increase of approximately 4.0 million and 1.0 million shares for the quarter and year ended December 31, 2005, respectively, related to share of common stock we issued in connection with the collaboration.

### **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.

### **Inventories**

Inventories are stated at the lower of cost or market, with costs approximating the first-in, first-out method. When the inventory carrying value exceeds the market estimated value, reserves are recorded for the difference between the cost and the estimated market value. These reserves are determined based on management's estimates. Inventories consist of finished goods, work-in-process and raw materials (including active pharmaceutical ingredients). As a result of the ESP Pharma and *Retavase* acquisitions (see Notes 4 and 5), we acquired and recorded inventories at their fair market values, which approximated the original cost of the inventory purchased from third-party manufacturers.

### **Revenue Recognition**

We currently recognize revenues resulting from product sales, from licensing and use of our technology, from research and development (R&D) services and from other services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." Royalty, licensing and other revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use as drugs, in drug development and production.

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If we determine that separate elements exist in a revenue arrangement under Emerging Issues Task Force 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, when 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.

In the fourth quarter of 2005, we entered into inventory management arrangements with three major pharmaceutical wholesalers that distribute more than 90 percent of our product sales for our three major products (Cardene IV, IV Busulfex, and Retavase). Under these arrangements, we agreed to pay the wholesalers a fee in exchange for product distribution and inventory management services. Such fees are recorded as a reduction to product sales in the consolidated statements of operations in accordance with Emerging Issues Task Force Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)" (EITF 01-9).

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

### **Product Sales**

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Product sales are recorded net of discounts, sales returns, chargebacks and rebates. Allowances and accruals are established for estimated discounts, sales returns, doubtful accounts, chargebacks and rebates.

### **Accounts Receivable, Sales Allowances and Rebate Accruals**

Accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, government chargebacks, rebates and sales returns. When we estimate cash discounts, government chargebacks and sales returns we consider contractual terms, historical trends experienced by ESP Pharma and the previous owner of the products, and expectations regarding the utilization rates for these programs. These amounts are recorded as an offset to product sales in the same period the related revenue is recognized. In determining allowances for product returns, chargebacks and rebates, we must make significant judgments and estimates. For example, in determining these amounts, we estimate hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers. Making these determinations involves estimating whether trends in past buying patterns will predict future product sales. Our estimates are based on the historical chargeback data we receive from wholesalers and the applicable customer chargeback rates, returns and rebate thresholds we have from Wyeth and Centocor with respect to *Cardene IV* and *Retavase*, respectively. Allowances for chargebacks, returns and rebate accruals require substantial judgment. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made, based on actual results.

Since our acquisition of ESP Pharma, we have adjusted our allowances for product returns, chargebacks and rebates based on more recent experience rates, and we will likely be required to make adjustments to these allowances in the future as we market and promote these products for ourselves. We continually monitor our allowances and make adjustments when we believe actual experience may differ from our estimates.

Accrued rebates include amounts due under Medicaid and other commercial contractual rebates. Rebates are recorded in the same period that the related revenue is recognized resulting in a reduction of product sales revenue and the establishment of either a contra asset or a liability, which are included in accounts receivable or other accrued liabilities, respectively. Accrued rebates are recorded based on a percentage of selling price determined from historical experience rates. Medicaid rebate accruals are evaluated based on historical rebate payments by product as a percentage of historical sales, product pricing and current contracts. Product returns allowance is calculated based on a percentage of total sales.

Estimates for our allowance for doubtful accounts are determined based on existing contractual obligations, historical payment patterns of our customers, credit quality of our customers and individual customer circumstances and are included in selling, general and administrative expenses.

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### **Royalties**

Under most of our patent license agreements, we receive royalty payments based upon our licensees' net sales of products. Generally, under these agreements 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 also receive royalties on a generic product that we have licensed for sale. 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 expenses in License and other revenues in our Consolidated Statements of Operations.

#### *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, 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 as the humanization work is performed, which is typically over three to six months, or upon acceptance of the humanized antibody by our licensee if such acceptance clause exists in the agreement.
- 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 milestones 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 involvement 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:

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- 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 licensees, such as product licenses. Under these agreements, our licensees may make milestone payments to us when they or we achieve certain levels of development with respect to the licensed technology.

### *R&D Services*

Reimbursement of development costs from our collaborators is recognized as revenue as the related services are performed. In certain instances, our collaboration agreements involve a combination of upfront fees, milestones and development costs where we are not able to establish fair value of all of the undelivered elements. We recognize these upfront fees, milestones and reimbursements of development costs as the services are performed and out-of-pocket costs are incurred.

### **Advertising and Promotional Expenses**

The Company engages in promotional activities, which typically take the form of industry publications, journal ads, exhibits, speaker programs, and other forms of media. In accordance with procedures defined under Statement of Position 93-7, "Reporting on Advertising Costs," advertising and promotion expenditures are expensed as incurred. These expenses for the years ended December 31, 2005, 2004 and 2003 were \$9.3 million, zero and zero, respectively.

### **Shipping and Handling**

The Company records costs related to shipping and handling of revenue in cost of product sales for all periods presented.

### **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.

### **Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Specifically, we include in other comprehensive loss the changes in unrealized gains and losses on our holdings of available-for-sale securities, which are excluded from our net loss. Our comprehensive loss for the years ended December 31, 2005, 2004 and 2003 is reflected in the Consolidated Statements of Stockholders' Equity.

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### Stock-Based Compensation

At December 31, 2005, we had six stock-based employee compensation plans, which are described more fully in Note 20. We account for our plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB No. 25) and related Interpretations. Accordingly, we recognize no compensation expense in our consolidated statements of operations with respect to options awarded to our employees with exercise prices greater than or equal to the fair value of the underlying common stock at the date of grant. However, we recognize compensation expense in our consolidated statements of operations with respect to the modification of certain employee stock option awards. In 2005, we recognized approximately \$0.3 million and \$0.4 million in stock-based compensation expense related to the issuance of restricted stock to certain employees and modification of certain employee stock option awards, respectively, compared to \$0 and \$0.4 million recognized in 2004, respectively. 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.

(In thousands, except per share data)	Year Ended December 31,		
	2005	2004	2003 (revised)
Net loss, as reported	<b>\$ (166,577)</b>	\$ (53,241)	\$ (129,814)
Add: Total stock-based employee compensation expense included in net loss, net of taxes	<b>640</b>	411	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of taxes	<b>(20,472)</b>	(19,594)	(25,220)
Pro forma net loss	<b><u>\$ (186,409)</u></b>	<b><u>\$ (72,424)</u></b>	<b><u>\$ (155,034)</u></b>
Basic and diluted net loss per share:			
As reported	<b><u>\$ (1.60)</u></b>	<b><u>\$ (0.56)</u></b>	<b><u>\$ (1.40)</u></b>
Pro forma	<b><u>\$ (1.79)</u></b>	<b><u>\$ (0.76)</u></b>	<b><u>\$ (1.68)</u></b>

For the periods presented in the table above, 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:

(In thousands, except per share data)	Year Ended December 31,		
	2005	2004	2003
Expected life, in years (revised for 2003)	<b>3.1</b>	2.4	2.8
Risk-free interest rate	<b>3.7%</b>	2.6%	2.9%
Volatility	<b>63%</b>	64%	72%
Dividend yield	—	—	—

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 \$0.3 million, \$0.8 million and \$0.3 million for the years ended December 31, 2005, 2004 and 2003, 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. Our chief operating decision-makers (or "CODMs") are comprised of our executive management with the oversight of our board of directors. Our CODMs review our operating results and operating plans and make resource allocation decisions on a company-wide or aggregate basis. Accordingly, we operate as one segment. Our facilities are located primarily within the United States.

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### **Capitalized Software**

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.

### **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.

### **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 \$11.9 million, \$8.8 million and \$12.0 million during the years ended December 31, 2005, 2004 and 2003, we capitalized interest of \$3.9 million, \$3.8 million and \$2.2 million, respectively.

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

On March 23, 2005, we recorded goodwill in connection with our acquisition of ESP Pharma (see Note 4). In accordance with SFAS 142, we do not amortize goodwill. We test goodwill for impairment using a two-step process on an annual basis, and between annual tests under certain circumstances. Factors that are considered important when evaluating whether impairment might exist include a significant adverse change in the business climate, unanticipated competition, loss of key personnel, significant continued under-performance compared to peers, or other factors specific to each asset or reporting unit 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 effect on our consolidated results of operations.

Other intangible assets consist of purchased core technology and product rights. In accordance with FASB Statement No. 142, "Goodwill and Other Intangible Assets," (SFAS 142), 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 core technology, product rights and licensed research technology assets on a straight-line basis over their estimated useful lives, 10, 4 to 12 and 5 years, respectively. Amortization of intangible assets is included primarily in research and development expenses and costs of product sales in the Consolidated Statement of Operations. (See Note 12 for further details on intangible assets.)

In accordance with FASB Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," (SFAS 144), 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. In 2005, we recorded asset impairment charges of \$31.3 million related to certain intangible assets we acquired from ESP Pharma and Hoffmann-La Roche (Roche; see Note 4).

### **Postretirement Benefits**

We sponsor 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 Pronouncement**

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 supersedes 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 and restricted stock, to be recognized in the financial statements based on their fair values, beginning with the first interim or annual period after June 15, 2005. The pro forma disclosures previously permitted under FAS 123, will no longer be an alternative to financial statement recognition. We are required to adopt FAS 123R on January 1, 2006. 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. The adoption of FAS 123R will have a material impact on our consolidated results of operations. We will adopt FAS 123R using the prospective method and the Black Scholes valuation model to calculate stock-based compensation expense. Based on this approach, we expect that total stock-based compensation expense for 2006 will be in the range of \$32 million to \$38 million. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors. Actual results may differ materially from our estimates as a result of these factors, and we disclaim any obligation to update or revise this or any other forward-looking statements in this Form 10-K.

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

**Biogen Idec, Inc.** In August 2005 we entered into a collaboration with Biogen Idec, Inc. (Biogen Idec) for the joint development, manufacture and commercialization of three Phase 2 antibody products. The agreement provides for shared development and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and for shared development and commercialization of M200 (volociximab) and *HuZAF* (fontolizumab) in all indications.

The collaboration and associated stock purchase agreements became effective in September 2005. We received an upfront license fee payment of \$40.0 million, and Biogen Idec purchased approximately 4.1 million shares of our common stock at \$24.637 per share, which represents the then fair market value of the stock, for approximately \$100.0 million in cash. These shares are subject to a lock-up period, half for six months and the remainder for one year from the closing date. Biogen Idec also agreed to a standstill period of one year during which it is restricted from acquiring or soliciting other parties to acquire our voting securities.

We and Biogen Idec will share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies will jointly oversee development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. We will be eligible to receive development and commercialization milestones based on the further successful development of these molecules. Each party will have co-promotion rights in the United States and Europe. Outside the United States and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to us on sales of collaboration products. If multiple products are developed successfully in multiple indications and all milestones are achieved, PDL could receive certain development and commercialization milestone payments totaling up to \$660 million. Of these, \$560 million are related to development and \$100 million are related to commercialization of collaboration products.

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We determined that all elements under the collaboration agreement should be accounted for as a single unit of accounting under EITF 00-21, *Multiple Element Arrangements*. As we have continuing obligations under the collaboration agreement, and as significant development risk remains, we recorded the \$40.0 million upfront license fee as deferred revenue and we will recognize this amount over development periods of the various molecules, ranging from 5 to 9 years. During the year ended December 31, 2005, we recognized revenue of approximately \$2.3 million related to the amortization of the upfront license fee and \$9.1 million for the reimbursement of certain research and development expenses.

**Roche.** Effective October 2003, we amended our 1999 collaboration agreement with Roche and its affiliates, pursuant to which we obtained worldwide rights to market, develop, manufacture and sell daclizumab (*Zenapax*) in all disease indications other than transplantation.

In connection with this 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, the agreement provided that we would 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. Under this agreement, if we did not receive transplantation rights, we would be required to pay modest royalties to Roche on any sales in all diseases other than transplantation, and we would have continued to receive royalties from Roche on sales of *Zenapax* in transplantation. This agreement was amended and restated in October 2005, as described below.

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 related 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 September 2004, we and Roche announced the co-development of the subcutaneous formulation of daclizumab (daclizumab s.c.) in asthma and related respiratory disorders. During 2005, we conducted a single-dose and a multiple-dose Phase 1 clinical trials of daclizumab s.c. in healthy volunteers, intended to gather additional experience with the PDL-manufactured subcutaneous formulation. We and Roche intend to initiate a subsequent Phase 2b clinical trial in patients with moderate-to-severe persistent asthma in the second half of 2006.
- In May 2004, we reported results from a Phase 2 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 related 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 wrote off the value of the reversion right of \$15.8 million in connection with the agreement signed with Roche in October 2005 (see below).

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.

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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 elements under the Collaboration Agreement should be accounted for as a single unit of accounting under EITF 00-21. 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 we will recognize this amount over the approximately six years that research and development expenses are expected to be performed for Roche. During 2005, we recognized approximately \$6.9 million in License and other revenue related to the amortization of the upfront license fee and \$1.3 million for the reimbursement of certain research and development expenses compared to \$3.7 million recognized in 2004 under the Collaboration Agreement.

In October 2005, we executed an Amended and Restated Co-Development and Commercialization Agreement and a Second Amended and Restated Worldwide Agreement (collectively, the Agreements) with Roche and its affiliates. The Agreements amended the Amended and Restated Worldwide Agreement dated October 1, 2003 and the Co-Development and Commercialization Agreement dated September 14, 2004 between Roche and PDL (the Prior Agreements).

The Agreements expand the existing relationship between us and Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer term maintenance therapy (transplant maintenance). Under the terms of the agreements, we received a \$10 million upfront payment and may receive up to \$145 million in development and commercialization milestone payments if the development of daclizumab in transplant maintenance is successful. We will share global development costs equally with Roche. In addition, we will have the option to co-promote daclizumab for transplant maintenance in the United States and will share in the profits in the United States, and we will receive royalties on net sales of the product in transplant maintenance outside the United States. During 2005, we recognized \$0.2 million of upfront license fee and \$0.2 million for certain R&D services rendered under the Agreements as revenue. The Agreements also provide that we will not exercise the reversion right under the Prior Agreements to promote *Zenapax* for prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2006. As a result, during the fourth quarter of 2005 we recorded a charge in asset impairment in the consolidated statements of operations to expense the carrying value of the reversion right of \$15.8 million acquired under the October 2003 agreement. The Agreements also amended the royalty obligations of Roche with respect to future sales of *Zenapax* in the existing transplant indication by including a revenue threshold below which royalties are not due. Based on our current expectations of *Zenapax* product sales, we do not expect to receive royalties from Roche under the Agreements.

**Exelixis, Inc.** In May 2001, we signed a collaborative agreement with Exelixis, Inc. (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. 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 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. 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, 2005, 2004 and 2003, we recognized approximately \$1.7 million of interest income. The principal and interest owed under the Note are due in May 2006.

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**Genentech, Inc.** In September 1998, we entered into an agreement covering patent rights under our humanization patents and under Genentech, Inc. (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.

In April 2005, we completed a license agreement with Genentech granting them rights to a novel prostate cancer antibody product developed by PDL. As a result, we recognized certain license fees at the time of signing, and may receive additional milestone payments and royalties in the event Genentech is successful in further developing and commercializing this antibody product.

**Millennium Pharmaceuticals, Inc.** In March 2001, we entered into a patent rights agreement with Millennium Pharmaceuticals, Inc. (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. Millennium exercised its right to obtain a patent license in the fourth quarters of 2003 and 2005, and pursuant to the agreement, we received additional patent license fees from Millennium of \$1.0 million and \$1.1 million, respectively.

**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. In December 2005, we entered into two Humanization Agreement with Abbott in which we agreed to provide humanization services for Abbott (for the IL-12 and IL-13 antigens).

**Seattle Genetics, Inc.** 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 \$0.5 million 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.

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In April 2005, we licensed certain worldwide exclusive rights related to a CD33 Antibody Program to SGI, including rights to certain intellectual property related to humanized antibodies and antibody humanization technology. In exchange for these rights, we received cash consideration of \$0.3 million from SGI. We are also entitled to royalty payments from SGI on net sales of the licensed products. In addition, we are obligated to transfer to SGI certain materials and documentation related to the CD33 Antibody Program, for which transfer was successfully completed in mid-2005.

**Morphotek, Inc.** In July 2004, we entered into an agreement with Morphotek, Inc. (Morphotek) in which we granted patent rights and a commercial license under our humanization patents in exchange for broad access to Morphotek's MORPHODOMA<sup>®</sup> 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.

**Human Genome Sciences, Inc.** In December 2005, we and Human Genome Sciences, Inc. (HGS) entered into a License Agreement whereby HGS granted a license to an undisclosed gene to PDL for purposes of conducting research, development and commercialization activities, and PDL granted HGS a nonexclusive license under the Queen patents for up to three antigens for purposes of conducting research, development and commercialization activities. Under the agreement, we paid HGS an upfront fee of \$1.5 million and we may be required to make milestones payments of up to \$28.8 million as well as pay future royalties. Additionally, HGS will pay a milestone payment of \$1 million at the time of regulatory approval of a licensed product and royalties related to our products under the Queen patents. In connection with the agreement, we recognized non-cash research and development expense and deferred revenue of \$1.5 million, which represents the fair value of the Queen patent licenses yet to be delivered to HGS. The fair value was determined based on the vendor-specific objective evidence of fair value of the patent licenses granted to HGS. We will recognize the deferred revenue as the licenses are delivered to HGS.

**Other Patent License and Humanization Agreements.** We have entered into patent license agreements with numerous companies that are independently developing humanized antibodies, including Abbott, Biogen Idec, Human Genome Sciences, Chugai Pharmaceutical Company, Ltd. (Chugai), Elan Corporation, Plc (Elan), Genentech, GLYCART Biotechnology AG (GLYCART), Medarex, Inc. (Medarex), MedImmune, Inc. (MedImmune), Merck & Co., Merck KGaA, Millennium, Morphotek, Sankyo Co., Ltd. (Sankyo), SGI, UCB Group (formerly Celltech Therapeutics Limited) 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 Genentech, GlaxoSmithKline, MedImmune, Millennium Pharmaceuticals, Tanox, Inc. (Tanox) and UCB Group. 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 UCB Group, Genentech, Morphotek and SGI 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 Co., Inc. (Ajinomoto), Eli Lilly and Company (Eli Lilly), InterMune Pharmaceuticals, Inc. (InterMune), Mochida Pharmaceutical Co., Ltd. (Mochida Pharmaceutical), Progenics Pharmaceuticals, Inc. (Progenics Pharmaceuticals), Teijin Limited (Teijin), Wyeth and Astellas Pharma Inc. (Astellas Pharma, formerly Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd.). 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.

### 3. NET LOSS PER SHARE

In accordance with FASB Statement No. 128, "Earnings Per Share," basic net loss per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net loss per share is computed using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted earnings per share result from the assumed release of shares in escrow from the ESP Pharma acquisition and the assumed exercise of stock options, restricted stock and convertible notes, using the treasury stock method. For all periods presented, we incurred a net loss, and as such, we did not include the effect of outstanding stock options, outstanding shares in escrow, outstanding restricted stock, or outstanding convertible notes in the diluted net loss per share calculations, as their effect would be anti-dilutive.

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The following table summarizes the number of common equivalent shares excluded from the calculation of diluted net loss per share reported in the statement of operations and excluded from the table presented in the Stock-Based Compensation section in Note 1 above, as their effect would have been anti-dilutive:

(In thousands)	December 31,		
	2005	2004	2003
Stock options	14,342,264	15,184,559	14,717,752
Common stock in escrow	1,262,746	—	—
Restricted Stock	103,200	—	—
Convertible notes	22,970,101	12,415,351	16,389,450
Total	38,698,311	27,599,910	27,133,202

#### 4. ESP PHARMA ACQUISITION

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma. We acquired ESP Pharma consistent with our business strategy of becoming a commercial enterprise that derives the majority of its revenues from sales of proprietary products. The ESP Pharma acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The aggregate purchase price was approximately \$435.2 million, including the cash paid to ESP Pharma stockholders of \$325.0 million, the fair value of 7,330,182 shares of PDL's common stock issued to ESP Pharma stockholders totaling approximately \$104.8 million, which excludes 2,523,588 shares deposited into escrow to be held for a period of between six months and one year from the date of the close of the acquisition, and direct transaction costs of approximately \$5.4 million. The value assigned to our common stock issued to ESP Pharma stockholders was based on the average closing market price of our common stock a few days before and after the "measurement date." In accordance with EITF Issue No. 99-12, "Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination," the measurement date was the date on which the number of shares issuable to ESP Pharma became fixed at 7,330,182 (March 4, 2005). The results of operations of ESP Pharma from March 24, 2005 have been included in our year ended December 31, 2005 consolidated financial statements.

In addition to the 7,330,182 shares of PDL common stock initially issued in the acquisition, 2,523,588 shares were deposited into an escrow account to be held for a period of between six months and one year from the date of the close of the acquisition, pursuant to the terms of the Amended and Restated Agreement and Plan of Merger. As there was reasonable doubt that substantially all of the shares held in the escrow account would ultimately be issued at the end of this contingency period, we excluded the value for all these shares in the computation of the revised purchase price. Pursuant to the terms of the Amended and Restated Agreement and Plan of Merger, 1,260,842 shares were released from escrow to the ESP Pharma stockholders on September 23, 2005. In connection with the issuance of these shares, we recorded an additional \$35.3 million of goodwill, which represents the fair value of the shares issued on that date.

In September 2005, prior to the release of the 1,260,842 shares from the escrow, we delivered a claim against 952 shares held in escrow based on ESP Pharma's breaches of certain representations and warranties under the Amended and Restated Agreement and Plan of Merger. As the agent representing the former ESP Pharma stockholders did not respond to this claim within 60 days from the date of the claim, the 952 shares will be released to us and cancelled. In December 2005, we delivered another claim against shares held in escrow primarily as a result of higher sales returns than allowable under the acquisition agreement and tax related items. The ESP Pharma stockholders have disputed the claim and we have initiated the process to resolve the dispute. We believe all current claims against the escrow shares are valid and we anticipate they will be resolved in PDL's favor.

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The net book value of acquired assets and liabilities, which approximated fair value as of March 23, 2005, was as follows (in thousands):

Assets:	
Cash and cash equivalents	\$ 2,442
Inventories	4,612
Other current assets	1,904
Fixed assets	808
Total assets	9,766
Liabilities:	
Accounts payable	1,836
Accrued compensation	1,803
Accrued royalties	5,432
Accrued sales rebates	4,817
Other current liabilities	10,518
Total liabilities	24,406
Net book value of acquired assets and liabilities	<u>\$ (14,640)</u>

We allocated the revised purchase price as follows (in thousands):

Net liabilities	\$ (14,640)
Goodwill	31,262
Intangible assets	339,200
Acquired in-process research and development	79,417
Total purchase price	<u>\$435,239</u>

The \$339.2 million value assigned to the intangible assets related to product rights for the six products sold by ESP Pharma. As discussed below, we concluded that the carrying amount of the product rights for the off-patent branded products, representing four of the six products purchased, was impaired as the fair value of these product rights was less than the net carrying value. Accordingly, we recorded an impairment charge of \$15.5 million in 2005 to reduce the carrying value of these product rights to the fair value. We are amortizing the value assigned to the remaining two products *Cardene IV* and *IV Busulfex* over 10 and 12 years, or a weighted-average period of 10.4 years, the estimated useful lives of these assets, respectively.

In 2005, we recognized an asset impairment charge of \$15.5 million to write down the carrying amounts of the product rights and related inventory of our four off-patent branded products to their fair value based on a revaluation completed in September 2005. We acquired these product rights as part of the acquisition of ESP Pharma, however, as we are committed to the development, manufacture and commercialization of proprietary biopharmaceutical products, marketing the off-patent branded products was inconsistent with our strategy. Accordingly, during the third quarter of 2005, we made a decision to market the assets relating to these products to potential acquirers, and engaged a financial advisor to assist us in this effort. At September 30, 2005, the fair value of these product rights and related inventory was estimated by management based on the indications of interests that we had received from potential buyers. We classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights in accordance with Financial Accounting Standards Board Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." In addition, we reserved \$1.1 million of this off-patent branded product inventory on hand as of December 31, 2005 based on its expected realizable amount. We completed the sale of these products in the first quarter of 2006 (see Note 22).

As we did not identify any pre-acquisition contingencies on the acquisition date, under FAS 141, charges incurred subsequent to our acquisition of ESP Pharma that were associated with pre-acquisition operations should be included in the Consolidated Statement of Operations. Accordingly, we have recognized other acquisition-related charges during 2005 totaling approximately \$19.4 million, of which \$18.6 million related to product sales returns and accounts receivable allowances related to pre-acquisition sales and \$0.8 million related to other miscellaneous liabilities. As such charges directly relate to ESP Pharma operations prior to our acquisition of the business, we recognized them as operating expenses rather than as a reduction to current year product sales.

Additionally in 2005, we reduced the amount of the purchase price originally allocated to goodwill by a \$10.1 million federal deferred tax asset related to the carry back of an ESP Pharma tax loss for the tax period from January 1, 2005 through March 23, 2005. This reduction in goodwill was partially offset by a \$1.1 million increase for tax exposure items related to tax years ended December 31, 2002, 2003 and 2004.

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As part of the allocation of the purchase price, \$79.4 million was allocated to acquired in-process research and development related to ESP Pharma's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date. A summary of these programs follows:

<u>Program</u>	<u>Description</u>	<u>Status of Development</u>	<u>Value</u> <u>(in thousands)</u>
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for hepatorenal syndrome	Our third-party licensor, Orphan Therapeutics (Orphan Therapeutics holds the IND and is conducting a Phase 3 trial in patients with type I hepatorenal syndrome in the United States.)	\$ 23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	Our third-party licensor, CardioPep Pharma (CardioPep Pharma has conducted SIRIUS II, a double-blind, placebo-controlled Phase 2 study)	55,652
			<u>\$ 79,417</u>

The nature of the remaining efforts for completion of ESP Pharma's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist which could prevent completion of development, including the uncertainty and timing of patient enrollment and uncertainties related to the results of the clinical trials, and obtaining FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that these potential products will be approved in the United States or the European Union or whether marketing approvals will have significant limitations on their use. 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. As a result, we may make a strategic decision to discontinue development of a given product if we do not believe successful commercialization is possible. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 14%, which at the time of our acquisition was thought to be an appropriate cost of capital. 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 the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the 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 in-process research and development, the assumed commercialization dates for these potential products begins in 2007, specifically for terlipressin.

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### Pro Forma Results

The unaudited pro forma results of operations for the years ended December 31, 2005 and 2004 are set forth below. This presentation assumes that the ESP Pharma acquisition had been consummated as of the beginning of each period presented. The net loss includes, on a pre-tax basis, \$79.4 million for the write-off of acquired in-process research and development costs, \$15.5 million for the impairment of off-patent branded product rights, \$15.8 million for the impairment of the reversion right to *Zenapax* in transplant indication and \$43.6 million for the amortization of intangible assets for the year ended December 31, 2005, and \$35.5 million for the year ended December 31, 2004, respectively.

<u>(In thousands, except per share amounts)</u>	<u>For Years Ended December 31,</u>	
	<u>2005</u>	<u>2004</u>
Revenue	\$ 299,942	\$ 186,260
Net loss	(181,555)	(151,790)
Basic and diluted net loss per share	\$ (1.74)	\$ (1.47)

The unaudited pro forma information is not necessarily indicative of the results that actually would have occurred had the above-noted acquisition been consummated on January 1, 2004 or 2005, or of results that may occur in the future.

### 5. RETAVASE® ACQUISITION

On March 23, 2005, ESP Pharma completed its acquisition of rights to manufacture, develop, market and distribute *Retavase* in the United States and Canada. The aggregate purchase price was approximately \$110.5 million, including the cash paid to Centocor of \$110.0 million and \$0.5 million of transaction costs. As we did not acquire any employees, and therefore the acquisition lacked the necessary inputs, processes and outputs to constitute a business, we have accounted for the *Retavase* acquisition as an acquisition of assets rather than as a business combination in accordance with EITF Issue No. 98-3, "Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business." *Retavase* product sales are included in our results of operations from the date of the re-launch of the product in April 2005.

The following table summarizes the purchase price allocation of the *Retavase* assets on March 23, 2005 (in thousands):

Tangible assets	\$ 16,500
Intangible assets	93,500
Transaction costs	500
Total purchase price	<u>\$110,500</u>

The \$93.5 million value assigned to the intangible assets is amortized over periods between 4 and 8 years, or a weighted-average period of 7.9 years, the estimated useful lives of these assets.

### 6. 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- $\alpha 5\beta 1$  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- $\alpha 5\beta 1$  integrin antibody (F200) for ocular indications, including age-related macular degeneration. In December 2004, we initiated Phase 2 clinical trials for M200. In early 2005, we terminated further development of F200, based on the potential utility of M200 in the same indication, which development rights are subject to our Biogen Idec collaboration.

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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)
Total purchase price	<u>\$38,814</u>

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

Approximately \$37.8 million of the purchase price was allocated to acquired in-process research and development due to Eos' incomplete research and development programs that had not yet reached technological feasibility as of April 4, 2003 and had no alternative future use as of that date. A summary and status of these programs at December 31, 2005 follows:

<u>Program</u>	<u>Description</u>	<u>Status of Development</u>	<u>Value Assigned (in thousands)</u>
Anti-angiogenesis (M200, Anti-a5β1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including melanoma, pancreatic, non-small lung and renal cancers	Phase 2 clinical trials initiated in December 2004	\$ 24,067
Ocular Neovascularization (F200, Anti-a5β1 Integrin Antibody)	Fab fragment of Anti-a5β1 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.

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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.

### **7. 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, 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 \$0.2 million 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 had 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 \$0.5 million was recognized during the first quarter of 2005 when the commercial license was delivered to Morphotek.

## 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.

(In thousands)	Available-for-Sale Securities			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2005</b>				
Securities of the U.S. Government and its agencies maturing:				
within 1 year	\$ 102,612	\$ —	\$ (995)	\$ 101,617
between 1-3 years	49,999	—	(1,071)	48,928
Total marketable debt securities	<u>\$ 152,611</u>	<u>\$ —</u>	<u>\$ (2,066)</u>	<u>\$ 150,545</u>
<b>December 31, 2004</b>				
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	<u>\$ 292,235</u>	<u>\$ 12</u>	<u>\$ (1,231)</u>	<u>\$ 291,016</u>

The following table summarizes the unrealized loss positions of our marketable debt securities for which other-than-temporary impairments have not been recognized at December 31, 2005 and 2004:

(in thousands)	Marketable Debt Securities			
	December 31, 2005		December 31, 2004	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Less than 12 months	\$ 49,430	\$ (568)	\$ 138,786	\$ (704)
Greater than 12 months	93,500	(1,498)	69,469	(526)
Total	<u>\$ 142,930</u>	<u>\$ (2,066)</u>	<u>\$ 208,255</u>	<u>\$ (1,230)</u>

During 2005, we realized \$0.3 million in losses on sales of available-for-sale securities. During 2004 and 2003, there were no realized gains or losses on the sale of available-for-sale securities. We do not believe that any of our marketable securities have suffered any other-than-temporary declines in value as of December 31, 2005 and we have the ability and intent to hold such securities to maturity. In addition to our available-for-sale portfolio, at December 31, 2005 and 2004 we had \$6.8 million and \$13.6 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."

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In July 2003, we issued 2.75% Convertible Subordinated Notes due August 16, 2023 with a principal amount of \$250.0 million (see Note 19 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 \$6.8 million at December 31, 2005 and \$13.6 million at December 31, 2004, consists of securities of the U.S. Government and its agencies. As of December 31, 2005, the pledged amount was reflected on the Consolidated Balance Sheet within marketable securities. As of December 31, 2004, the portion related to payments to be made within one year, \$6.9 million, was reflected on the Consolidated Balance Sheet within marketable securities, and the portion related to payments to be made thereafter, \$6.7 million, was 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 approximated the fair market value at December 31, 2005 and 2004.

### 9. INVENTORY

Inventories consisted of the following:

(In thousands)	December 31,	
	2005	2004
Raw materials	\$ 6,249	\$ —
Work-in-process	9,332	—
Finished goods	2,147	—
	<u>\$17,728</u>	<u>\$ —</u>

### 10. LAND, PROPERTY AND EQUIPMENT

Land, property, and equipment consisted of the following:

(In thousands)	December 31,	
	2005	2004
Land	\$ 12,229	\$ 10,743
Buildings and improvements	43,069	41,001
Leasehold improvements	22,008	19,846
Laboratory and manufacturing equipment	31,310	28,787
Construction-in-process	180,381	157,073
Computer and office equipment	28,629	17,493
Furniture and fixtures	4,053	3,627
	<u>321,679</u>	<u>278,570</u>
Less accumulated depreciation and amortization	<u>(55,626)</u>	<u>(40,493)</u>
	<u>\$ 266,053</u>	<u>\$ 238,077</u>

Depreciation and amortization expense for 2005, 2004 and 2003 was \$15.4 million, \$11.8 million and \$8.2 million, respectively.

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**11. INTANGIBLE ASSETS**

Intangible assets consisted of the following at December 31, 2005 and 2004 (in thousands):

	2005			2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Product rights	\$ 416,500	\$ (32,632)	\$ 383,868	\$ —	\$ —	\$ —
Assembled workforce	1,410	(1,410)	—	1,410	(1,234)	176
Core technology	16,053	(3,705)	12,348	16,053	(2,058)	13,995
Roche reversion right	—	—	—	15,788	—	15,788
Licensed research technology	1,500	(450)	1,050	1,500	(150)	1,350
Net intangible assets	\$ 435,463	\$ (38,197)	\$ 397,266	\$ 34,751	\$ (3,442)	\$ 31,309

Amortization expense for our intangible assets included in research and development expenses during the years ended December 31, 2005, 2004 and 2003 was approximately \$2.1 million, \$2.5 million and \$0.9 million, respectively. Amortization expense for our intangible assets included in cost of product sales during the year ended December 31, 2005 was approximately \$35.4 million.

We acquired product rights through our acquisition of ESP Pharma and Retavase in March 2005. During the third quarter of 2005, we determined that the carrying value of the off-patent branded products was impaired. Accordingly, we wrote down the related product rights to fair value and ceased the amortization of the related product rights. See Note 4 for further details.

Pursuant to the terms of the Amended Agreements with Roche in October 2005, we agreed not to exercise the reversion right to promote and sell *Zenapax* for prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2006. As a result, during the fourth quarter of 2005 we wrote off the carrying value of the reversion right of \$15.8 million. See the *Roche* section within Note 2 for details regarding the Roche reversion right.

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 the *Morphotek* section within Note 2 for details of the agreement.

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

	Product Rights	Core Technology	Licensed Research Technology
<b>For the year ending December 31,</b>			
2006	\$ 42,258	\$ 1,646	\$ 300
2007	42,258	1,647	300
2008	42,241	1,646	300
2009	41,485	1,647	150
2010	41,485	1,646	—
Thereafter	163,141	4,116	—
Total amortization expense	\$ 372,868	\$ 12,348	\$ 1,050

[Table of Contents](#)**12. ACCRUED LIABILITIES**

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

	December 31,	
	2005	2004
Consulting and services	\$ 9,757	\$ 5,229
Off-patent branded product sale deposit and accruals	9,175	—
Accrued clinical and pre-clinical trial costs	6,287	1,324
Sales rebates	4,785	—
Accrued interest	4,454	2,593
Construction-in-process	1,694	3,810
Income taxes payable	2,829	—
Other	1,528	288
Total	<u>\$40,509</u>	<u>\$ 13,244</u>

The off-patent branded product sale deposit and accruals relate to the sales of the off-patent branded products. Of the \$9.2 million accrued, \$8.3 million represents net cash received in December 2005 for the sale of *Declomycin* to Glades Pharmaceuticals, LLC (Glades), and the remaining \$0.9 million represents accrued commission and legal fees. The necessary consent to transfer the rights to Glades was obtained and the transfer of the rights completed in February 2006.

**13. POSTRETIREMENT BENEFIT PLAN**

In June 2003, we established a postretirement health care plan (the Plan), which covers medical, dental and vision coverage for certain of our former officers and their dependents. 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, 2005 and 2004, we have recognized net periodic postretirement benefit cost of approximately \$0.3 million and \$0.2 million, respectively.

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

	December 31,	
	2005	2004
Accumulated postretirement benefit obligation at beginning of year	\$ 1,296	\$ 1,039
Service cost	109	98
Interest cost	72	67
Actuarial loss	356	115
Plan participants' contributions	6	4
Benefits paid	(45)	(27)
Accumulated postretirement benefit obligation at end of year	<u>\$ 1,794</u>	<u>\$ 1,296</u>

We calculated the accumulated postretirement benefit obligation using an assumed discount rate of 5.50% and 5.75% for the years ended December 31, 2005 and 2004, respectively. In 2005 and 2004, we assumed the rate of increase in per capita costs of covered health care benefits to be 9% for both years, decreasing gradually to 5.5% by the year 2010 and 2009, respectively. The benefit amounts recognized in our balance sheets in accrued compensation and other long-term liabilities are as follows (in thousands):

	December 31,	
	2005	2004
Funded status	\$ (1,794)	\$ (1,296)
Unrecognized net actuarial loss	606	258
Unrecognized prior service cost	624	699
Net liability recognized	<u>\$ (564)</u>	<u>\$ (339)</u>

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

	December 31,	
	2005	2004
Service cost	\$109	\$ 98
Interest cost	72	67
Amortization of prior service cost	74	74
Other	8	4
Net periodic benefit cost	<u>\$263</u>	<u>\$243</u>

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, 2005	\$ 32	\$ (28)
Effect on total of service and interest cost in 2005	163	(145)

In connection with the Plan, we expect to pay health care net premiums aggregating approximately \$318,000 and \$412,000 during the years 2006 through 2010, and during the years 2011 through 2015, respectively.

## 14. COMMITMENTS

We occupy leased facilities under agreements that have expiration dates between 2006 and 2013. We also have leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately \$3.8 million, \$2.5 million and \$2.3 million for the years ended December 31, 2005, 2004 and 2003, respectively. Future payments under non-cancelable operating leases at December 31, 2005, are as follows:

Year Ending December 31,	
2006	\$4,323
2007	3,397
2008	1,450
2009	267
2010	137
Thereafter	365
	<u>\$9,939</u>

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 \$1.7 million for the year ending December 31, 2006.

## 15. 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 \$7.4 million at December 31, 2005, and is subject to the terms and covenants of the loan agreement.

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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, 2005 are as follows (in thousands):

<b>Year Ending December 31,</b>	
2006	\$ 1,227
2007	1,139
2008	1,139
2009	1,139
2010	1,139
Thereafter	<u>4,587</u>
Total	10,370
Less amount representing interest	<u>(2,901)</u>
Present value of future payments	7,469
Less current portion	<u>(676)</u>
Non-current portion	<u>\$ 6,793</u>

We believe that the fair values of the facility and equipment loans at December 31, 2005 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.

In addition, we have a long-term liability of approximately \$0.5 million relating to the non-current portion of our accumulated postretirement benefit obligation recognized in 2005. See Note 13 for further detail.

## **16. CONVERTIBLE NOTES**

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.

Issuance costs associated with the 2005 Notes aggregating \$8.0 million are included in other assets and are being amortized to interest expense over the term of the debt, or approximately seven years. The accumulated amortization at December 31, 2005 was \$1.0 million. The estimated fair value of the 2005 Notes at December 31, 2005 was approximately \$332.8 million based upon publicly available pricing information.

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.

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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, 2005 was \$3.0 million. The estimated fair value of the 2003 Notes at December 31, 2005 was approximately \$373.4 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 (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 5.50% Convertible Notes indenture, was 102.75% of the principal amount, or \$1,027.50 per \$1,000 of principal amount of the 5.50% Convertible Notes.

In November 2003, we paid approximately \$155.9 million in cash to redeem the 5.50% 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.

## 17. STOCKHOLDERS' EQUITY

### Common Stock Reserved for Future Issuance

Shares of our common stock reserved for future issuance at December 31, 2005 were as follows (in thousands):

All stock option plans	20,463
Employee stock purchase plan	616
Convertible debt	<u>22,970</u>
Total	<u>44,049</u>

### Stock Option Plans

At December 31, 2005, 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 for options granted prior to July 13, 2005 is ten years, and the option term for all options granted on or subsequent to July 13, 2005 is seven 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 \$0.3 million in 2005, \$1.2 million in 2004 and \$276,000 in 2003.

#### 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 available for grant under the 1991 Plan were transferred to the 1999 Stock Option Plan. During 2003, 361,630 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 or expired 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, 2005.

### **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 available for grant under the 1991 Plan were transferred to 1999 Stock Option Plan. During 2003, 361,630 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 or expired 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, 2005.

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 15,000 shares of our common stock, vesting monthly over 12 months. Options must be granted under the 2002 Directors Plan with an exercise price equal to the market price of our stock on the grant date.

### **2005 Equity Incentive Plan**

Our stockholders approved the 2005 Plan at the annual meeting of the Company's stockholders in June 2005. The 2005 Plan was approved in order to permit grants of certain equity incentives, including stock appreciation rights, restricted stock and restricted stock unit awards, performance share and performance unit awards, deferred compensation awards and other stock-based or cash-based awards, to the Company's service providers. The issuance and terms of such equity incentive awards pursuant to the 2005 Plan is at the discretion of the Board of Directors. A total of 2,300,000 shares of the our common stock was initially authorized for issuance under the 2005 Plan. Shares issued under the 2005 Plan may be authorized but unissued or reacquired shares of the common stock, and may be subject to vesting at the discretion of the board of directors. Shares issued under the 2005 Plan that expire, are forfeited, or are repurchased by us shall again be available for issuance under the Plan.

A summary of the status of our stock option and equity incentive plans at December 31, 2005, 2004 and 2003, and changes during the years then ended, is presented below.

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	2005		2004		2003	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
<b>(In thousands, except exercise price data)</b>						
Outstanding at beginning of year	15,215	\$ 16.36	14,537	\$ 15.69	12,310	\$ 17.18
Granted	3,882	20.17	3,367	17.59	3,228	10.37
Exercised	(3,260)	11.22	(1,807)	8.69	(317)	6.75
Forfeited	(1,495)	22.96	(882)	25.73	(684)	21.65
Outstanding at end of year	14,342	17.89	15,215	16.36	14,537	15.69
Exercisable at end of year	8,041		9,377		8,230	
Weighted-average fair value of options granted during the year		\$ 8.98		\$ 6.93		\$ 7.27

The following information applies to all stock options outstanding under our stock option plans at December 31, 2005:

Range of Exercise Prices	Number Outstanding	Outstanding		Exercisable	
		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 - \$11.28	3,411	5.38	\$ 7.75	2,584	\$ 7.61
\$11.48 - \$20.11	5,533	8.36	16.59	2,065	16.46
\$20.17 - \$30.00	4,851	6.01	23.97	2,845	24.22
\$30.75 - \$41.69	397	4.90	37.50	397	37.51
\$42.11 - \$56.84	150	4.89	48.34	150	48.34
Totals	14,342		\$ 17.89	8,041	\$ 18.00

To date, an aggregate of approximately 38,040,000 shares have been authorized for grant under our stock option plans and as of December 31, 2005, approximately 6,121,000 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, 2005, 1,014,497 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 2005, an aggregate of 191,893 shares were purchased by employees under the Employee Purchase Plan at prices of \$17.10 or \$17.18 per share. 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.

### 18. REVENUES BY GEOGRAPHIC AREA AND SIGNIFICANT CUSTOMERS

Our chief operating decision-maker (CODM) is comprised of our executive management. Our CODM reviews our operating results and makes resource allocation decisions on a company-wide or aggregate basis. Accordingly, we operate as one segment.

Our facilities and long-lived assets are located primarily within the United States. Revenues from product sales are as follows:

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(in thousands)	Years Ended December 31,		
	2005	2004	2003
Cardene IV	\$ 62,143	\$—	\$—
Retavase	31,800	—	—
IV Busulfex	17,417	—	—
Off-patent brands	9,831	—	—
Total revenues from product sales, net	<u>\$ 121,191</u>	<u>\$—</u>	<u>\$—</u>

Products sales from McKesson, Inc., Cardinal Health, Inc. and AmerisourceBergen, Corp. accounted for 13%, 13% and 11% of total revenues, respectively, in 2005 compared to none in 2004 and 2003. Royalty, license and other revenues from Genentech in 2005, 2004 and 2003 accounted for 31%, 51% and 40% of total revenues, and royalty, license and other revenues from MedImmune in 2005, 2004 and 2003 accounted for 12%, 30% and 37% of total revenues, respectively. Royalty, license and other revenues from Roche accounted for 6% and 11% of total revenues in 2005 and 2004, respectively. No other revenue from any other source exceeded 10% of total revenues for any periods presented.

Revenue from product sales by geographic area are based on the customers' shipping locations rather than the customers' country of domicile. Royalty revenues and license and other revenues by geographic area are based on the country of domicile of the counterparty to the agreement.

(in thousands)	Years Ended December 31,		
	2005	2004	2003
United States	\$ 249,565	\$ 84,021	\$ 62,039
Canada	888	—	—
Europe	28,274	11,373	3,517
Asia	525	630	630
Other	402	—	500
Total revenues	<u>\$ 279,654</u>	<u>\$ 96,024</u>	<u>\$ 66,686</u>

## 19. INCOME TAXES

The provision for income taxes consists of the following:

(in thousands)	Years Ended December 31,		
	2005	2004	2003
Current:			
Federal	\$ 100	\$—	\$—
State	721	20	18
Foreign	47	60	55
Total Current	<u>\$ 868</u>	<u>\$ 80</u>	<u>\$ 73</u>

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:

(in thousands)	Year Ended December 31,		
	2005	2004	2003
Tax (benefit) at U.S. statutory rate	\$ (57,998)	\$ (18,074)	\$ (44,107)
Unutilized net operating losses	30,202	18,074	31,243
Nondeductible acquired in-process research and development	27,796	—	12,864
State taxes	721	20	18
Other	100	—	—
Foreign taxes	47	60	55
Total	<u>\$ 868</u>	<u>\$ 80</u>	<u>\$ 73</u>

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As of December 31, 2005, we had federal and California net operating loss carryforwards of approximately \$425.9 million and \$152.4 million, respectively. We also had federal and California state research and other tax credit carryforwards of approximately \$15.1 million and \$9.2 million, respectively. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in the year 2006 through 2025, if not utilized. The California state net operating losses will expire at various dates beginning in 2006 through 2015, if not utilized. The majority of the state tax credits do not expire.

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

Deferred income tax assets and liabilities are determined based on the differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The significant components of our net deferred tax assets and liabilities are as follows:

(in thousands)	December 31,	
	2005	2004
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 159,549	\$ 147,909
Net operating loss carryback	10,070	—
Research and other tax credits	24,300	20,237
Intangible assets	—	17,481
Reserves and accruals	13,586	—
Capitalized research and development costs	4,599	9,145
Deferred revenue	5,979	—
Other	11,267	1,974
Total deferred tax assets	229,350	196,746
Valuation allowance	(144,178)	(196,746)
Total deferred tax assets	85,172	—
<b>Deferred tax liabilities:</b>		
Intangible assets	(73,398)	—
Other	(2,139)	—
Total deferred tax liabilities	(75,537)	—
Net deferred tax assets	\$ 9,635	\$ —

The net deferred tax assets represent a \$10.1 million federal deferred tax asset related to the carry back of ESP Pharma’s tax loss for the period January 1, 2005 through March 23, 2005 partially offset by a net \$0.4 million state deferred tax liability related to future amortization expense of intangible assets from the acquisition of ESP Pharma that are not deductible for tax purposes. Because of our lack of earnings history, the remaining net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$52.6 million for the year ended December 31, 2005 and increased by \$33.3 million and \$55.7 million during the years ended December 31, 2004 and 2003, respectively.

Approximately \$97.2 million of the deferred tax assets at December 31, 2005 relates to benefits of stock option deductions which, when recognized, will be allocated directly to contributed capital.

## 20. 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 (entitlement to priority, 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. In February 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to take place on July 10, 2006 through July 13, 2006. Due to a schedule conflict we have requested that the oral proceeding take place later in 2006. We are awaiting response from the European Patent Office to our request. 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, 2005.

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.

## 21. 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 continued to receive certain fringe benefits through June 30, 2005. In addition, 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 recognized stock-based compensation expense as these stock options vested under the fair value method of accounting. During the year ended December 31, 2005, we recognized approximately \$110,000 in stock-based compensation expense for the stock options vested in 2005.

## 22. SUBSEQUENT EVENTS

We entered into an agreement regarding the sale of rights to *Declomycin* with Glades in December 2005. During the first quarter of 2006, we obtained the consent from Wyeth necessary to transfer all rights to *Declomycin* and our other three off-patent branded products. The transfer of rights to *Declomycin* to Glades for total cash proceeds of \$8.3 million was completed in February 2006, and we sold the rights to *Sectral*, *Tenex* and *Ismo* to Dr. Reddy's Laboratories Limited for total cash proceeds of \$2.7 million in March 2006. Currently, we do not expect to recognize any material gain or loss from the sale. We are now entitled to receive royalty payments in the future from Glades on sales of *Declomycin*.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of  
PDL BioPharma, Inc.

We have audited the accompanying consolidated balance sheets of PDL BioPharma, Inc. (formerly Protein Design Labs, Inc.) as of December 31, 2005 and 2004, and the related consolidated statements of operations, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 PDL BioPharma, Inc. at December 31, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of PDL BioPharma, Inc.'s internal control over financial reporting as of December 31, 2005, 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 10, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

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**QUARTERLY FINANCIAL DATA (UNAUDITED)**

(in thousands, except per share data)	2005 Quarter Ended							
	December 31		September 30		June 30		March 31	
	revised <sup>(1)</sup>	as furnished	revised <sup>(1)</sup>	as reported	revised <sup>(1)</sup>	as reported	revised <sup>(1)</sup>	as reported
<b>Revenues:</b>								
Product sales	\$ 39,012	\$ 39,012	\$ 43,144	\$ 43,144	\$ 38,087	\$ 35,345	\$ 948	\$ 948
Royalties	33,373	33,373	26,003	26,003	37,528	37,528	33,164	33,164
License and other	11,268	11,268	7,536	7,536	4,888	4,888	4,703	4,703
Total revenues	83,653	83,653	76,683	76,683	80,503	77,761	38,815	38,815
<b>Costs and expenses:</b>								
Cost of product sales	16,776	16,776	22,209	22,209	20,135	20,135	1,137	1,137
Research and development	46,959	46,959	49,480	49,480	40,339	40,339	35,261	35,261
Selling, general and administrative	28,119	28,028	26,795	26,795	19,806	19,806	7,666	7,666
Acquired in-process research and development <sup>(2)</sup>	—	—	—	—	—	—	79,417	79,417
Other acquisition-related charges <sup>(3)</sup>	10,876	—	5,816	—	2,742	—	—	—
Asset impairment charge <sup>(4)</sup>	16,044	16,044	15,225	15,225	—	—	—	—
Total costs and expenses	118,774	107,807	119,525	113,709	83,022	80,280	123,481	123,481
Gross profit (loss) from product sales	22,236	22,236	20,935	20,935	17,952	15,210	(189)	(189)
Operating income (loss)	(35,121)	(25,154)	(42,842)	(37,026)	(2,519)	(2,519)	(84,666)	(84,666)
Interest and other income, net	2,781	2,781	2,027	2,027	1,873	1,873	2,935	2,935
Interest expense	(2,655)	(2,655)	(2,671)	(2,671)	(2,709)	(2,709)	(2,142)	(2,142)
Loss before income taxes	(34,995)	(24,028)	(43,486)	(37,670)	(3,355)	(3,355)	(83,873)	(83,873)
Income tax expense (benefit)	(899)	(899)	1,680	1,680	65	65	22	22
<b>Net loss</b>	<b>\$ (34,096)</b>	<b>\$ (23,129)</b>	<b>\$ (45,166)</b>	<b>\$ (39,350)</b>	<b>\$ (3,420)</b>	<b>\$ (3,420)</b>	<b>\$ (83,895)</b>	<b>\$ (83,895)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.31)</b>	<b>\$ (0.22)</b>	<b>\$ (0.43)</b>	<b>\$ (0.37)</b>	<b>\$ (0.03)</b>	<b>\$ (0.03)</b>	<b>\$ (0.87)</b>	<b>\$ (0.87)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>111,571</b>	<b>107,512</b>	<b>105,272</b>	<b>105,272</b>	<b>103,705</b>	<b>103,705</b>	<b>96,754</b>	<b>96,754</b>

(in thousands, except per share data)	2005							
	December 31		September 30		June 30		March 31	
	revised <sup>(1)</sup>	as furnished	revised <sup>(1)</sup>	as reported	revised <sup>(1)</sup>	as reported	revised <sup>(1)</sup>	as reported
Goodwill	\$ 57,783	N/A	\$ 56,714	\$ 57,520	\$ 31,262	\$ 67,359	\$ 31,262	\$ 67,359
Total assets	1,166,001	\$1,170,262	1,176,171	1,176,977	1,018,799	1,054,896	1,012,680	1,048,777
Total liabilities	639,936	N/A	625,003	625,003	577,303	577,303	578,234	578,234
Total stockholders' equity	526,065	531,144	551,168	551,974	441,496	477,593	434,446	470,543

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(in thousands, except per share data)	2004 Quarter Ended			
	December 31	September 30	June 30	March 31
<b>Revenues:</b>				
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
<b>Costs and expenses:</b>				
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)
Income tax expense	12	12	8	48
<b>Net loss</b>	<b>\$ (14,582)</b>	<b>\$ (13,589)</b>	<b>\$ (12,452)</b>	<b>\$ (12,618)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.15)</b>	<b>\$ (0.14)</b>	<b>\$ (0.13)</b>	<b>\$ (0.13)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>95,613</b>	<b>95,196</b>	<b>94,587</b>	<b>94,000</b>

(in thousands, except per share data)	2004			
	December 31	September 30	June 30	March 31
Goodwill	\$ —	\$ —	\$ —	\$ —
Total Assets	\$ 713,732	\$ 727,780	\$ 721,809	\$ 730,052
Total Liabilities	\$ 301,222	\$ 304,063	\$ 288,355	\$ 291,947
Total Stockholders' Equity	\$ 412,510	\$ 423,717	\$ 433,454	\$ 438,105

- (1) Represents revisions of certain amounts previously reported in our Form 10-Q for the first and second quarters, Form 10-Q/A for the third quarter and as furnished in our Form 8-K dated March 3, 2006 which included the February 27, 2006 Press Release for the fourth quarter. See Note 1 to the Consolidated Financial Statements.
- (2) Represents acquired in-process research and development. The amount for 2005 relates to the ESP Pharma acquisition. For a description of these charges, see Notes 1, 4 and 6 to the Consolidated Financial Statements.
- (3) Represents product sales returns, accounts receivable allowances and other liabilities related to ESP Pharma operations prior to our acquisition of the business. See Note 1 to the Consolidated Financial Statements.
- (4) Represents non-cash charges related to the impairment of off-patent branded products and termination of reversion right. For a description of these charges, see Note 4 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 Principal Accounting 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 Principal Accounting 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 Principal Accounting 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, 2005.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected.

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 appears below, and the report on the audit of the consolidated financial statements appears in Part II, Item 8 of this Annual Report on Form 10-K.

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### *(c) Report of Independent Registered Public Accounting Firm*

The Board of Directors and Stockholders of PDL BioPharma, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that PDL BioPharma, Inc. (formerly Protein Design Labs, Inc.) maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). PDL BioPharma, 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 PDL BioPharma, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, PDL BioPharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, 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 PDL BioPharma, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2005 and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

*(d) Changes in Internal Control Over Financial Reporting:* The Chief Executive Officer and Principal Accounting Officer also conducted an evaluation of our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) to determine whether any changes in internal control occurred during the quarter ended December 31, 2005, that have materially effected or which are reasonable likely to materially affect our internal control over financial reporting. Based on that evaluation, the following changes occurred during the quarter ended December 31, 2005:

During our review of the results of operations for the quarter ended September 30, 2005, we identified a material weakness in the operations of our internal control over financial reporting as defined in Public Company Accounting Oversight Board Standard No. 2 related to the failure of an existing internal control to operate effectively. Specifically, with respect to the third quarter of 2005, we did not complete an impairment review with regard to the net carrying value of certain of the intangible assets and inventory acquired in the business combination with ESP Pharma which was completed on March 23, 2005. During the third quarter of 2005, the Company decided to sell four off-patent branded products acquired from ESP Pharma. Also, during September 2005, there was an indication of impairment as the proceeds likely to be received in such a sale would be materially less than the net carrying value of the related intangible assets and inventory as of September 30, 2005.

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A key control in our non-recurring transactions process specifically requires that at least quarterly management undertake a review of our long-lived assets to assess whether any indicators of impairment exist and, if necessary, complete the associated test to determine if the asset value is recoverable or if an impairment charge is required. This key control also requires that the final analysis and related journal entry be reviewed and approved by the VP of Finance. This control did not operate effectively during the financial statement close process for the quarter ended September 30, 2005, due in principal part to staffing resource limitations. While adjustments were recorded in the consolidated condensed financial statements to reflect the correct impairment charge and associated reporting as of September 30, 2005 and for the three and nine month periods then ended, the impairment review and related test were not completed in a manner such that the resultant outcome, which was an impairment charge of \$15.2 million, was reflected timely in our consolidated condensed financial statements provided to our independent registered public accounting firm for their review.

We discussed this matter with our independent registered public accounting firm and our Audit Committee in connection with our evaluation of internal control over financial reporting for both the third and fourth quarters of 2005. In order to remediate this matter during the fourth quarter of 2005, we implemented plans to recruit additional full-time staff in the accounting and finance functions. Further, during that quarter, we retained additional finance consulting resources, which we intend to retain through at least the first quarter of 2006, while we increase our permanent staffing levels, to facilitate the effective operation of our internal control over financial reporting. Finally, during that quarter, we completed a more timely review during our financial statement close process to ensure compliance with our existing internal control over financial reporting.

In addition, since our acquisition of ESP Pharma on March 23, 2005, we have expanded our internal control over financial reporting to include consolidation of ESP Pharma's results of operations, as well as acquisition-related accounting and disclosures. We are in the process of evaluating and assessing whether these expanded internal control have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Although we have expended significant resources, such evaluation and assessment is ongoing. Since ESP Pharma operated as a private company, they were not required to, and did not complete the documentation, testing and possible remediation efforts that would have been required had they been subject to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404). As it was not possible for us to conduct an assessment of ESP Pharma's internal control over financial reporting prior to the management report for Section 404 compliance, we are permitted and have elected to exclude the ESP Pharma operations from the Section 404 compliance requirements for the year ended December 31, 2005.

Also, in April 2005, we implemented a new enterprise resource planning software, SAP, in part in order to increase the automation of our internal control over financial reporting. We have evaluated and assessed this system for our 2005 fiscal year, and we have determined that this change in our internal control has not materially affected, and is not reasonably likely to materially affect, our internal control over financial reporting.

There were no other changes in our internal control over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

Not applicable.

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### PART III

#### ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS

##### Executive Officers of the Registrant

Information relating to our executive officers is incorporated by reference from the information provided in Item 1 in Part I of this Annual Report on Form 10-K under the caption "Executive Officers of the Registrant."

##### Directors of the Registrant

Certain information concerning our directors as of December 31, 2005, except as otherwise noted, is set forth below.

<u>Director</u>	<u>Positions with the Company</u>	<u>Age</u>	<u>Director Since</u>	<u>Class*</u>
Samuel Broder, M.D.	Director	60	2005	I
Karen A. Dawes	Director	54	2003	II
L. Patrick Gage, Ph.D.	Director	63	2003	I
Laurence Jay Korn, Ph.D.	Director	56	1986	III
Max Link, Ph.D.	Director, Chairman of the Board	65	1993	III
Mark McDade	Chief Executive Officer, Director	50	2002	II
Cary L. Queen, Ph.D.**	Director	55	1987	II
Jon S. Saxe, Esq.	Director	69	1989	I

\* Class I directors' terms expire at the 2008 annual meeting of stockholders. Class II directors' terms expire at the 2006 annual meeting of stockholders. Class III directors' terms expire at the 2007 annual meeting of stockholders.

\*\* Dr. Queen was a director as of December 31, 2005, but resigned from the Board on February 21, 2006.

**Samuel Broder, M.D.**, has been a director of the Company since September 2005. He is currently Chief Medical Officer at Celera Genomics and Celera Diagnostics. In 1995, Dr. Broder became Senior Vice President for Research and Development at the IVAX Corporation (now in process of being acquired by TEVA Pharmaceutical Industries, Ltd.) in Florida, where he directed a broad range of pharmaceutical research on new drugs for heart disease, diabetes and diseases of the lung. In 1989, President Ronald Reagan named Dr. Broder Director of the National Cancer Institute (NCI). Under his leadership, the NCI initiated a number of important large-scale human trials in the prevention, diagnosis, and treatment of cancer. Dr. Broder began his research career in the Metabolism Branch of the NCI in 1972. During his tenure at the NCI, Dr. Broder performed research that led to the development of several important anti-retroviral drugs for the therapy of HIV/AIDS. He has authored or co-authored over 300 scientific papers, and is the inventor or co-inventor on numerous patents. Dr. Broder received his bachelor's and medical degrees from the University of Michigan.

**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 (formerly known as American Home Products), where she held responsibility for worldwide strategic marketing. She also served as Vice President, Commercial Operations for Genetics Institute, Inc. (which was acquired by Wyeth in January 1997), designing and implementing that company's initial commercialization strategy to launch *BeneFIX*<sup>®</sup> and *Neumega*<sup>®</sup>. 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*<sup>®</sup>, *Zoloft*<sup>®</sup>, and *Cardura*<sup>®</sup>. Ms. Dawes is also a director of Repligen, Inc.

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**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. 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. Prior to that time, Dr. Gage held various positions in research management at Roche over an 18-year period. Dr. Gage is also a Director of Neose Technologies and Serono S A, and serves as an advisor to Flagship Ventures and to Warburg Pincus, both private equity firms, and is on the science advisory boards of Perkin Elmer, Inc. and Functional Genetics.

**Laurence Jay Korn, Ph.D.**, has been a director of the Company since July 1986. From July 1986 through May 1, 2002, Dr. Korn served as a director and Chairperson of the Board, and from May 1, 2002 through June 2004, he served as a director and Chairman of the Board. From January 1987 until April 2002, Dr. Korn served as Chief Executive Officer. Previously, Dr. Korn headed a research laboratory and served on the faculty of the Department of Genetics at the Stanford University School of Medicine from March 1981 to December 1986. Dr. Korn received his Ph.D. from Stanford University and was a Helen Hay Whitney Postdoctoral Fellow at the Carnegie Institution of Washington and a Staff Scientist at the MRC Laboratory of Molecular Biology in Cambridge, England, before becoming an Assistant Professor at Stanford.

**Max Link, Ph.D.**, has been a director of the Company since June 1993, and Chairman of the Board since July 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 is also a director of Access Pharmaceuticals, Inc., Alexion Pharmaceuticals, Inc., CytRx Corp., Discovery Laboratories, Inc., Human Genome Sciences, Inc. and Celsion Corporation.

**Mark McDade** has been a Chief Executive Officer and a director of the Company since November 2002. 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. and Cytokinetics, Inc. Mr. McDade earned his M.B.A. from Harvard Business School.

**Cary L. Queen, Ph.D.**, was a director of the Company from January 1987 until February 21, 2006, when he resigned from the Board. He served as the Company's 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., and Durect Corporation.

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### **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 (until June 8, 2005), Jon S. Saxe (since June 8, 2005) 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)(3)(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://media.corporate-ir.net/media\\_files/IROL/10/100463/CG/codeofconduct.pdf](http://media.corporate-ir.net/media_files/IROL/10/100463/CG/codeofconduct.pdf).

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

PDL BioPharma, 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, 2005, under Section 16(a) by our directors, executive officers and greater than 10% beneficial owners were timely filed, with the following exceptions:

- George T. Jue was designated as an officer subject to Section 16(a) on June 8, 2005, and filed a delinquent Form 3 on August 2, 2005.
- Jon S. Saxe, a director on our Board, filed a delinquent Form 4 on October 20, 2005 with respect to a transaction in our securities that occurred on October 4, 2005.
- David Iwanicki, an officer subject to Section 16(a), filed a delinquent Form 4 on February 15, 2006 with respect to a transaction in our securities that occurred on July 13, 2005.

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

The information required by this Item 11 is incorporated by reference from the information provided under the heading "EXECUTIVE COMPENSATION AND OTHER MATTERS" of the Proxy Statement, other than the information provided under the subheadings "- Equity Compensation Plan Information" and "- Indebtedness of Management" thereunder. Also, the information specified in Item 402 (k) and (l) of Regulation S-K and set forth in the Proxy Statement is not incorporated herein by reference.

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

The information required by this Item 12 is incorporated by reference from the information provided under the heading "SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT" of the Proxy Statement and from the information provided under the subheading "- Equity Compensation Plan Information" under the heading "EXECUTIVE COMPENSATION AND OTHER MATTERS" of the Proxy Statement.

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

None.

**Indebtedness of Management**

The information required by this subsection “Indebtedness of Management” of this Item 13 is incorporated by reference from the information provided under the subheading “- Indebtedness of Management” under the heading “EXECUTIVE COMPENSATION AND OTHER MATTERS” of the Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this Item 14 is incorporated herein by reference from the information provided under the heading “APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM” of the Proxy Statement.

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### PART IV

#### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

- (1) Index to financial statements

Our financial statements and the Report of the Independent Registered Public Accounting Firm are included in Part II, Item 8.

<u>Item</u>	<u>Page</u>
<a href="#">Consolidated Balance Sheets</a>	64
<a href="#">Consolidated Statements of Operations</a>	65
<a href="#">Consolidated Statements of Cash Flows</a>	66
<a href="#">Consolidated Statements of Stockholders' Equity</a>	67
<a href="#">Notes to Consolidated Financial Statements</a>	68
<a href="#">Report of Independent Registered Public Accounting Firm</a>	99

(2) The following schedule is filed as part of this report on Form 10-K and should be read in conjunction with the financial statements:

Schedule II – Valuation and Qualifying Accounts and Reserves for the year ended December 31, 2005

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

- (3) Index to Exhibits

<u>Exhibit Number</u>	<u>Exhibit Title</u>
2.1	Amended and Restated Agreement and Plan of Merger by and among the Company, Big Dog Bio, Inc., a Delaware corporation and wholly owned subsidiary of the Company, and ESP Pharma Holding, dated as of March 22, 2005. (Incorporated by reference to Exhibit 2.1 to Registration Statement on Form S-3 filed March 25, 2005.)
2.2	Asset Purchase Agreement between Centocor, Inc., a Pennsylvania corporation, and ESP Pharma, Inc., a Delaware corporation and wholly owned subsidiary of ESP Pharma Holding Company, Inc., dated as of January 31, 2005. (Incorporated by reference to Exhibit 2.2 to Current Report on Form 8-K filed March 25, 2005.) (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)
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	Certificate of Amendment of Certificate of Incorporation. (Incorporated by reference to Exhibit 3.3 to Annual Report on Form 10-K filed March 14, 2002.)
3.3	Certificate of Amendment of Certificate of Incorporation of Protein Design Labs, Inc. effective as of January 9, 2006. (Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed January 10, 2006.)
3.4	Amended and Restated Bylaws of Protein Design Labs, Inc. effective as of June 8, 2005. (Incorporated by reference to Exhibit 99.3 to Current Report on Form 8-K filed June 14, 2005.)
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	Indenture between the Company and J.P. Morgan Trust Company, National Association, as trustee, dated as of February 14, 2005. (Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed February 14, 2005.)
4.3	Registration Rights Agreement between the Company and Goldman, Sachs & Co., Citigroup Global Markets Inc. and UBS Securities LLC dated as of February 14, 2005. (Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed February 14, 2005.)
*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.)

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- 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 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.)
- 10.24 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.)
- 10.25 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.)
- 10.26 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.)
- \*10.27 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).
- \*10.28 2002 Outside Directors Plan, as amended on June 8, 2005. (Incorporated by reference to Exhibit 99.2 to Current Report on Form 8-K filed June 14, 2005), 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).

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- \*10.29 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).
- \*10.30 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).
- \*10.31 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).
- \*10.32 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).
- \*10.33 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).
- \*10.34 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).
- \*10.35 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).
- \*10.36 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 10K filed March 8, 2004.)
- 10.37 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).
- 10.38 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.)
- 10.39 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.)
- 10.40 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.)
- 10.41 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.)
- 10.42 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.)
- \*10.43 Postretirement Healthcare Plan. (Incorporated by reference to Exhibit 10.50 to Annual Report on Form 10K filed March 8, 2004.)
- \*10.44 Amendment No. 1 to Special Compensation and Employment Agreement Dated May 1, 2002 Between Laurence Jay Korn and the Company (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10Q filed May 5, 2004).
- 10.45 Co-Development and Commercialization Agreement between the Company and Hoffmann-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).
- 10.46 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). (Incorporated by reference to Exhibit 10.51 to Annual Report on Form 10-K filed March 16, 2006).
- 10.47 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). (Incorporated by reference to Exhibit 10.52 to Annual Report on Form 10-K filed March 16, 2006).
- 10.48 Sublicense and Supply Agreement between Syntex (U.S.A.) LLC and American Home Products Corporation dated September 1, 1993, re: Nicardipine IV and related letter assigning such agreement to ESP Pharma, Inc. dated October 30, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 10, 2005.)
- 10.49 Letter dated September 5, 2003 between Roche Palo Alto LLC and ESP Pharma, Inc., amending Sublicense and Supply Agreement (with certain confidential portions deleted and marked by notation indicating such deletion). (Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 10, 2005.)
- \*10.50 Offer letter for employment between the Company and George Jue, dated as of April 8, 2005. (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 8, 2005.)
- \*10.51 PDL BioPharma, Inc. 2005 Equity Incentive Plan. (Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed June 14, 2005.)

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- 10.52 Collaboration Agreement between the Company and Biogen Idec, dated as of September 12, 2005. (Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed November 8, 2005.) (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)
- \*10.53 Transition Agreement dated as of September 15, 2005 between the Company and Glen Sato. (Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed September 19, 2005.)
- 10.54 Amended and Restated Co-Development and Commercialization Agreement between the Company and Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd dated as of October 28, 2005. (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)
- 10.55 Second Amended and Restated Worldwide Agreement between the Company and Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd dated as of October 28, 2005. (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)
- \*10.56 Amended and Restated Consulting Agreement between the Company and Cary Queen dated as of February 1, 2006.
- 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 Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act, as amended.
- 31.2 Certification of Principal Accounting Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act, as amended.
- 32.1 Certification by the Principal Executive Officer and the Principal Accounting Officer of PDL BioPharma, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

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\* Management contract or compensatory plan or arrangement.

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

(c) See (a)(1) above.

**SCHEDULE II****VALUATION AND QUALIFYING ACCOUNTS AND RESERVES**

(In thousands)

	<u>Balance at Beginning of Year</u>	<u>Balance at ESP Pharma Acquisition</u>	<u>Charged to Costs and Expenses</u>	<u>Deductions(1)</u>	<u>Charged to Other Accounts</u>	<u>Balance at End of Year</u>
Year ended December 31, 2005:						
Allowances for accounts receivable	\$ —	\$ 7,697	\$ 24,097	\$ (22,096)	\$ 350	\$ 10,048
Reserve for excess and obsolete inventory	\$ —	\$ 1,826	\$ 1,695	\$ (2,242)	\$ —	\$ 1,279

(1) Deductions represent costs charged or amounts written off against the reserve.

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**SIGNATURES**

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

**PDL BIOPHARMA, INC. (Registrant)**

By: /s/ MARK MCDADE  
Mark McDade,  
**Chief Executive Officer**

March 16, 2006  
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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ MARK MCDADE</u> (Mark McDade)	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2006
<u>/s/ GEORGE T. JUE</u> (George T. Jue)	Vice President, Finance and Corporate Controller (Principal Accounting Officer)	March 16, 2006
<u>/s/ LAURENCE JAY KORN</u> (Laurence Jay Korn)	Director	March 16, 2006
<u>/s/ JON S. SAXE</u> (Jon S. Saxe)	Director	March 16, 2006
<u>/s/ SAMUEL BRODER</u> (Samuel Broder)	Director	March 16, 2006
<u>/s/ MAX LINK</u> (Max Link)	Chairman of the Board of Directors	March 16, 2006
<u>/s/ L. PATRICK GAGE</u> (L. Patrick Gage)	Director	March 16, 2006
<u>/s/ KAREN A. DAWES</u> (Karen A. Dawes)	Director	March 16, 2006

**CONFIDENTIAL PROVISIONS REDACTED****AMENDED AND RESTATED CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This Amended and Restated Co-Development and Commercialization Agreement (the **“Agreement”**) is entered into as of October 29, 2005 (the **“Amendment Effective Date”**), by and among PROTEIN DESIGN LABS, INC., a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555 (**“PDL”**), and 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 individually and collectively referred to as **“Roche”**).

**RECITALS**

**WHEREAS**, Roche currently markets a humanized antibody against the interleukin-2 (IL-2) receptor (Daclizumab), under the trademark Zenapax®, for the prevention of acute organ rejection in patients receiving kidney transplants;

**WHEREAS**, pursuant to the Amended and Restated Worldwide Agreement between PDL and Roche dated October 1, 2003, as amended (the **“Original Worldwide Daclizumab Agreement”**), certain rights previously granted to Roche reverted to PDL, and PDL acquired, among other rights, the sole and exclusive worldwide rights to develop, market and sell Daclizumab for autoimmune indications, and the option to acquire the sole and exclusive worldwide rights to develop, market and sell Daclizumab for all transplant indications;

**WHEREAS**, pursuant to the Co-Development and Commercialization Agreement between PDL and Roche dated September 14, 2004 (the **“Effective Date”**), as amended on May 19, 2005 (the **“Original Asthma Agreement”**), PDL and Roche entered into a worldwide collaboration for the joint development and commercialization of Daclizumab for the treatment of asthma and other respiratory diseases; and

**CONFIDENTIAL TREATMENT**

**WHEREAS**, PDL and Roche have further amended and restated the Original Worldwide Daclizumab Agreement as of October 28, 2005 to grant PDL the sole and exclusive worldwide rights to develop, market and sell Daclizumab for all transplant indications, except for the form of Daclizumab currently marketed by Roche, to which Roche retains sole and exclusive worldwide rights. Such further amended and restated agreement is referred to herein as the **“Worldwide Daclizumab Agreement.”**

**WHEREAS**, PDL and Roche now wish to amend and restate the Original Asthma Agreement to provide for, in addition to the existing asthma collaboration, a worldwide collaboration for the joint development and commercialization of Daclizumab for transplant indications, with an emphasis on transplant maintenance.

**NOW THEREFORE**, the Parties agree as follows:

## **ARTICLE 1**

### DEFINITIONS

**1.1 “Affiliate”** means any corporation or other business entity controlled by, controlling, or under common control with another entity, with **“control”** meaning direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock of, or more than a fifty percent (50%) interest in the income of, such corporation or other business entity. Notwithstanding anything to the contrary in this paragraph, [\*\*\*\*].

**1.2 “Asthma Commercialization Plan”** shall have the meaning set forth in Section 6.1(a).

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

1.3 **“Asthma Co-Promotion Term”** shall have the meaning set forth in Section 6.4(a).

1.4 **“Asthma Development Plan”** shall have the meaning set forth in Section 4.1(a).

1.5 **“Asthma Field”** means the treatment and/or prevention of asthma or other respiratory diseases.

1.6 **“Asthma Joint Development Committee”** or **“Asthma JDC”** shall have the meaning set forth in Section 3.6.

1.7 **“Autoimmune Indications”** 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, polymyositis, Type I diabetes, sarcoidosis, Sjogrens syndrome, chronic active non-pathogenic hepatitis, non-infectious uveitis (Behcets), aplastic anemia, regional non-pathogenic enteritis (including ulcerative colitis, Crohn’s Disease and inflammatory bowel disease), Kawasaki’s disease, post-infectious encephalitis, multiple sclerosis, and tropic spastic paraparesis.

1.8 **“cGMP”** means current Good Manufacturing Practices pursuant to the U.S. Federal Food, Drug and Cosmetics Act as amended (21 USC 301 et seq.), as well as any equivalent laws or regulations in the European Union pertaining to the manufacture of pharmaceutical products.

1.9 **“Change of Control”** shall mean a transaction in which a Party: (a) sells, conveys or otherwise disposes of all or substantially all of its property or business; or (b)(i) merges or consolidates with any other entity (other than a wholly-owned subsidiary of such Party); or (ii) effects any other transaction or series of transactions; in each case of clause (i) or (ii), such that the stockholders of such Party 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.

**1.10 “Closing Date”** means, if the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the “**HSR Act**”) applies to the transaction contemplated by this Agreement that was not contemplated by the Original Asthma Agreement, two business days after the earlier of (a) the date of approval of such transaction by the Federal Trade Commission or the appropriate US anti-trust authorities or (b) the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

**1.11 “Collaborative Fields”** shall have the meaning set forth in Section 2.5. For clarity, a Collaborative Field (i.e., used in the singular) shall refer either to the [\*\*\*\*] or [\*\*\*\*].

**1.12 “Combination Product”** means a Licensed Product that contains one or more therapeutically active ingredients in addition to Daclizumab.

**1.13 “Commercial Supply Agreement”** shall have the meaning set forth in Section 8.2.

**1.14 “Commercialization Plan”** means the Asthma Commercialization Plan or the Transplant Commercialization Plan, as applicable.

**1.15 “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.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

**1.16 “Co-Promotion Term”** means the Asthma Co-Promotion Term or the Transplant Co-Promotion Term.

**1.17 “Cost of Goods Sold” or “COGS”** means, with respect to a Licensed Product (in bulk, vial or finished product form, as the case may be), the sum of the following, all of which shall be calculated in accordance with U.S. generally accepted accounting principles consistently applied by PDL to all of its products:

[\*\*\*\*] provided, however, that Cost of Goods Sold shall not include any costs or expenses included or includible in Distribution Expenses.

**1.18 “Daclizumab”** means that certain humanized murine monoclonal antibody directed against the p55 component of IL-2R and given the generic name “Daclizumab” by the United States Adopted Names Council. Daclizumab does not include fragments of such antibody or any antibodies having a different amino acid sequence from such antibody.

**1.19 “Data Services”** shall have the meaning set forth in Section 7.6(b).

**1.20 “Detail” or “Detailing”** shall mean a [\*\*\*\*] presentation by a Party’s sales representative, to one or several medical professional(s) having prescribing authority in the U.S. Territory in a Collaborative Field, as well as to other individuals or entities that have significant impact or influence on prescribing decisions in the U.S. Territory in a Collaborative Field, as identified in the Commercialization Plan approved by the Asthma JDC or the Transplant JCC (as appropriate) (collectively, the “**Target Audience**”), in which the principal objective of such presentation is to emphasize the features and function of such Licensed Product in a Collaborative Field. [\*\*\*\*].

**1.21 “Development”** means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of a Licensed Product in a Collaborative

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Field or (b) developing the ability to manufacture the same. This includes, without limitation, (i) preclinical testing, toxicology, formulation, manufacturing-related technology development, and clinical studies of a Licensed Product in a Collaborative Field; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a governmental authority to obtain and/or maintain Regulatory Approval of a Licensed Product in a Collaborative Field, and outside counsel regulatory legal services related thereto; and (iii) manufacturing process development and scale-up, bulk production and fill/finish work associated with the supply of Licensed Products for preclinical and clinical studies, and related quality assurance technical support activities.

**1.22 “Development Expenses”** shall have the meaning set forth in Exhibit A.

**1.23 “Development Plan”** means the Asthma Development Plan or the Transplant Development Plan, as applicable.

**1.24 “Diligent Efforts”** means the carrying out of obligations or tasks in a diligent, sustained manner using efforts equivalent to the efforts a Party devotes to a product of similar market potential, profit potential and strategic value resulting from its own research efforts, based on conditions then prevailing. Diligent Efforts requires that the Party: (a) promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives. The Parties acknowledge that Roche does not, as of the Effective Date, develop, register, market, and sell its products in every country in the Territory, and it is understood that the exercise by Roche of Diligent Efforts shall be judged in light of this fact.

**1.25 “Distribution Expenses”** means the costs, excluding administration costs, incurred by a Party or for its account, specifically attributable to the distribution of a Licensed Product in the U.S. Territory, to be calculated in the manner set forth in Exhibit A.

**1.26 “Dollars” or “\$”** means the legal tender of the U.S.

**1.27 “Drug Approval Application”** means a Biologics License Application or an equivalent application for Regulatory Approval required before commercial sale or use of a Licensed Product in a Collaborative Field in a regulatory jurisdiction.

**1.28 “European Union”** means all countries that are officially recognized as member states of the European Union.

**1.29 “Executive Officers”** means, for Roche, the CEO of the Roche Pharmaceuticals Division (or such individual’s designee), and, for PDL, the Chief Executive Officer of PDL (or such individual’s designee). If either position is vacant or either position does not exist, then the person having the most nearly equivalent position (or such individual’s designee) shall be deemed to be the Executive Officer of the relevant Party.

**1.30 “Failure to Supply”** shall have the meaning set forth in Section 8.2.

**1.31 “FDA”** means the U.S. Food and Drug Administration or any successor agency thereto.

**1.32 “First Commercial Sale”** means, for each Licensed Product in each country in each Collaborative Field, the first sale to a Third Party of such Licensed Product in such country in such Collaborative Field by a Party, its Affiliate, or its sublicensee, after the granting by the relevant governing authorities of all Regulatory Approvals required for commercial sale of the Licensed Product in such country in such Collaborative Field.

**1.33 “FTE”** means the equivalent of one employee working full time in a Development-related capacity, for or on behalf of a Party for one 12-month period.

**1.34 “Generic Product”** means a Third Party product (a) that contains Daclizumab or an antibody with a substantially identical amino acid sequence, whether or not the glycosylation pattern of such antibody is identical to Daclizumab; and (b) that has received Regulatory Approval for use in a particular indication in the applicable

Collaborative Field through an expedited regulatory approval process governing approval of generic biologics, should such a regulatory approval process ever be implemented. Notwithstanding the foregoing, Generic Products do not include Licensed Products sold by either Party's sublicensees or distributors pursuant to this Agreement or the Worldwide Daclizumab Agreement or Licensed Products to the extent sold for use outside of the Collaborative Fields.

**1.35 "Global Net Sales"** means the sum of PDL Net Sales and Roche Net Sales.

**1.36 "IL-2R"** means the IL-2 receptor.

**1.37 "Incremental Development Expenses"** means the expenses incurred by Roche or for its account that are attributable to Development performed solely in support of Regulatory Approval with respect to the ROW Territory and that were not requested by either the Asthma JDC or the Transplant JDC (as appropriate) to support Regulatory Approval with respect to the U.S. Territory or the European Union. Such expenses shall include the transfer price paid by Roche, pursuant to Section 8.1(c), for Licensed Product supplied by PDL for such Development.

**1.38 "Information"** means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, physical, biological, chemical, biochemical, toxicological, clinical and veterinary test data, analytical and quality control data, stability data, studies and procedures, dosage regimens and control assays, financial information, procurement requirements, purchasing information, manufacturing information, customer lists, business and contractual relationships, business forecasts, sales and merchandising information, marketing plans, and patent and other legal information or descriptions.

**1.39 "Joint Finance Committee" or "JFC"** means that subcommittee of the JSC established pursuant to Section 3.3(g).

**1.40 “Joint Inventions”** means any inventions:

(a) related to humanized or chimeric antibodies that bind to IL-2R, whether patented or not, that were jointly made during the period beginning on January 31, 1989 and continuing until the Effective Date 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 employee or person contractually required to assign or license patent rights covering such inventions to Roche; or

(b) related to antibodies that bind to IL-2R, whether patented or not, that are jointly made during the period beginning on the Effective Date and continuing until the expiration or termination of this Agreement 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 employee or person contractually required to assign or license patent rights covering such inventions to Roche.

**1.41 “Joint Patent Committee”** or “JPC” means that subcommittee of the JSC established pursuant to Section 3.3(f).

**1.42 “Joint Roche-PDL Patents”** means all patent applications and patents claiming Joint Inventions.

**1.43 “Joint Steering Committee”** or “JSC” shall have the meaning set forth in Section 3.1.

**1.44 “Know-How”** means all inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results related to antibodies that bind to IL-2R, and improvements thereon, including any information regarding the physical, chemical, biological, toxicological, pharmacological, clinical, and veterinary data, dosage regimens, control assays and specifications of Licensed Products.

**1.45 “Licensed Product”** shall mean any pharmaceutical product having as an active ingredient Daclizumab, but excluding Nutley Dac.

**1.46 “Major Pharmaceutical Company”** shall mean any entity that, together with its Affiliates, has annual worldwide pharmaceutical sales of [\*\*\*\*] or more for the last full fiscal year preceding the date of consummation of a Change of Control.

**1.47 “Major Regulatory Jurisdiction”** means the [\*\*\*\*].

**1.48 “Medical Activities”** shall mean continuing medical education, scientific communication and exchange and medical liaison activities.

**1.49 “Non-Registrational Trial”** means a clinical trial in a Collaborative Field for a Licensed Product that (a) is initiated or ongoing after completion of the first Phase III Trial in such Collaborative Field, and (b) is not conducted to obtain, maintain or expand Regulatory Approval of the Licensed Product in such Collaborative Field. A Non-Registrational Trial shall be deemed initiated upon the enrollment of the first patient.

**1.50 “Nutley Dac”** means the FDA-approved form of the pharmaceutical product containing Daclizumab manufactured at Roche’s Nutley, New Jersey facility, as of the Amendment Effective Date.

**1.51 “Operating Expenses”** shall have the meaning set forth in Exhibit A.

**1.52 “Party”** means PDL or Roche individually, and **“Parties”** means PDL and Roche collectively.

**1.53 “PDL Adjusted Gross Sales”** means the gross invoice price of Licensed Products sold or otherwise disposed of for consideration in the U.S. Territory by PDL, its Affiliates or sublicensees (other than Roche and its Affiliates hereunder) to independent Third Parties (not Affiliates of the seller) for use in a Collaborative Field, reduced by the following amounts: (a) [\*\*\*\*] and (b) [\*\*\*\*] [\*\*\*\*].

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In the case of the sale by PDL, its Affiliates or sublicensees (other than Roche and its Affiliates hereunder) in such Collaborative Field in the U.S. Territory of Combination Products for which a Licensed Product 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 [\*\*\*\*] by [\*\*\*\*]. 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 such Combination Product.

If PDL or its Affiliates or sublicensees receive non-cash consideration for Licensed Products 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 will be [\*\*\*\*] and shall be deemed [\*\*\*\*].

**1.54 “PDL Gross Margin”** means, with respect to a particular Collaborative Field and calendar quarter during the Co-Promotion Term for such field, PDL Adjusted Gross Sales for Licensed Products sold in the U.S. Territory in such quarter for use in such field minus [\*\*\*\*].

**1.55 “PDL House Marks”** means the corporate name of PDL and associated logos and designs.

**1.56 “PDL Know-How”** means, except as otherwise set forth in this Section 1.56, all Know-How that is possessed, as of the Effective Date, by PDL or by any entity that is a PDL Affiliate as of the Effective Date, or that is developed during the term of this Agreement by PDL or by any entity while it is a PDL Affiliate, and which Know-How is owned or Controlled by PDL or its Affiliates and is reasonably required or useful for seeking registration of, using or selling Licensed Products in the Collaborative Fields;

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provided, however, that PDL Know-How excludes any know-how 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.

**1.57 “PDL Net Sales”** means the amount determined by deducting [\*\*\*\*] from PDL Adjusted Gross Sales to account for standard deductions from gross sales such as shipping, insurance, taxes (to the extent not included in calculations of PDL Adjusted Gross Sales).

**1.58 “PDL Patents”** means all patent applications owned or Controlled by PDL or its Affiliates alone or with a Third Party (“**Sole PDL Patents**”) and all Joint Roche-PDL Patents claiming Licensed Products or their manufacture or use in the Collaborative Fields, which are filed prior to or during the term of this Agreement in the U.S. 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 U.S. or foreign patent or inventor’s certificate covering Licensed Products in the Collaborative Fields.

**1.59 “PDL Technology”** means PDL Know-How and PDL Patents.

**1.60 “PDL Trademarks”** means all trademarks owned by PDL (except for any PDL House Marks or trade names) and used by PDL or its sublicensee(s) in connection with the marketing, promotion, and sale of Licensed Products in the Collaborative Fields and all trademark registrations and applications therefor, and all goodwill associated therewith. The PDL Trademarks shall not include the Zenapax Trademark.

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**1.61 “Phase II Trial”** means a human clinical trial in a Collaborative Field performed to evaluate the effectiveness of a Licensed Product for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug, as described in 21 CFR 312.21(b). For the purposes of Section 9.3, a Phase II Trial shall be deemed initiated upon the dosing of the first patient.

**1.62 “Phase IIa Trial”** means a human clinical trial performed to estimate the biologic or clinical effect of a pharmaceutical product in a target population. A Phase IIa Trial shall be deemed initiated upon the dosing of the first patient.

**1.63 “Phase IIb Trial”** means a human clinical trial performed to gain evidence of the efficacy of a pharmaceutical product in a target population, and to establish the optimal dosing regimen for such product. A Phase IIb Trial shall be deemed initiated upon the dosing of the first patient.

**1.64 “Phase III Trial”** means a human clinical trial in a Collaborative Field performed to gain evidence of the efficacy of a Licensed Product in a target population, and to obtain expanded evidence of safety for such Licensed Product that is needed to evaluate the overall benefit-risk relationship of such Licensed Product and provide an adequate basis for physician labeling, as described in 21 CFR 312.21(c). For the purposes of Sections 9.2 and 9.3, a Phase III Trial shall be deemed initiated upon the dosing of the first patient.

**1.65 “Phase IV Trial”** means a clinical trial in the Asthma Field or Transplant Field for a Licensed Product that (a) is initiated or ongoing after completion of the first Phase III Trial in the Asthma Field or Transplant Field, respectively, and (b) is not a Non-Registrational Trial in such field. A Phase IV Trial shall be deemed initiated upon the enrollment of the first patient.

**1.66 “Post-Launch Product R&D Expenses”** shall have the meaning set forth in Exhibit A.

**1.67 “Promotion” or “Promote”** shall mean the marketing and advertising of a Licensed Product in the Asthma Field in the U.S. Territory in accordance with the Asthma Commercialization Plan or in the Transplant Field in the U.S. Territory in accordance with the Transplant Commercialization Plan, including information and communication and market development, but not including Detailing or Medical Activities.

**1.68 “Queen Patents”** means those worldwide PDL Patents claiming priority to U.S. Patent Application Serial No. 07/290,975, filed December 28, 1988.

**1.69 “Region”** shall mean each region set forth in Exhibit F, provided that such Exhibit may be modified by Roche with PDL’s written consent, such consent not to be unreasonably withheld, if Roche modifies the regions that it uses to generally manage its pharmaceuticals business.

**1.70 “Regulatory Approval”** means all approvals (including pricing and reimbursement approvals), product and/or establishment licenses, registrations or authorizations of any regional, federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the manufacture, use, storage, import, export, transport or sale of Licensed Products in the Collaborative Fields in a regulatory jurisdiction.

**1.71 “Roche Adjusted Gross Sales”** means the gross invoice price of Licensed Products 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 Affiliates of the seller), reduced by the following amounts: (a) [\*\*\*\*] and (b) [\*\*\*\*].

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When calculating the Roche Adjusted Gross Sales, the amount of such sales in foreign currencies shall be converted into Dollars at the average rate of exchange at the time for the applicable calendar quarter in accordance with Roche's then-current standard practices. Roche shall provide reasonable documentation of the calculation and reconciliation of the conversion figures on a country-by-country basis as part of its report of Roche Adjusted Gross Sales for the period covered under the report.

In the case of the sale by Roche, its Affiliates or sublicensees (other than PDL and its Affiliates hereunder) of Combination Products for which a Licensed Product 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 [\*\*\*\*] by [\*\*\*\*]. 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 such Combination Product.

If Roche or its Affiliates or sublicensees receive non-cash consideration for Licensed Products 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 will be [\*\*\*\*] and shall be deemed [\*\*\*\*].

**1.72 "Roche Fill/Finish Costs"** shall have the meaning set forth in Section 8.3(a).

**1.73 "Roche Gross Margin"** means, with respect to a particular calendar quarter during the Transplant Co-Promotion Term, Roche Adjusted Gross Sales for Licensed Products sold in the U.S. Territory in such quarter for use in the Transplant Field minus (a) [\*\*\*\*]; and (b) [\*\*\*\*].

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**1.74 “Roche Inventions”** means all inventions that (a) relate to or are useful with antibodies that bind the IL-2 receptor (IL-2R) and (b) are made during the term of this Agreement by employees of Roche or persons contractually required to assign or license patent rights covering such inventions to Roche, in the course of performing Roche’s obligations, or exercising Roche’s rights, under this Agreement.

**1.75 “Roche Know-How”** means, except as otherwise set forth in this Section 1.75, all Know-How that is possessed, as of the Effective Date, by Roche or by any entity that is a Roche Affiliate as of the Effective Date, or that is developed during the term of this Agreement by Roche or by any entity while it is a Roche Affiliate, and which Know-How is owned or Controlled by Roche or its Affiliates and is reasonably required or useful for seeking registration of, manufacturing, using or selling the Licensed Products; provided, however, that Roche Know-How excludes any Know-How 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.

**1.76 “Roche Net Sales”** means the amount determined by deducting [\*\*\*\*] from Roche Adjusted Gross Sales to account for standard deductions from gross sales such as shipping, insurance, taxes (to the extent not included in calculations of Roche Adjusted Gross Sales).

**1.77 “Roche Patents”** means all patent applications owned or Controlled by Roche or its Affiliates (“**Sole Roche Patents**”) alone or with a Third Party, and all Joint Roche-PDL Patents claiming Licensed Products or their manufacture or use in the Collaborative Fields, which are filed prior to or during the term of this Agreement in the

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U.S. 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 U.S. or foreign patent or inventor's certificate covering Licensed Products in the Collaborative Fields.

**1.78 "Roche Technology"** means Roche Know-How and Roche Patents.

**1.79 "ROW Commercialization Activities"** has the meaning set forth in Section 7.1.

**1.80 "ROW Territory"** means all parts of the Territory not included in the U.S. Territory.

**1.81 "[\*\*\*\*] Daclizumab"** means a [\*\*\*\*] humanized murine monoclonal antibody prepared against the p55 component of IL-2R [\*\*\*\*] and covered by claims under [\*\*\*\*].

**1.82 "Sole PDL Patents"** shall have the meaning set forth in Section 1.58.

**1.83 "Sole Roche Patents"** shall have the meaning set forth in Section 1.78.

**1.84 "Successful GMP Audit"** shall have the meaning set forth in Exhibit B.

**1.85 "Target Audience"** shall have the meaning set forth in Section 1.20.

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

**1.87 "Third Party"** means any person or entity other than a Party or its Affiliates.

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**1.88 “Third Party License”** means (a) any of the license agreements set forth on Exhibit C and (b) any other license agreement entered into by a Party with a Third Party after the Amendment Effective Date that the Parties agree in writing is necessary for the use, manufacture, sale, offering for sale, or importation of Licensed Product in a Collaborative Field in the Territory under this Agreement.

**1.89 “Transfer Price”** means, with respect to a particular unit of Licensed Product, the amount paid by Roche to PDL for supply of such unit of Licensed Product pursuant to the Commercial Supply Agreement in either bulk or finished form.

**1.90 “Transplant Branded Product”** shall mean a Licensed Product that is marketed in the U.S. Territory using the Transplant Trademark. If the FDA does not allow for use of different registered trademarks to market the Licensed Product in the Collaborative Fields, then the Licensed Product shall be deemed a Transplant Branded Product for the U.S. Territory only for so long as the Licensed Product has received Regulatory Approval in the Transplant Field and not the Asthma Field.

**1.91 “Transplant Commercialization Plan”** shall have the meaning set forth in Section 6.1(b).

**1.92 “Transplant Co-Promotion Term”** shall have the meaning set forth in Section 6.4(b).

**1.93 “Transplant Development Plan”** shall have the meaning set forth in Section 4.1(b).

**1.94 “Transplant Field”** means the Transplant Indications.

**1.95 “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).

**1.96 “Transplant Joint Commercialization Committee” or “Transplant JCC”** shall have the meaning set forth in Section 3.18.

**1.97 “Transplant Joint Development Committee” or “Transplant JDC”** shall have the meaning set forth in Section 3.12.

**1.98 “Transplant Trademark”** shall have the meaning set forth in Section 13.1.

**1.99 “U.S.”** means the United States of America.

**1.100 “U.S. Territory”** means the U.S. and its territories and possessions.

**1.101 “Valid Claim”** means a claim in any unexpired and issued patent in the PDL Patents or Roche Patents that has not been disclaimed, revoked, or held invalid or unenforceable by a final unappealable decision of a court or government agency of competent jurisdiction.

**1.102 “Zenapax Trademark”** means the trademark “Zenapax®,” and all trademark registrations and applications therefor, and all goodwill associated therewith.

ARTICLE 2

LICENSES AND OPTION

2.1 Grants to Roche.

(a) U.S. Territory

**(i) Technology License.** Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche a co-exclusive license (together with PDL), under the PDL Technology, to develop Licensed Products in the Collaborative Fields with respect to the U.S. Territory and the European Union, in accordance with the Asthma Development Plan and Transplant Development Plan, and to import and use Licensed Products for such purposes. The foregoing licenses include the right to perform Development outside the U.S. Territory and European Union in accordance with the Asthma Development Plan and Transplant Development Plan with respect to any Licensed Product, solely in order to obtain Regulatory Approval of such Licensed Product in the Collaborative Fields in the U.S. Territory or the European Union.

**(ii) Asthma Promotion Right.** Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche a co-exclusive (together with PDL), non-transferable (subject to Section 19.1) right to Promote and Detail Licensed Products in the Asthma Field in the U.S. Territory, in accordance with applicable law and the Asthma Commercialization Plan. If not sooner terminated pursuant to Article 17, such right shall terminate at the end of the Asthma Co-Promotion Term.

**(iii) Commercialization in the Transplant Field.**

**(1)** Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche the exclusive (even as to PDL) license, under the PDL Technology, to (a) offer for sale and sell Transplant Branded Products in the Transplant Field in the U.S. Territory in accordance with the Transplant Commercialization Plan, and (b) use and import Transplant Branded Products in the Transplant Field in the U.S. Territory for such purposes; provided, however, that the license granted under this Section 2.1(a)(iii)(1) with respect to the Queen Patents shall be nonexclusive. If not sooner terminated pursuant to Article 17, such license shall terminate at the end of the Transplant Co-Promotion Term or, if there is no Transplant Trademark and Regulatory Approval of the Licensed Product in the Asthma Field in the U.S. Territory is received prior to the end of the Transplant Co-Promotion Term, upon such Regulatory Approval.

(2) Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche, the exclusive (except to the extent of PDL's right to co-promote pursuant to Sections 2.2(b) and 6.2(c)), right and license to use the PDL Trademarks solely in connection with the marketing, promotion, detailing, offering for sale and sale of Transplant Branded Products in the Transplant Field in the U.S. Territory in accordance with the Transplant Commercialization Plan. If not sooner terminated pursuant to Article 17, such right and license shall terminate at the end of the Transplant Co-Promotion Term or, if there is no Transplant Trademark and Regulatory Approval of the Licensed Product in the Asthma Field in the U.S. Territory is received prior to the end of the Transplant Co-Promotion Term, upon such Regulatory Approval.

(3) Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche a co-exclusive (together with PDL), non-transferable (subject to Section 19.1) right to Promote and Detail Licensed Products (other than Transplant Branded Products) in the Transplant Field in the U.S. Territory, in accordance with applicable law and the Transplant Commercialization Plan. If not sooner terminated pursuant to Article 17, such right shall terminate at the end of the Transplant Co-Promotion Term.

(iv) **Sublicenses.** The rights granted to Roche in Sections 2.1(a)(i), 2.1(a)(ii) and 2.1(a)(iii) are sublicensable, without the prior written consent of PDL, only to Roche's Affiliates, provided, however, that the license granted to Roche in Section 2.1(a)(iii)(2) is sublicensable only to a sublicensee of the licenses set forth in Section 2.1(a)(iii)(1).

**(b) ROW Territory**

(i) **Technology License.** Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche and Roche's Affiliates the exclusive (even as to PDL) license, under the PDL Technology, to (1) develop Licensed Products in the Collaborative Fields in the ROW Territory (other than the European Union), (2) use and import Licensed Products in the Collaborative Fields in the ROW Territory (other than the European Union) for such Development purposes, (3) offer for sale and

sell Licensed Products in the Collaborative Fields in the ROW Territory, (4) use and import Licensed Products in the Collaborative Fields in the ROW Territory for such commercialization purposes; provided, however, that the license granted under this Section 2.1(b)(i) with respect to the Queen Patents shall be nonexclusive. The foregoing licenses include the right to perform Development in the European Union and the U.S. Territory in accordance with the Asthma Development Plan and Transplant Development Plan with respect to any Licensed Product, solely in order to obtain Regulatory Approval of such Licensed Product in the Collaborative Fields in the ROW Territory (other than the European Union). Notwithstanding the exclusivity of the foregoing license, PDL retains the right to perform Development activities in the ROW Territory (other than the European Union) with respect to the Licensed Product solely in order to obtain Regulatory Approval of the Licensed Product in the Collaborative Fields in the U.S. Territory or the European Union, in accordance with the Development Plan or as approved by the JSC.

**(ii) Trademark License.** Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche and Roche's Affiliates, the exclusive right and license to use the PDL Trademarks solely in connection with the development, use, marketing, promotion, detailing, offering for sale and sale of Licensed Products in the Collaborative Fields in the ROW Territory; provided, however, that Roche's license under this Section 2.1(b)(ii) shall be co-exclusive (together with PDL) with respect to Development in the European Union. PDL agrees to execute any required documents, to provide on request any required records, and otherwise to cooperate fully with Roche as may be necessary to accomplish the recordation of the license set forth in this Section 2.1(b)(ii) in any jurisdiction in the ROW Territory that Roche seeks such recordation. In such event, the documented expenses for recordation (not including any PDL internal costs) will be borne by Roche.

**(iii) Sublicenses.** The licenses granted to Roche and its Affiliates in Sections 2.1(b)(i) and 2.1(b)(ii) are sublicensable only with the prior written consent of PDL, which shall not be unreasonably withheld. It shall be deemed reasonable for PDL to withhold consent with respect to sublicense by Roche of the

license set forth in Section 2.1(b)(i) to any other entity that is [\*\*\*\*] [\*\*\*\*] in the [\*\*\*\*] for which the Parties are selling, developing or planning to develop the Licensed Product. Roche and its Affiliates may use Third Party distributors in the ROW Territory in accordance with their customary practices. The license granted to Roche in Section 2.1(b)(ii) is sublicensable only to a sublicensee of the licenses set forth in Section 2.1(b)(i).

## 2.2 Grants to PDL.

**(a) Technology License.** Subject to the terms and conditions of this Agreement, Roche hereby grants to PDL, under the Roche Technology, Roche Inventions, and all patents claiming Roche Inventions, (i) a co-exclusive license (together with Roche) to develop in accordance with the Asthma Development Plan and Transplant Development Plan and use Licensed Products in the Collaborative Fields with respect to U.S. Territory and the European Union, (ii) a co-exclusive license (together with Roche) to import Licensed Products in the Collaborative Fields into the European Union for such Development purposes, (iii) an exclusive license to import, offer for sale and sell Licensed Products in the Collaborative Fields in the U.S. Territory, and (iv) an exclusive license to make Licensed Products in the Collaborative Fields in the Territory. The foregoing licenses include the right to perform Development outside the U.S. Territory and the European Union in accordance with the Development Plan with respect to any Licensed Product solely in order to obtain Regulatory Approval of such Licensed Product in the Collaborative Fields in the U.S. Territory or the European Union. The license granted to PDL in Section 2.2(a)(i) shall, with respect to the U.S. Territory, automatically convert from a co-exclusive license to an exclusive license: (i) at the end of the Asthma Co-Promotion Term (but only in the Asthma Field); and (ii) at the end of the Transplant Co-Promotion Term (but only in the Transplant Field). If there is a

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Transplant Branded Product and a Transplant Trademark, then the license set forth in Section 2.2(a)(iii) shall not go into effect with respect to the Transplant Field until the end of the Transplant Co-Promotion Term. If there is a Transplant Branded Product but no Transplant Trademark, then the license set forth in Section 2.2(a)(iii) shall not go into effect with respect to the Transplant Field until the earlier of (1) Regulatory Approval in the U.S. Territory for Licensed Product in the Asthma Field or (2) the end of the Transplant Co-Promotion Term. Roche hereby covenants that it and its Affiliates will not grant to any Third Party a license that overlaps with the scope of the licenses granted to PDL under Sections 2.2(a)(i) and 2.2(a)(ii) and that it and its Affiliates will not practice the Roche Technology and Roche Inventions within the scope of the licenses granted to PDL under Sections 2.2(a)(i) and 2.2(a)(ii) on behalf of or for the benefit of any Third Party.

**(b) Transplant Promotion Right.** Subject to the terms and conditions of this Agreement, Roche hereby grants to PDL a co-exclusive (together with Roche), non-transferable (subject to Section 19.1) option to Promote and Detail Transplant Branded Products in the Transplant Field in the U.S. Territory, in accordance with applicable law and the Transplant Commercialization Plan. If not sooner terminated pursuant to Article 17, such option shall terminate at the end of the Transplant Co-Promotion Term or, if there is no Transplant Trademark and Regulatory Approval in the U.S. Territory in the Asthma Field is received prior to the end of the Transplant Co-Promotion Term, upon such Regulatory Approval.

**(c) Additional Licenses to Roche Inventions.** Subject to the terms and conditions of this Agreement, Roche hereby grants to PDL, under the Roche Inventions and all patents claiming Roche Inventions (i) a co-exclusive license to develop, make, use, import, offer for sale and sell products containing antibodies that bind to IL-2R (other than Nutley Dac, Licensed Products, and Excluded Products) in the Collaborative Fields in the Territory; and (ii) a co-exclusive license to develop, make, use, import, offer for sale, and sell Licensed Products and other products containing antibodies that bind to IL-2R (other than Nutley Dac and Excluded Products) outside the Collaborative Fields in the Territory. For the purpose of this Section 2.2(c), the term

**“Excluded Products”** shall have the meaning given to such term in the Worldwide Daclizumab Agreement. Roche hereby covenants that it and its Affiliates will not grant to any Third Party a license that overlaps with the scope of the licenses granted to PDL under Section 2.2(c)(i) and Section 2.2(c)(ii) and that it and its Affiliates will not practice the Roche Inventions within the scope of the licenses granted to PDL under Sections 2.2(c)(i) and 2.2(c)(ii) on behalf of or for the benefit of any Third Party.

**(d) Sublicenses.** Prior to the end of the Asthma Co-Promotion Term, the license granted to PDL in Section 2.2(a) is sublicensable in the Asthma Field: (i) without the prior written consent of Roche, only to PDL’s Affiliates; and (ii) with Roche’s consent (such consent not to be unreasonably withheld) to subcontractors performing, on behalf of PDL, PDL’s obligations under, and consistent with, the Asthma Development Plan or the Asthma Commercialization Plan. After the Asthma Co-Promotion Term, PDL may grant sublicenses in the Asthma Field under the licenses granted to PDL in Section 2.2(a) without the consent of Roche. Prior to the end of the Transplant Co-Promotion Term, the licenses granted to PDL in Sections 2.2(a) and 2.2(b) are sublicensable in the Transplant Field: (i) without the prior written consent of Roche, only to PDL’s Affiliates; and (ii) with Roche’s consent (such consent not to be unreasonably withheld) to subcontractors performing, on behalf of PDL, PDL’s obligations under, and consistent with, the Transplant Development Plan or the Transplant Commercialization Plan. After the Transplant Co-Promotion Term, PDL may grant sublicenses in the Transplant Field under the licenses granted to PDL in Section 2.2(a) without the consent of Roche. PDL may grant sublicenses under the license granted to PDL in Section 2.2(c) without the consent of Roche.

### **2.3 Negative Covenants**

**(a)** Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to knowingly use or practice, directly or indirectly, any PDL Know-How, PDL Patents or PDL Trademarks for any purposes other than those expressly permitted by this Agreement or any other written agreements between the Parties which are currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties.

(b) PDL hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to: knowingly use or practice, directly or indirectly, any Roche Know-How, Roche Patents or Roche Inventions for any purposes other than those expressly permitted by this Agreement or any other written agreements between the Parties which are currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties.

(c) Subject to the terms and conditions of any grant of existing rights under the Queen Patents with respect to Licensed Products in the Collaborative Fields on or after the Effective Date, PDL hereby covenants that it shall not, nor shall it cause any Affiliate to, grant to any Third Party a license under the Queen Patents to: (1) develop Licensed Products in the Collaborative Fields in the ROW Territory (other than the European Union), (2) use and import Licensed Products in the Collaborative Fields in the ROW Territory (other than the European Union) for such Development purposes, (3) offer for sale and sell Licensed Products in the Collaborative Fields in the ROW Territory, (4) use and import Licensed Products in the Collaborative Fields in the ROW Territory for such commercialization purposes.

#### 2.4 [\*\*\*\*] Daclizumab.

(a) For the purpose of keeping Roche informed as to the status and results of [\*\*\*\*] involving [\*\*\*\*] Daclizumab, PDL's presentation of an update on such matters shall be specifically listed as an agenda item for [\*\*\*\*] Asthma JDC meetings and [\*\*\*\*] Transplant JDC meetings per year.

(b) When PDL first obtains [\*\*\*\*] in the Asthma Field from a [\*\*\*\*] for a

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product containing [\*\*\*\*] Daclizumab, PDL shall notify Roche in writing and provide a detailed summary of such data to Roche. Upon Roche's request, Roche may [\*\*\*\*] on [\*\*\*\*] Daclizumab in the Asthma Field for up to [\*\*\*\*] after Roche's receipt of such summary, and PDL shall reasonably cooperate with Roche with respect to such [\*\*\*\*] activities. Upon Roche's further request, PDL and Roche shall [\*\*\*\*]. If the Parties do not [\*\*\*\*], then PDL [\*\*\*\*], provided that PDL does not [\*\*\*\*] with respect to the [\*\*\*\*] of [\*\*\*\*]. If Roche has previously provided [\*\*\*\*] to PDL to [\*\*\*\*] and the Parties have not [\*\*\*\*], then within [\*\*\*\*] of [\*\*\*\*], PDL shall [\*\*\*\*]. Roche shall have [\*\*\*\*] following receipt to notify PDL [\*\*\*\*] that [\*\*\*\*]. For clarity, PDL shall not [\*\*\*\*] until the earlier of: (i) expiration of the [\*\*\*\*] period after Roche's receipt of PDL's summary of [\*\*\*\*], without Roche [\*\*\*\*], and (ii) expiration of the [\*\*\*\*] after Roche's receipt of such summary, without [\*\*\*\*]n the [\*\*\*\*].

(c) When PDL first obtains [\*\*\*\*] in the Transplant Field from a [\*\*\*\*] for a product containing [\*\*\*\*] Daclizumab, PDL shall notify Roche in writing and provide a detailed summary of such data to Roche. Upon Roche's request, Roche may [\*\*\*\*] on [\*\*\*\*] Daclizumab in the Transplant Field for up to [\*\*\*\*] after Roche's receipt of such summary, and PDL shall reasonably cooperate with Roche with respect to [\*\*\*\*] activities. Upon Roche's further request, PDL and Roche shall [\*\*\*\*]. If the Parties do not [\*\*\*\*], then PDL is [\*\*\*\*], provided that PDL does not [\*\*\*\*] with respect to the [\*\*\*\*] of such [\*\*\*\*]. If Roche has previously provided [\*\*\*\*] to PDL to [\*\*\*\*] and the Parties have not [\*\*\*\*], then within [\*\*\*\*] of [\*\*\*\*], PDL shall [\*\*\*\*] [\*\*\*\*]. Roche shall have [\*\*\*\*] following receipt to notify PDL [\*\*\*\*] that [\*\*\*\*]. For clarity, PDL shall not [\*\*\*\*] until the earlier of: (i) expiration of the [\*\*\*\*] period after Roche's receipt of PDL's summary [\*\*\*\*], without Roche r[\*\*\*\*], and (ii) expiration of the [\*\*\*\*] after Roche's receipt of such summary, without [\*\*\*\*] in the [\*\*\*\*].

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**2.5 Collaborative Fields.** This Agreement is intended to govern the Parties' development and commercialization of the Licensed Product in both the Asthma Field and the Transplant Field (together, the "**Collaborative Fields**"). Notwithstanding the foregoing, to the extent that the Parties' rights in either the Asthma Field or the Transplant Field are terminated pursuant to various provisions of Article 17, the term "Collaborative Fields" shall be deemed to exclude the field (i.e., Asthma Field or Transplant Field) with respect to which the rights are so terminated.

**ARTICLE 3[\*\*\*\*]**

**GOVERNANCE**

**3.1 Joint Steering Committee; Minutes.** Prior to the Amendment Effective Date, PDL and Roche formed a Joint Steering Committee ("**JSC**") consisting of three [\*\*\*\*] representatives from PDL and [\*\*\*\*] representatives from Roche. Each Party may replace its JSC representatives at any time upon prior written notice to the other Party. [\*\*\*\*] designated the first chairperson of the JSC, whose term shall run until [\*\*\*\*], and the right to designate the chairperson of the JSC shall thereafter alternate between the Parties on a calendar year basis. The JSC chairperson shall be responsible for providing an agenda for each JSC meeting at least fifteen (15) days in advance of such meeting. The Party not chairing the JSC shall prepare written draft minutes of all JSC meetings in reasonable detail and distribute such draft minutes to all members of the JSC for comment and review within thirty (30) days after the relevant meeting. The members of the JSC shall have fifteen (15) days to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute revised minutes to all members of the JSC for their final review and approval within forty-five (45) days of the relevant meeting.

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**3.2 Meetings of the JSC.** The JSC shall meet at least [\*\*\*\*], on such dates and at such times as agreed to by Roche and PDL, with all scheduled in-person meetings to alternate between Fremont, California and a Roche site to be designated by Roche prior to such meeting, or at such other locations as determined by the Joint Steering Committee. Meetings may be held by audio- or videoconference with the consent of each Party. The JSC shall hold at least [\*\*\*\*] per calendar year in person; provided, however, if such [\*\*\*\*] not reasonably possible, then the JSC may meet by videoconference in lieu of such [\*\*\*\*]. Each Party may permit such visitors to attend meetings of the Joint Steering Committee. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating.

**3.3 Responsibilities of the JSC.** The JSC shall have the responsibility and authority to:

(a) define and oversee the implementation of the strategy for developing and commercializing Licensed Products in the Collaborative Fields;

(b) review the efforts of the Asthma JDC, Transplant JDC and Transplant JCC (as appropriate) in the conduct of the development and commercialization programs for Licensed Products in the Collaborative Fields;

(c) review and revise, as required, the budget forecasts for the Asthma Development Plan, Asthma Commercialization Plan, Transplant Development Plan, and Transplant Commercialization Plan, including any [\*\*\*\*] with respect to [\*\*\*\*], all in accordance with the schedule set forth in Exhibit A.

(d) review and approve the Asthma Commercialization Plan, Transplant Commercialization Plan and any proposed amendments or updates to the

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(e) review and approve the [\*\*\*\*] and [\*\*\*\*] of the [\*\*\*\*] for Licensed Products in the Collaborative Fields, and the commercialization of Licensed Products in the Collaborative Fields in the U.S. Territory; and review the commercialization of Licensed Products in the Collaborative Fields in the ROW Territory, including the [\*\*\*\*] of [\*\*\*\*] and such [\*\*\*\*] and the [\*\*\*\*] of the Licensed Products in the Collaborative Fields;

(f) create and oversee the Joint Patent Committee which will address intellectual property issues with respect to Licensed Products in the Collaborative Fields;

(g) create and oversee the Joint Finance Committee which will address [\*\*\*\*] and related finance and accounting issues with respect to the Asthma Development Plan, Asthma Commercialization Plan, Transplant Development Plan, and Transplant Commercialization Plan;

(h) address disputes or disagreements arising in the Asthma JDC, Transplant JDC, Transplant JCC, JPC, or JFC;

(i) relax any deadlines and timeframes specified in this Article 3;

(j) select trademarks in accordance with Section 13.1;

(k) manage the implementation of sales tracking in accordance with Section 10.3(b);

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(l) prior to the filing of the second Drug Approval Application (at least one of which, despite the definition in Section 1.27, shall be for an indication outside the Collaborative Fields) establish a mechanism (pursuant to Section 7.6(e)) for use in the event of Cross-Field Sales; and

(m) perform such other functions as the Parties may agree in writing.

**3.4 Areas Outside the JSC's Authority.** The JSC shall have no authority other than that expressly set forth in Section 3.3 and, specifically, shall have no authority to amend this Agreement. The JSC shall have no authority to make any decisions that would commit a Party to incur an expense that it had not previously agreed to incur or that would increase any expenses a Party is otherwise responsible for, without obtaining the agreement of that Party as evidenced by written notice of approval by the appropriate internal decision-making bodies of that Party. No reference in this Agreement to the consent or approval of the JSC (or a subordinate body) shall be interpreted to diminish the requirement set forth in the preceding sentence. For clarity, each Party, by its entry into this Agreement, has agreed to pay [\*\*\*\*] of those expenses, to the extent incurred, that are set forth in the budget associated with the Asthma Development Plan as of the Amendment Effective Date and Transplant Development Plan as of the Amendment Effective Date.

### 3.5 JSC Decisions.

**(a) Consensus; Good Faith; Action Without Meeting.** The JSC shall decide all matters by [\*\*\*\*], with each Party [\*\*\*\*]. Consistent with Section 3.24, the members of the JSC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the JSC. Action that may be

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taken at a meeting of the Joint Steering Committee also may be taken without a meeting if a written consent setting forth the action so taken is signed by all members of the Joint Steering Committee.

**(b) Failure to Reach Consensus.** If the members of the JSC cannot come to consensus [\*\*\*\*] with respect to any matter over which the JSC has authority and responsibility, then the JSC shall submit the respective positions of the Parties with respect to such matter for discussion in good faith by the [\*\*\*\*]. If such [\*\*\*\*] are not able to mutually agree upon the resolution to such matter within [\*\*\*\*] of its submission to them, then PDL shall have the right to decide such matter in good faith, giving due consideration to the input of [\*\*\*\*] and the economic interests of both Parties under this Agreement, except that any decision that primarily pertains to (i) the sale and marketing of Licensed Products in the Collaborative Fields in the ROW Territory, (ii) the Development of Licensed Products in the Collaborative Fields [\*\*\*\*]that[\*\*\*\*], (iii) the determination of a [\*\*\*\*] in the Asthma Field for the purpose [\*\*\*\*] of [\*\*\*\*], (iv) selection or FDA approval of a Transplant Trademark or (v) [\*\*\*\*] during the Transplant Co-Promotion Term, shall be decided by [\*\*\*\*] in good faith, giving due consideration to the input of [\*\*\*\*] and the economic interests of both Parties under this Agreement. With regard to 3.5(b)(v), if there is a dispute regarding the scope of the [\*\*\*\*] not otherwise targeted by [\*\*\*\*], then [\*\*\*\*] shall have the right to decide such matter in good faith, giving due consideration to the input of [\*\*\*\*] and the economic interests of both Parties under this Agreement. Any dispute regarding the Parties' relative percentages of [\*\*\*\*] obligations in the Transplant Field pursuant to Section 6.2(c) shall be decided pursuant to Section 18.2. Notwithstanding the foregoing, any decision: (1) related to [\*\*\*\*] and [\*\*\*\*] in the Transplant Field, (2) to initiate a development program for [\*\*\*\*] for Licensed Products in a Collaborative Field, or (3) to select a vendor for such a [\*\*\*\*], shall be made [\*\*\*\*], and [\*\*\*\*] shall have the right to make such decision if the JSC and the

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Executive Officers fail to reach agreement. Any dispute related to the establishment or implementation of a reimbursement mechanism to be used in the event of Cross-Field Sales shall be decided pursuant to Section 18.2. Furthermore, nothing in this Section 3.5(b) shall be interpreted to limit Roche's rights under Section 17.7 as a result of a delay in Development in the Asthma Field.

**3.6 Asthma Joint Development Committee; Minutes.** Prior to the Amendment Effective Date, PDL and Roche formed an Asthma Joint Development Committee ("Asthma JDC") consisting of [\*\*\*\*] representatives from PDL and [\*\*\*\*] representatives from Roche, or such number(s) of representatives as set from time to time by the JSC. Each Party may replace its Asthma JDC representatives at any time upon prior written notice to the other Party. [\*\*\*\*] designated the first chairperson of the Asthma JDC, whose term shall run until [\*\*\*\*], and the right to designate the chairperson of the Asthma JDC shall thereafter alternate between the Parties on a calendar year basis. The Asthma JDC chairperson shall be responsible for providing an agenda for each Asthma JDC meeting at least fifteen (15) days in advance of such meeting. PDL shall prepare written draft minutes of all Asthma JDC meetings in reasonable detail and distribute such draft minutes to all members of the Asthma JDC for comment and review within thirty (30) days after the relevant meeting. The members of the Asthma JDC shall have fifteen (15) days to provide comments. PDL shall incorporate timely received comments and distribute revised minutes to all members of the Asthma JDC for their final review and approval within forty-five (45) days of the relevant meeting.

**3.7 Subcommittees.** The Asthma JDC shall have the right to establish subcommittees, which may include, but will not be limited, to the following: a [\*\*\*\*] subcommittee, a [\*\*\*\*] subcommittee, a [\*\*\*\*], a [\*\*\*\*], and a [\*\*\*\*].

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**3.8 Meetings of the Asthma JDC.** The Asthma JDC shall meet as frequently as members of the Joint Development Committee determine is required (but in no event, less frequently than [\*\*\*\*] [\*\*\*\*] following the Effective Date and [\*\*\*\*] thereafter), on such dates and at such times as agreed to by Roche and PDL, with all scheduled in-person meetings to alternate between Fremont, California and a Roche site to be designated by Roche prior to such meeting, or at such other locations as determined by the Asthma JDC. Meetings may be held by audio or video conference with the consent of each Party, provided that at least [\*\*\*\*] shall be held in person at locations to which both Parties have mutually consented. Each Party may permit such visitors to attend meetings of the Asthma Joint Development Committee as the Asthma Joint Development Committee determines. All out-of-pocket expenses incurred by a Party as a result of its participation in the Asthma JDC, to the extent not captured in the FTE rate set forth in Section 4.6(b) (which shall only apply to Asthma JDC and Transplant JDC members), shall be borne solely by such Party. Meetings of the Asthma JDC shall be effective only if at least [\*\*\*\*] of each Party are present or participating.

**3.9 Responsibilities of the Asthma JDC.** The Asthma JDC shall have the responsibility and authority to:

(a) oversee all aspects of the execution of the JSC-approved Development and commercialization of Licensed Products in the Asthma Field;

(b) review and comment upon, and where appropriate, recommend to the JSC for approval, all updates or amendments to the Asthma Development Plan thereto, in accordance with Sections 4.1 and 4.2;

(c) review and comment upon, and where appropriate, recommend to the JSC for approval, the Asthma Commercialization Plan and amendments and updates thereto, in accordance with Section 6.1;

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- (d) monitor the Development of Licensed Products in the Asthma Field in the Territory against the applicable Asthma Development Plan;
- (e) review the overall strategy for and design of all clinical trials and other studies conducted under the Asthma Development Plan;
- (f) discuss the requirements for Regulatory Approval in the Asthma Field in applicable countries in the Territory and oversee and coordinate regulatory matters in the Asthma Field with respect to Licensed Products in the Territory;
- (g) establish subcommittees pursuant to Section 3.7, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;
- (h) oversee and approve a multi-year estimate of supply requirements with respect to the Asthma Field to be used for capacity planning purposes;
- (i) present disputes not resolvable by the Asthma JDC to the JSC for resolution;
- (j) discuss Roche Development activities in the Asthma Field in the ROW Territory;
- (k) select CROs and other non-manufacturing vendors needed to carry out the Asthma Development Plan, except for any CRO or other non-manufacturing vendor whose agreement with the relevant Party has, or is anticipated to have, [\*\*\*\*];
- (l) propose and discuss possible manufacturing vendors to carry out activities associated with clinical or commercial supply of the Licensed Product (provided that [\*\*\*\*] alone shall be responsible for ultimately selecting such manufacturing vendors);

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(m) perform the functions set forth in Sections 1.20, 4.6(a), 4.6(c), 5.1(a), 6.3(c), and 8.1(a) and Exhibit D; and

(n) perform such other functions as the Parties may agree in writing.

**3.10 Areas Outside the Asthma JDC's Authority.** The Asthma JDC shall have no authority other than that expressly set forth in Section 3.9.

**3.11 Asthma JDC Decisions.**

**(a) Consensus; Good Faith; Action Without Meeting.** The Asthma JDC shall decide all matters by consensus, with each Party having one collective vote. Consistent with Section 3.24, the members of the Asthma JDC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the Asthma JDC. Action that may be taken at a meeting of the Asthma JDC also may be taken without a meeting if a written consent setting forth the action so taken is signed by all of the Asthma JDC members.

**(b) Failure to Reach Consensus.** In the event that the members of the Asthma JDC cannot come to consensus within thirty (30) days with respect to any matter over which the Asthma JDC has authority and responsibility, the Asthma JDC shall submit the respective positions of the Parties with respect to such matter to the JSC for decision.

**3.12 Transplant Joint Development Committee; Minutes.** Within [\*\*\*\*], PDL and Roche shall form a Transplant Joint Development Committee ("**Transplant JDC**") consisting of [\*\*\*\*] representatives from PDL and [\*\*\*\*] representatives from Roche, or such number(s) of representatives as set from time to time by the JSC. Each Party may

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replace its Transplant JDC representatives at any time upon prior written notice to the other Party. [\*\*\*\*] shall have the right to designate the first chairperson of the Transplant JDC, whose term shall run until [\*\*\*\*], and such right shall thereafter alternate between the Parties on a calendar year basis. The Transplant JDC chairperson shall be responsible for providing an agenda for each Transplant JDC meeting at least fifteen (15) days in advance of such meeting. PDL and Roche shall take alternating turns preparing written draft minutes of Transplant JDC meetings in reasonable detail and distributing such draft minutes to all members of the Transplant JDC for comment and review within thirty (30) days after the relevant meeting. The members of the Transplant JDC shall have fifteen (15) days to provide comments. The Party that prepared such draft minutes shall incorporate timely received comments and distribute revised minutes to all members of the Transplant JDC for their final review and approval within forty-five (45) days of the relevant meeting.

**3.13 Subcommittees.** The Transplant JDC shall have the right to establish subcommittees, which may include, but will not be limited, to the following: a [\*\*\*\*]subcommittee, a [\*\*\*\*]subcommittee, and a [\*\*\*\*]subcommittee.

**3.14 Meetings of the Transplant JDC.** The Transplant JDC shall meet as frequently as members of the Transplant Joint Development Committee determine is required (but in no event, [\*\*\*\*]), on such dates and at such times as agreed to by Roche and PDL, with all scheduled in-person meetings to alternate between Fremont, California and a Roche site to be designated by Roche prior to such meeting, or at such other locations as determined by the Transplant JDC. Meetings may be held by audio or video conference with the consent of each Party, provided that at least [\*\*\*\*] shall be held in person at locations to which both Parties have mutually consented. Each Party

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may permit such visitors to attend meetings of the Transplant Joint Development Committee as the Transplant Joint Development Committee determines. All out-of-pocket expenses incurred by a Party as a result of its participation in the Transplant JDC, to the extent not captured in the FTE rate set forth in Section 4.6(b) (which shall only apply to Asthma JDC members and Transplant JDC members), shall be borne solely by such Party. Meetings of the Transplant JDC shall be effective only if at [\*\*\*\*] of each Party are present or participating.

**3.15 Responsibilities of the Transplant JDC.** The Transplant JDC shall have the responsibility and authority to:

(a) oversee all aspects of the execution of the JSC-approved Development of Licensed Products in the Transplant Field;

(b) review and comment upon, and where appropriate, recommend to the JSC for approval, all updates or amendments to the Transplant Development Plan thereto, in accordance with Sections 4.1 and 4.2;

(c) monitor the Development of Licensed Products in the Territory in the Transplant Field against the applicable Transplant Development Plan;

(d) review the overall strategy for and design of all clinical trials and other studies conducted under the Transplant Development Plan;

(e) discuss the requirements for Regulatory Approval in the Transplant Field in applicable countries in the Territory and oversee and coordinate regulatory matters in the Transplant Field with respect to Licensed Products in the Territory;

(f) establish subcommittees pursuant to Section 3.13, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;

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(g) prior to the formation of the Transplant JCC, oversee and approve a multi-year estimate of supply requirements with respect to the Transplant Field to be used for capacity planning purposes;

(h) present disputes not resolvable by the Transplant JDC to the JSC for resolution;

(i) discuss Roche Development activities in the Transplant Field in the ROW Territory;

(j) select CROs and other non-manufacturing vendors needed to carry out the Transplant Development Plan, except for any CRO or other non-manufacturing vendor whose agreement with the relevant Party has, or is anticipated to have, [\*\*\*\*];

(k) propose and discuss possible manufacturing vendors to carry out activities associated with clinical supply of the Licensed Product (provided that [\*\*\*\*] alone shall be responsible for ultimately selecting such manufacturing vendors);

(l) perform the functions set forth in Sections 4.6(a), 4.6(c), 5.1(b), and 8.1(a); and

(m) perform such other functions as the Parties may agree in writing.

**3.16 Areas Outside the Transplant JDC's Authority.** The Transplant JDC shall have no authority other than that expressly set forth in Section 3.15.

### **3.17 Transplant JDC Decisions.**

(a) [\*\*\*\*]; **Good Faith; Action Without Meeting.** The Transplant JDC shall decide all matters [\*\*\*\*], with each Party having [\*\*\*\*]. Consistent with Section

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3.24, the members of the Transplant JDC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the Transplant JDC. Action that may be taken at a meeting of the Transplant JDC also may be taken without a meeting if a written consent setting forth the action so taken is signed by all of the Transplant JDC members.

(b) [\*\*\*\*]. If the members of the Transplant JDC cannot [\*\*\*\*] within [\*\*\*\*] with respect to any matter over which the Transplant JDC has authority and responsibility, then the Transplant JDC shall submit the respective positions of the Parties with respect to such matter to the JSC for decision.

**3.18 Transplant Joint Commercialization Committee; Minutes.** At least [\*\*\*\*] to the anticipated commencement of the first Phase III Trial of the Licensed Product for the Transplant Field, PDL and Roche shall form a Transplant Joint Commercialization Committee (“**Transplant JCC**”) consisting of [\*\*\*\*] representatives from PDL and [\*\*\*\*] representatives from Roche, or such number(s) of representatives as set from time to time by the JSC. Each Party may replace its Transplant JCC representatives at any time upon prior written notice to the other Party. [\*\*\*\*] shall have the right to designate the first chairperson of the Transplant JCC, whose term shall run until [\*\*\*\*] of the first full calendar year in which the Transplant JCC is formed. Thereafter, such right shall alternate between the Parties on a calendar year basis. The Transplant JCC chairperson shall be responsible for providing an agenda for each Transplant JCC meeting at least fifteen (15) days in advance of such meeting. PDL and Roche shall take alternating turns preparing written draft minutes of Transplant JCC meetings in reasonable detail and distributing such draft minutes to all members of the Transplant JCC for comment and review within thirty (30) days after the relevant

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meeting. The members of the Transplant JCC shall have fifteen (15) days to provide comments. The Party that prepared such draft minutes shall incorporate timely received comments and distribute revised minutes to all members of the Transplant JCC for their final review and approval within forty-five (45) days of the relevant meeting.

**3.19 Subcommittees.** The Transplant JCC shall have the right to establish subcommittees.

**3.20 Meetings of the Transplant JCC.** The Transplant JCC shall meet as frequently as members of the Joint Commercialization Committee determine is required (but in no event, [\*\*\*\*]), on such dates and at such times as agreed to by Roche and PDL, with all scheduled in-person meetings to alternate between Fremont, California and a Roche site to be designated by Roche prior to such meeting, or at such other locations as determined by the Transplant JCC. Meetings may be held by audio or video conference with the consent of each Party, provided that at [\*\*\*\*] shall be held in person at locations to which both Parties have mutually consented. Each Party may permit such visitors to attend meetings of the Joint Commercialization Committee as the Joint Commercialization Committee determines. All out-of-pocket expenses incurred by a Party as a result of its participation in the Transplant JCC shall be borne solely by such Party. Meetings of the Transplant JCC shall be effective only if at [\*\*\*\*] of each Party are present or participating.

**3.21 Responsibilities of the Transplant JCC.** The Transplant JCC shall have the responsibility and authority to:

(a) oversee all aspects of the execution of the JSC-approved commercialization of Licensed Products in the Transplant Field including Detailing, Promotion and Medical Activities;

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(b) review and comment upon, and where appropriate, recommend to the JSC for approval, the Transplant Commercialization Plan and amendments and updates thereto, in accordance with Section 6.1;

(c) establish subcommittees pursuant to Section 3.19, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;

(d) oversee and approve a multi-year estimate of supply requirements with respect to the Transplant Field to be used for capacity planning purposes;

(e) present disputes not resolvable by the Transplant JCC to the JSC for resolution;

(f) discuss ROW Commercialization Activities in the Transplant Field;

(g) propose and discuss possible manufacturing vendors to carry out activities associated with commercial supply of the Licensed Product (provided that PDL alone shall be responsible for ultimately selecting such manufacturing vendors);

(h) specify in detail each Party's obligations, consistent with Sections 6.1 through 6.5, with respect to Licensed Product Promotion and Detailing in the Transplant Field in the U.S. Territory during the Transplant Co-Promotion Term;

(i) perform the functions set forth in Sections 1.20, 6.2(c), and 6.3(c); and

(j) perform such other functions as the Parties may agree in writing.

**3.22 Areas Outside the Transplant JCC's Authority.** The Transplant JCC shall have no authority other than that expressly set forth in Section 3.21.

### 3.23 Transplant JCC Decisions.

(a) [\*\*\*\*]; **Good Faith; Action Without Meeting.** The Transplant JCC shall decide all matters [\*\*\*\*], with each Party having [\*\*\*\*]. Consistent with Section 3.24, the members of the Transplant JCC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the Transplant JCC. Action that may be taken at a meeting of the Transplant JCC also may be taken without a meeting if a written consent setting forth the action so taken is signed by all of the Transplant JCC members.

(b) **Failure to Reach [\*\*\*\*].** If the members of the Transplant JCC cannot come to consensus within [\*\*\*\*] with respect to any matter over which the Transplant JCC has authority and responsibility, then the Transplant JCC shall submit the respective positions of the Parties with respect to such matter to the JSC for decision.

**3.24 Operating Principles.** The deliberations and decision-making of the JSC, Asthma JDC, Transplant JDC, Transplant JCC, JPC, JFC and any subcommittee established by the Asthma JDC, Transplant JDC or Transplant JCC shall be in accordance with the following operating principles:

(a) Time is of the essence in addressing the market for Licensed Products in the Collaborative Fields.

(b) The Parties' mutual objective is to maximize the clinical and commercial success of the Licensed Products in the Collaborative Fields, consistent with sound and ethical business and scientific practices.

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ARTICLE 4

DEVELOPMENT

**4.1 Development Plans.**

(a) Development in the Asthma Field with respect to the U.S. Territory and the European Union shall be governed by an asthma development plan (“**Asthma Development Plan**”), which shall set forth all anticipated Development activities and timelines for obtaining, maintaining, or expanding (to the extent mutually agreed) Regulatory Approval in such countries or jurisdictions, allocate responsibility for carrying out such activities between PDL and Roche (including the anticipated minimum and maximum number of FTEs to be expended by each Party on Development in the Asthma Field with respect to the U.S. Territory and the European Union on a quarterly basis), include an associated twelve (12) month development budget, and specify the extent to which each Party is anticipated to use internal or external (i.e. subcontractors) resources to fulfill its obligations. Prior to the Amendment Effective Date, the Parties agreed to an initial Asthma Development Plan, and a copy of the Asthma Development Plan in existence of the Effective Date was attached to the Original Asthma Agreement as Exhibit D. The Asthma Development Plan has subsequently been amended by the Parties in accordance with the procedures set forth in the Original Asthma Agreement.

(b) Development in the Transplant Field with respect to the U.S. Territory and the European Union shall be governed by a transplant development plan (“**Transplant Development Plan**”), which shall set forth all anticipated Development activities in the Transplant Field and [\*\*\*\*]. As of the Amendment Effective Date, the Parties have agreed to an initial Transplant Development Plan and have attached such initial Transplant Development Plan to a [\*\*\*\*] between the Parties dated as of the

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Amendment Effective Date. The Parties anticipate that promptly following the Amendment Effective Date and the formation of the Transplant JDC, the Transplant JDC shall review in detail the initial Development Plan [\*\*\*\*].

#### 4.2 Updating the Development Plans.

(a) The Asthma JDC may decide from time to time to propose for approval by the JSC updates to the Asthma Development Plan on a rolling basis as necessary to reflect changes in the progress, strategy, or costs of Development in the Asthma Field with respect to the U.S. Territory and the European Union. In any event, so long as the JSC intends to continue Development in the Asthma Field with respect to the U.S. Territory and the European Union, the Asthma JDC shall confirm, or propose for JSC approval an update to, the Asthma Development Plan in accordance with the schedule set forth in Exhibit A. Any proposed change shall, for the appropriate time period as determined by the JSC, set forth all anticipated Development activities in the Asthma Field and timelines for obtaining, maintaining, or expanding (to the extent mutually agreed) Regulatory Approval in the Asthma Field in such countries or jurisdictions, allocate responsibility for carrying out such activities between PDL and Roche (including a maximum number of FTEs to be expended by each Party on Development in the Asthma Field with respect to the U.S. Territory and the European Union on a quarterly basis), and include an associated development budget. All mutually agreed activities directed toward the expansion of Regulatory Approval in the Asthma Field with respect to the U.S. Territory and/or the European Union shall be included in the updated Asthma Development Plan. The JSC shall not approve an updated Asthma Development Plan that is inconsistent with or contradicts the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Asthma Development Plan and this Agreement, the terms of this Agreement shall prevail.

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(b) The Transplant JDC may decide from time to time to propose for approval by the JSC updates to the Transplant Development Plan on a rolling basis as necessary to reflect changes in the progress, strategy, or costs of Development in the Transplant Field with respect to the U.S. Territory and the European Union. In any event, so long as the JSC intends to continue Development in the Transplant Field with respect to the U.S. Territory and the European Union, the Transplant JDC shall confirm, or propose for JSC approval an update to, the Transplant Development Plan in accordance with the schedule set forth in Exhibit A. Any proposed change shall, for the appropriate time period as determined by the JSC, set forth all anticipated Development activities in the Transplant Field and timelines for obtaining, maintaining, or expanding (to the extent mutually agreed) Regulatory Approval in the Transplant Field in such countries or jurisdictions, allocate responsibility for carrying out such activities between PDL and Roche (including a maximum number of FTEs to be expended by each Party on Development in the Transplant Field with respect to the U.S. Territory and the European Union on a quarterly basis), and include an associated development budget. All mutually agreed activities directed toward the expansion of Regulatory Approval in the Transplant Field with respect to the U.S. Territory and/or the European Union shall be included in the updated Transplant Development Plan. The JSC shall not approve an updated Transplant Development Plan that is inconsistent with or contradicts the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Transplant Development Plan and this Agreement, the terms of this Agreement shall prevail.

**4.3 Goals of Joint Development.** The Parties hereby acknowledge and agree that the goals for joint development of Licensed Products hereunder will be to obtain and maintain Regulatory Approval for use in the Asthma Field and in the Transplant Field (and, in particular, in transplant maintenance) for the Licensed Product in the U.S. Territory and the European Union.

**4.4 Standards of Conduct.** Each Party shall perform, or shall ensure that its Third Party contractors perform, the Development activities for which it is responsible under the Development Plans or which it undertakes independent of the Development

Plans in good scientific manner and in compliance with applicable laws, rules and regulations. At each Asthma JDC meeting and each Transplant JDC meeting, each Party will keep the Asthma JDC or Transplant JDC (as appropriate) fully informed regarding the progress and results of such Party's Development activities in the appropriate field with respect to Licensed Products in the Territory.

**4.5 Diligent Development.** Each of the Parties shall use Diligent Efforts to achieve the goals set forth in Section 4.3 and to execute and carry out the Development Plans within the associated budget. Roche shall use Diligent Efforts to obtain Regulatory Approval for use in the Asthma Field for the Licensed Product in each country in the ROW Territory (other than the European Union). Roche's efforts in this regard shall be discussed with PDL through the Asthma JDC. Roche shall use Diligent Efforts to obtain Regulatory Approval for use in the transplant maintenance setting for the Licensed Product in each country in the ROW Territory (other than the European Union). Roche's efforts in this regard shall be discussed with PDL through the Transplant JDC. Roche from time to time (but in any event no less frequently than yearly) shall provide PDL with written updates discussing in reasonable detail its clinical trial activities and plans with respect to Development for all countries of the ROW Territory outside the European Union for which Roche has current or contemplated activities and plans. Each of the Parties agrees to cooperate with the other in carrying out the Development Plans.

**4.6 Development Expenses.**

(a) All Development Expenses shall be shared [\*\*\*\*] by the Parties as set forth in greater detail in Section 4.6(c). [\*\*\*\*] shall be responsible for [\*\*\*\*] of all Incremental Development Expenses. Any expenses incurred by a Party for Development activities that do not fall within the definitions of [\*\*\*\*] or [\*\*\*\*] shall be borne [\*\*\*\*] unless the Asthma JDC or Transplant JDC determines otherwise.

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(b) The Development Expenses of each Party that are attributable to Development activities performed by its employees pursuant to the Development Plan shall be calculated on an FTE basis. Each Party shall keep accurate records of its FTEs expended with respect to such Development activities, and shall report such FTE expenditures relating to Development in the Asthma Field to the Asthma JDC, and such FTE expenditures relating to Development in the Transplant Field to the Transplant JDC, in each case on a quarterly basis as part of the report filed pursuant to Section 4.6(c). All FTE expenditures shall be converted to Development Expenses at an initial rate of [\*\*\*\*], subject to [\*\*\*\*] effective as of [\*\*\*\*], beginning [\*\*\*\*].

(c) Each Party shall keep detailed records of the Development Expenses it incurs, including all supporting documentation for such expenses. Each Party shall keep such records for at least [\*\*\*\*] after the date that such expense was incurred. The Parties shall only share pursuant to this Section 4.6 those Development Expenses in the Transplant Field that are incurred on or after [\*\*\*\*]. For the purposes of the preceding sentence, Development Expenses attributable to the manufacture prior to [\*\*\*\*] of Licensed Products that are used on or after [\*\*\*\*] in a clinical trial or for formulation or other Development purposes in the Transplant Field shall be deemed expenses incurred at the time of such use. Within [\*\*\*\*] after the end of each calendar quarter, each Party shall provide to the JFC representatives of the other Party a report specifying and documenting, both in reasonable detail, such Party's Development Expenses in the Asthma Field and Development Expenses in the Transplant Field for such quarter. Within [\*\*\*\*] after the end of each calendar quarter, each Party shall provide (i) [\*\*\*\*] (ii) [\*\*\*\*]. Each Party shall promptly provide all additional information and documentation requested by the JFC, Asthma JDC or Transplant JDC to verify such Development Expenses. Within [\*\*\*\*] after the end of each such calendar quarter, each Party shall provide the other Party with one or more invoices (the format and

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accounting detail of such invoices to be agreed upon by the JFC) that together equal [\*\*\*\*] of such Party's Development Expenses in the Collaborative Fields for such quarter. Each Party shall pay to the other Party the amount specified in any invoice delivered under this Section 4.6(c) within [\*\*\*\*] of its receipt of such invoice, provided that each Party shall have the right to dispute in good faith through the JFC any Development Expenses not reasonably documented or supported by appropriate accounting detail. A Party shall be entitled to withhold only those amounts in dispute until verified or agreed upon by the JFC. In the event that the JFC does not reach consensus on a disputed amount, such dispute shall be referred to the JSC for resolution.

(d) To the extent a Party has previously paid a share of the cost of any item included in Development Expenses (including the cost of manufacturing clinical supply of Licensed Product), then that Party shall receive a credit for the amounts paid in the event that such item is subsequently used for development to obtain Regulatory Approval outside of the U.S. Territory and European Union or sold outside of the U.S. Territory (i.e., no double payments for amounts previously paid). For example and without limitation, if Roche desires to use, in a clinical trial intended to obtain Regulatory Approval in Japan, one hundred (100) [\*\*\*\*] of Licensed Product that were originally ordered for the purposes of a clinical trial intended to obtain Regulatory Approval in the U.S. Territory or the European Union and the cost of supplying such one hundred (100) [\*\*\*\*] was previously included as a Development Expense, then Roche shall pay PDL the amount it normally would for supplying such one hundred (100) [\*\*\*\*] less [\*\*\*\*] already paid by Roche with respect to the supply of such one hundred (100) [\*\*\*\*].

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REGULATORY

**5.1 Drug Approval Applications in U.S. Territory.**

**(a) Asthma Field.**

(i) Consistent with the Asthma Development Plan but subject to the remainder of this Section 5.1(a), PDL shall be responsible for preparing and filing Drug Approval Applications and seeking Regulatory Approvals for Licensed Products in the Asthma Field in the U.S. Territory. All such Drug Approval Applications shall be filed in the name of PDL, and PDL alone shall be responsible for all communications and other dealings with the regulatory agencies relating to the Licensed Products in the Asthma Field in the U.S. Territory. The Asthma JDC shall develop and implement a set of procedures for drafting and review of such Drug Approval Applications, which shall provide sufficient time for Roche to provide substantive comments and which shall be consistent with the procedures developed by the Transplant JDC for drafting and review of Drug Approval Applications pursuant to Section 5.1(b). Roche shall have the right of cross-reference to all such Drug Approval Applications for the purposes set forth in Section 5.2.

(ii) After receipt of any Regulatory Approval of the Drug Approval Application for the Licensed Product in the Asthma Field in the U.S. Territory hereunder, PDL shall retain primary responsibility for dealings with any regulatory agency with respect thereto, including filing all supplements and other documents with such agency with respect to such Drug Approval Application. Notwithstanding the foregoing, the reporting of all adverse drug experiences and other safety issues relating to Licensed Products shall be handled in accordance with Sections 5.3 and 5.5. In the

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event that any regulatory agency threatens or initiates any action to remove a Licensed Product from the market in the Asthma Field in the U.S. Territory during the Asthma Co-Promotion Term, PDL shall notify Roche of such communication within one business day of receipt by PDL. PDL agrees to provide Roche with a copy (which may be wholly or partly in electronic form) of all filings to regulatory agencies with respect to Licensed Products in the Asthma Field in the U.S. Territory that it makes hereunder. PDL shall provide Roche with reasonable advance notice of any scheduled meeting with a regulatory agency relating to Development and/or a Drug Approval Application in the Asthma Field in the U.S. Territory, and Roche shall have the right to observe and, if the Parties mutually agree in advance, participate in any such meeting. PDL shall promptly furnish Roche with copies of all material correspondence or minutes of material meetings with any regulatory agency in each case relating to Development and/or a Drug Approval Application in the Asthma Field in the U.S. Territory. As between the Parties, PDL shall be the legal and beneficial owner of all Drug Approval Applications and related approvals in the Asthma Field in the U.S. Territory.

**(b) Transplant Field.**

(i) Consistent with the Transplant Development Plan but subject to the remainder of this Section 5.1(b) and Section 5.1(c), Roche shall be responsible for preparing and filing Drug Approval Applications and seeking Regulatory Approvals for Licensed Products in the Transplant Field in the U.S. Territory. All such Drug Approval Applications shall be filed in the name of Roche, and Roche alone shall be responsible for all communications and other dealings with the regulatory agencies relating to the Licensed Products in the Transplant Field in the U.S. Territory. The Transplant JDC shall develop and implement a set of procedures for drafting and review of such Drug Approval Applications, which shall provide sufficient time for PDL to provide substantive comments and which shall be consistent with the procedures developed by the Asthma JDC for drafting and review of Drug Approval Applications pursuant to Section 5.1(a). PDL shall have the right of cross-reference to all such Drug Approval Applications.

**(ii)** After receipt of any Regulatory Approval of the Drug Approval Application for the Licensed Product in the Transplant Field in the U.S. Territory hereunder and until the end of the Transplant Co-Promotion Term, Roche shall retain primary responsibility for dealings with any regulatory agency with respect thereto, including filing all supplements and other documents with such agency with respect to such Drug Approval Application. Notwithstanding the foregoing, the reporting of all adverse drug experiences and other safety issues relating to Licensed Products shall be handled in accordance with Sections 5.3 and 5.5. In the event that any regulatory agency threatens or initiates any action to remove a Licensed Product from the market in the Transplant Field in the U.S. Territory during the Transplant Co-Promotion Term, Roche shall notify PDL of such communication within one business day of receipt by Roche. Roche agrees to provide PDL with a copy (which may be wholly or partly in electronic form) of all filings to regulatory agencies with respect to Licensed Products in the Transplant Field in the U.S. Territory that it makes hereunder. Roche shall provide PDL with reasonable advance notice of any scheduled meeting with a regulatory agency relating to Development and/or a Drug Approval Application in the Transplant Field in the U.S. Territory, and PDL shall have the right to observe and, if the Parties mutually agree in advance, participate in any such meeting. Roche shall promptly furnish PDL with copies of all material correspondence or minutes of material meetings with any regulatory agency in each case relating to Development and/or a Drug Approval Application in the Transplant Field in the U.S. Territory. As between the Parties until the end of the Transplant Co-Promotion Term (or, if there is no Transplant Trademark and Regulatory Approval in the U.S. Territory in the Asthma Field is received prior to the end of the Transplant Co-Promotion Term, then until such Regulatory Approval), Roche shall be the legal and beneficial owner of all Drug Approval Applications and related approvals in the Transplant Field in the U.S. Territory.

**(iii)** Immediately following the end of the Transplant Co-Promotion Term or, if there is no Transplant Trademark and Regulatory Approval in the U.S. Territory in the Asthma Field is received prior to the end of the Transplant Co-Promotion Term, then immediately following such Regulatory Approval, Roche shall assign to PDL its entire right, title and interest in and to all Drug Approval Applications

and related approvals in the Transplant Field in the U.S. Territory, and PDL shall be the legal and beneficial owner of such applications and approvals. Thereafter, Roche may keep a copy of such Drug Approval Applications and related approvals in the Transplant Field and, PDL shall have sole responsibility for (1) dealings with any regulatory agency with respect thereto, including filing all supplements and other documents with such agency with respect to such Drug Approval Application and (2) preparing and filing any additional Drug Approval Applications and seeking additional Regulatory Approvals for Licensed Products in the Transplant Field in the U.S. Territory and communicating with regulatory agencies with regard thereto. Notwithstanding the foregoing, the reporting of all adverse drug experiences and other safety issues relating to Licensed Products shall be handled in accordance with Sections 5.3 and 5.5. Roche shall have the right of cross-reference to all such Drug Approval Applications for the purposes set forth in Section 5.2.

**(c) Manufacture of Licensed Product.** PDL shall be responsible for obtaining appropriate regulatory approvals in the U.S. Territory for the manufacture of bulk Licensed Product by PDL or its Third Party manufacturer(s). Roche shall have the right of cross-reference to all such Drug Approval Applications for the purposes set forth in Sections 5.1(b)(i), 5.1(b)(ii) and 5.2.

#### **5.2 Drug Approval Applications in ROW Territory.**

**(a)** Roche shall be responsible for preparing and filing Drug Approval Applications and seeking Regulatory Approvals for Licensed Products in the Collaborative Fields in the ROW Territory. The Parties intend that such Drug Approval Applications will be comprised of the Drug Approval Application submitted to the FDA, plus such additional data and reports not required to be submitted to the FDA. All such Drug Approval Applications shall be filed in the name of Roche, and Roche alone shall be responsible for all communications and other dealings with the regulatory agencies relating to the Licensed Products in the Collaborative Fields in the ROW Territory. The Asthma JDC and Transplant JDC shall together develop and implement procedures for review of such Drug Approval Applications, which procedures shall be equivalent to

those procedures developed pursuant to Section 5.1(a) with respect to Roche's review of Drug Approval Applications for the U.S. Territory and shall provide sufficient time for PDL to provide substantive comments. Roche shall be responsible for obtaining appropriate regulatory approvals in the ROW Territory for the manufacture of bulk Licensed Product by PDL or its Third Party manufacturer(s). PDL shall have the right of cross reference to all such Drug Approval Applications filed in the ROW Territory.

**(b)** If required to support Regulatory Approvals in the ROW Territory in the Asthma Field, PDL shall be responsible for providing to Roche, in the format required by the FDA, the data and information required to be submitted to the FDA in the Asthma Field, and such additional data and information relating to the Development activities in the Asthma Field for which it was responsible, including all clinical trials performed by it and all manufacturing and controls information.

**(c)** In connection with all Drug Approval Applications being prosecuted by Roche hereunder, Roche agrees to provide PDL with a copy (which may be wholly or partly in electronic form) of all filings to regulatory agencies in each Major Regulatory Jurisdiction that it makes hereunder. Roche will provide PDL with reasonable advance notice of any scheduled meeting with any regulatory agency relating to Development and/or any Drug Approval Application in the ROW Territory, and PDL shall have the right to observe and, if the Parties mutually agree in advance, participate in any such meeting. Roche also shall promptly furnish PDL with copies of all material correspondence or minutes of material meetings with any regulatory agency in each case relating to Development and/or a Drug Approval Application in the ROW Territory. Within thirty (30) days following the end of each calendar quarter, Roche shall report to PDL regarding the status of each pending and proposed Drug Approval Application in the ROW Territory. In the event that any regulatory agency threatens or initiates any action to remove such Licensed Product from the market in any country in the Collaborative Fields in the ROW Territory, Roche shall notify PDL of such communication within one business day of receipt by Roche. As between the Parties, Roche shall be the legal and beneficial owner of all Drug Approval Applications and related approvals in the ROW Territory.

### 5.3 Adverse Event Reporting.

(a) Each Party shall notify the other of all information coming into its possession concerning any and all side effects, injury, toxicity, pregnancy or sensitivity events associated with commercial or clinical uses, studies, investigations or tests with Licensed Products, throughout the world, whether or not determined to be attributable to Licensed Products (“**Adverse Event Reports**”). Pursuant to the Worldwide Daclizumab Agreement, the Parties have already identified a person from each Party 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 Pharmacovigilance Agreement executed by the Parties immediately prior to the Amendment Effective Date (“**Pharmacovigilance Agreement**”), which replaced and superseded the Procedure for the Exchange of Licensed Product Adverse Event Reports between the Parties dated December 2000. The Pharmacovigilance Agreement (and any subsequent amendments thereto) shall survive the end of the Co-Promotion Term.

(b) Roche and PDL agree that discussions between Roche, PDL and any of PDL’s Third Party co-developers of Licensed Product would be desirable for confirming an aligned strategy with respect to pharmacovigilance obligations. Discussions with any of PDL’s Third Party co-developers of Licensed Product will be initiated through the JSC.

**5.4 Copies of Responses.** Within a reasonable time frame prior to submission of responses to any regulatory authority on product safety issues regarding Licensed Products, 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 [\*\*\*\*] of document finalization.

**5.5 Regulatory Actions.** The Party responsible for interacting with regulators on a specific safety issue regarding Licensed Products must communicate any 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.

## ARTICLE 6

### COMMERCIALIZATION IN U.S. TERRITORY

#### 6.1 Commercialization Plans.

(a) During the Asthma Co-Promotion Term, all commercialization of Licensed Products in the Asthma Field in the U.S. Territory shall be conducted pursuant to a commercialization plan (the “**Asthma Commercialization Plan**”), which shall set forth the anticipated activities (including without limitation Medical Activities, market studies, launch plans, Detailing and Promotion in the Asthma Field) and timelines, shall allocate responsibility for carrying out such activities between PDL and Roche, and shall include an associated budget. No later than [\*\*\*\*] after [\*\*\*\*] for a Licensed Product in the Asthma Field, and on an annual basis thereafter until the end of the Asthma Co-Promotion Term, PDL (or, at the Asthma JDC’s election, a subcommittee established by the Asthma JDC) shall submit to the Asthma JDC an initial or updated Asthma Commercialization Plan, which the Asthma JDC and JSC shall review and the JSC

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(after consulting with the Asthma JDC) shall approve or reject on a timely basis. It is understood that the initial Asthma Commercialization Plan may be very preliminary but nevertheless shall be effective for the purposes of commencing the Party's sharing of Operating Expenses in the Asthma Field. Each updated Asthma Commercialization Plan shall include the plan for Detailing and Promotion activities for the Licensed Product in the Asthma Field in the U.S. Territory for the next [\*\*\*\*] and timelines for performing such activities. Once approved by the JSC, such updated Asthma Commercialization Plan shall become effective and supersede the previous Asthma Commercialization Plan as of the date of such approval or at such other time decided by the JSC. The JSC shall not approve an updated Asthma Commercialization Plan that is inconsistent with or contradicts the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Asthma Commercialization Plan and this Agreement, the terms of this Agreement shall prevail.

(b) During the Transplant Co-Promotion Term, all commercialization of Licensed Products in the Transplant Field in the U.S. Territory shall be conducted pursuant to a commercialization plan (the "**Transplant Commercialization Plan**"), which shall set forth the anticipated activities (including without limitation Medical Activities, market studies, launch plans, Detailing and Promotion in the Transplant Field) and timelines, shall allocate responsibility for carrying out such activities between PDL and Roche, and shall include an associated budget. No later than [\*\*\*\*] after [\*\*\*\*] for a Licensed Product in the Transplant Field, and on an annual basis thereafter until the end of the Transplant Co-Promotion Term (or Regulatory Approval of Licensed Product in the U.S. Territory in the Asthma Field, if earlier and if there is no Transplant Trademark), the Party responsible for booking sales of Licensed Product in the U.S. Territory in the Transplant Field shall submit to the Transplant JCC an initial or updated Transplant Commercialization Plan, which the Transplant JCC and JSC shall review and the JSC (after consulting with the Transplant JCC) shall approve or reject on a

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timely basis. It is understood that the initial Transplant Commercialization Plan may be very preliminary but nevertheless shall be effective for the purposes of commencing the Party's sharing of Operating Expenses in the Transplant Field. Each updated Transplant Commercialization Plan shall include a plan for Detailing and Promotion activities for the Licensed Product in the Transplant Field in the U.S. Territory for the next [\*\*\*\*] and timelines for performing such activities. Once approved by the JSC, such updated Transplant Commercialization Plan shall become effective and supersede the previous Transplant Commercialization Plan as of the date of such approval or at such other time decided by the JSC. The JSC shall not approve an updated Transplant Commercialization Plan that is inconsistent with or contradicts the terms of this Agreement, including but not limited to Section 6.2(c) herein, without the written consent of the Parties, and in the event of any inconsistency between the Transplant Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. If Roche is the party responsible for the booking of sales of Licensed Product in the U.S. Territory in the Transplant Field, then the Transplant Commercialization Plan that covers the last year of the Transplant Co-Promotion Term (or the year in which Regulatory Approval of Licensed Product in the U.S. Territory in the Asthma Field is expected, if such approval is expected prior to the end of the Transplant Co-Promotion Term and if there is no Transplant Trademark) shall include provisions addressing the manner in which responsibility for booking sales and other Licensed Product commercialization-related activities shall be transferred from Roche to PDL at the end of the Transplant Co-Promotion Term or upon Regulatory Approval in the U.S. Territory in the Asthma Field, as applicable.

**6.2 Commercialization in the U.S. Territory; Co-Promotion.**

(a) PDL will be solely responsible for the booking of sales of Licensed Products in the Asthma Field in the U.S. Territory and the supply and distribution of

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Licensed Product in respect to such sales. If there is both a Transplant Branded Product and a Transplant Trademark, then (i) Roche will be solely responsible for the booking of sales of Licensed Products in the Transplant Field in the U.S. Territory during the Transplant Co-Promotion Term and for the distribution of Licensed Product in respect to such sales, (ii) PDL will be solely responsible for the booking of sales of Licensed Products in the Transplant Field in the U.S. Territory after the end of the Transplant Co-Promotion Term and for the distribution of Licensed Product in respect to such sales, and (iii) PDL will be solely responsible for the supply of Licensed Product in respect to all such sales (whether booked by Roche or PDL). Subject to this Section 6.2(a), if there is a Transplant Branded Product but no Transplant Trademark, then (1) Roche will be solely responsible for the booking of sales of Licensed Products in the Transplant Field in the U.S. Territory and for the distribution of Licensed Product in respect to such sales until the earlier of (A) the end of the Transplant Co-Promotion Term or (B) Regulatory Approval in the U.S. Territory in the Asthma Field, (2) PDL will be solely responsible for the booking of sales of Licensed Products in the Transplant Field in the U.S. Territory and for the distribution of Licensed Product in respect to such sales after the earlier of (A) the end of the Transplant Co-Promotion Term or (B) Regulatory Approval in the U.S. Territory in the Asthma Field, and (3) PDL will be solely responsible for the supply of Licensed Product in respect to all such sales (whether booked by Roche or PDL). If there is a Transplant Branded Product but no Transplant Trademark and it is possible that Regulatory Approval in the U.S. Territory in the Asthma Field might be received within [\*\*\*\*] of the First Commercial Sale in the U.S. Territory in the Transplant Field, then the Parties shall discuss in good faith whether Roche should book sales of the Transplant Branded Product during the time prior to Regulatory Approval in the U.S. Territory in the Asthma Field or if PDL should book such sales, and if the Parties agree that PDL should book sales, then the terms of this Agreement that are directed to circumstances in which there is no Transplant Branded

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Product should nevertheless apply. If there is no Transplant Branded Product, then PDL will be solely responsible for the booking of sales of Licensed Products in the Transplant Field in the U.S. Territory and the supply and distribution of Licensed Product in respect to such sales. The Party responsible for booking sales shall determine the U.S. Territory selling price (including volume discounts, rebates, and similar matters), credit terms, and return policies for all formulations of Licensed Products that are sold for use in a Collaborative Field by such Party.

**(b) Detailing in the Asthma Field.** During the Asthma Co-Promotion Term, PDL and Roche will co-promote Licensed Products in the Asthma Field in the U.S. Territory in accordance with the Asthma Commercialization Plan. As part of this co-promotion, PDL shall contribute [\*\*\*\*] of the Details required by the Asthma Commercialization Plan (measured as an average across each calendar quarter), and Roche shall be responsible for the remaining [\*\*\*\*] of such Details. Each Party's sales force shall promote the Licensed Product in the Asthma Field in the U.S. Territory in a manner that reflects such Party's capacities and that is consistent with such Party's promotional efforts for its own products of similar market potential. During the Asthma Co-Promotion Term, Roche and PDL agree to deploy their respective sales forces to Detail Licensed Product in the Asthma Field in the U.S. Territory (i) at such level of effort as is required pursuant to this Section 6.2(b) and (ii) in a manner consistent with the Asthma Commercialization Plan and applicable law. The Parties shall agree upon a sales calling plan, which plan shall include mechanisms to address possible underperformance and failure to perform Detailing in the Asthma Field at the agreed upon levels.

**(c) Detailing in the Transplant Field.** No later than [\*\*\*\*] prior to the anticipated filing of a Drug Approval Application in the Transplant Field in the U.S. Territory, the Transplant JCC shall recommend and the JSC shall approve terms and

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conditions under which the Parties will Detail Licensed Product in the Transplant Field in the U.S. Territory. Such terms and conditions shall include that: (i) only one representative from either Party may Detail to any given transplant center to prevent redundancy of field activity; (ii) Roche shall be the Party to Detail Licensed Product to any Target Audience that is a predominantly solid organ transplant center that Roche targets for detailing with respect to Roche's other products for use in solid organ transplant patients; and (iii) PDL shall have an option to Detail Licensed Product to any Target Audience other than a predominantly solid organ transplant center that Roche targets for detailing with respect to Roche's other products for use in solid organ transplant patients. Each Party shall be responsible for the actions of its own field force in the Transplant Field. To the extent Roche's Detailing obligations under this Section 6.2(c) exceed the Detailing obligations of PDL, PDL shall be responsible for [\*\*\*\*] of the Sales Force Expenses of Roche that are attributable to Roche's excess Detailing obligations. For example, if Roche is responsible for eighty percent (80%) of the Detailing in the Transplant Field and PDL is responsible for twenty percent (20%) of such Detailing, then PDL shall reimburse Roche for [\*\*\*\*] of Roche's Sales Force Expenses attributable to the extra sixty percent (60%) Detailing performed by Roche in the Transplant Field. The Transplant Commercialization Plan shall specify each Party's relative percentage of Detailing obligations in the Transplant Field and the following principles shall be considered when making such determination: (1) only representatives that Detail to transplant centers shall be considered (i.e. Detailing to community nephrologists will not be considered); (2) PDL will not be credited for more than [\*\*\*\*] of the total Detailing by both Parties in the Transplant Field; and (3) the number of calls shall not be the sole criterion used to measure responsibility, but other factors, such as the effectiveness of the sales force, shall be considered. If only one Party Details Licensed Product in the Transplant Field ("Promoting Party"), then the other Party ("Non-Promoting Party") shall be responsible for [\*\*\*\*] of all Sales Force

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Expenses of the Promoting Party in the Transplant Field. For example, if the Promoting Party's cost per representative (fully burdened) is \$250,000, and the representative carries the Licensed Product and another product for which the Promoting Party equally allocates cost per representative, then the Non-Promoting Party shall be responsible for [\*\*\*\*] of the Promoting Party's Sales Force Expenses in the Transplant Field that are allocated to the Licensed Product. The Promoting Party shall be responsible for the other [\*\*\*\*] of such Sales Force Expenses.

(d) Each Party agrees to permit its Detailing records to be examined by the other Party for the purpose of verifying each Parties' compliance with the Detailing requirements set forth in this Section 6.2. Such audit shall be performed at the request of either Party, but in any event shall not be performed more frequently than [\*\*\*\*] per [\*\*\*\*] nor more frequently than [\*\*\*\*] with respect to Detailing records covering any specific period of time. The expense of any such examination shall be borne by the auditing Party unless such examination reveals a discrepancy of [\*\*\*\*] or more in favor of the audited Party, in which case such expense shall be borne by the audited Party.

(e) Following the end of the Asthma Co-Promotion Term, PDL shall have sole responsibility and decision-making authority for the Detailing, marketing, Promotion, Medical Activities, sale and distribution of Licensed Product in the Asthma Field in the U.S. Territory. Except as explicitly provided in Section 10.2(a), PDL shall owe Roche no consideration in respect to sales of Licensed Product in the Asthma Field in the U.S. Territory after the end of the Asthma Co-Promotion Term.

(f) Following the end of the Transplant Co-Promotion Term, PDL shall have sole responsibility and decision-making authority for the Detailing, marketing, Promotion, Medical Activities, sale and distribution of Licensed Product in the Transplant Field in the U.S. Territory. Except as explicitly provided in Section 10.2(b),

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PDL shall owe Roche no consideration in respect to sales of Licensed Product in the Transplant Field in the U.S. Territory after the end of the Transplant Co-Promotion Term.

### 6.3 Sharing of Operating Expenses; Sales Force Expenses

(a) During the Asthma Co-Promotion Term, all Operating Expenses in the Asthma Field shall be shared [\*\*\*\*]. [\*\*\*\*] will be solely responsible for [\*\*\*\*] Sales Force Expenses in the Asthma Field, unless the sales calling plan specifies otherwise due to a Party's failure to deploy sufficient numbers of sales representatives to meet the number of Details required of such Party under Section 6.2(b).

(b) During the Transplant Co-Promotion Term, all Operating Expenses in the Transplant Field shall be shared [\*\*\*\*] and all Sales Force Expenses in the Transplant Field shall be allocated between the Parties as specified in Section 6.2(c). Neither the Sales Force Expenses of a Party in the Transplant Field, nor the amounts paid by a Party to reimburse the other Party for its Sales Force Expenses in the Transplant Field, shall be included in such Party's Operating Expenses.

(c) During the Asthma Co-Promotion Term and the Transplant Co-Promotion Term, each Party shall keep detailed records of the Operating Expenses it incurs and the Sales Force Expenses it incurs in the Transplant Field, including all supporting documentation for such expenses, in accordance with procedures to be agreed upon between the Parties. Each Party shall keep such records for at [\*\*\*\*] after the date that such expense was incurred. Within [\*\*\*\*] after the end of each calendar quarter during the Asthma Co-Promotion Term, each Party shall provide to the JFC representatives of the other Party an accounting for its Operating Expenses in the Asthma Field for such quarter. Within [\*\*\*\*] after the end of such quarter, each Party shall also provide a report to the Asthma JDC (with a copy to the other Party) specifying

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and documenting, in reasonable detail, such Party's Operating Expenses in the Asthma Field during such quarter. Within [\*\*\*\*] after the end of each calendar quarter during the Transplant Co-Promotion Term, each Party shall provide to the JFC representatives of the other Party an accounting for its Operating Expenses in the Transplant Field and Sales Force Expenses in the Transplant Field for such quarter. Within [\*\*\*\*] after the end of such quarter, each Party shall also provide a report to the Transplant JCC (with a copy to the other Party) specifying and documenting, in reasonable detail, such Party's Operating Expenses in the Transplant Field and Sales Force Expenses in the Transplant Field during such quarter. Each Party shall promptly provide all additional information and documentation requested by the Asthma JDC or Transplant JCC to verify the Operating Expenses or Sales Force Expenses submitted to it. Within [\*\*\*\*] after the end of each such calendar quarter, the Asthma JDC shall provide each Party with an accounting of the Parties' Operating Expenses in the Asthma Field for such quarter and the Asthma JDC shall send the Party that incurred lower Operating Expenses in the Asthma Field during such quarter an invoice for an amount equal to one half of the difference between such Party's Operating Expenses in the Asthma Field for such quarter and the other Party's Operating Expenses in the Asthma Field for such quarter. Within [\*\*\*\*] after the end of each such calendar quarter, the Transplant JCC shall (i) provide each Party with an accounting of the Parties' Operating Expenses in the Transplant Field and Sales Forces Expenses in the Transplant Field for such quarter, (ii) send the Party that incurred lower Operating Expenses in the Transplant Field during such quarter an invoice for an amount equal to [\*\*\*\*] of the difference between such Party's Operating Expenses in the Transplant Field and the other Party's Operating Expenses in the Transplant Field for such quarter, and (iii) determine whether either Party is obligated to reimburse the other Party for any Sales Force Expenses incurred in the Transplant Field during such quarter and send such Party an invoice for the amount of such reimbursement obligation. A Party shall pay to the other Party the amount specified in any invoice delivered under this Section 6.3(c) within [\*\*\*\*] of its receipt of such invoice.

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(d) For each quarter during the Asthma Co-Promotion Term that falls (in whole or in part) in the period commencing [\*\*\*\*] in the U.S. Territory and ending on [\*\*\*\*] in the U.S. Territory, if the budget for such quarter specifies that Operating Expenses in the Asthma Field will be greater than [\*\*\*\*] and if [\*\*\*\*] for such quarter exceed [\*\*\*\*] for such quarter, then [\*\*\*\*] an amount equal to [\*\*\*\*] for such quarter, which payment shall be due within [\*\*\*\*] after [\*\*\*\*] receipt of a written invoice from [\*\*\*\*] specifying the amount of such payment. Payments advanced under this Section 6.3(d) shall be credited against any amounts owed by [\*\*\*\*] under Section 6.3(c) for the quarter with respect to which [\*\*\*\*]. Within [\*\*\*\*] following the end of each calendar year to which this Section 6.3(d) applies, [\*\*\*\*] shall [\*\*\*\*] any payments [\*\*\*\*] under this Section 6.3(d) during such calendar year for which [\*\*\*\*].

(e) For each quarter during the Transplant Co-Promotion Term that falls (in whole or in part) in the period commencing [\*\*\*\*] in the U.S. Territory and ending [\*\*\*\*] in the U.S. Territory, if [\*\*\*\*] for such quarter exceed [\*\*\*\*] [\*\*\*\*] for such quarter, then [\*\*\*\*] shall [\*\*\*\*] an amount equal to [\*\*\*\*] which payment shall be due within [\*\*\*\*] after [\*\*\*\*] receipt of a written invoice from [\*\*\*\*] specifying the amount of such payment. Payments advanced under this Section 6.3(e) shall be credited against any amounts owed by [\*\*\*\*] in the Transplant Field under Section 6.3(c) for the quarter with respect to which such advance was made to [\*\*\*\*]. Within [\*\*\*\*] following the end of each calendar year to which this Section 6.3(e) applies, [\*\*\*\*] shall [\*\*\*\*] any payments [\*\*\*\*] under this Section 6.3(e) during such calendar year for which [\*\*\*\*].

#### **6.4 Co-Promotion Term.**

(a) The Parties' co-promotion of the Licensed Products in the Asthma

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Field in the U.S. Territory shall commence on the date that the first Operating Expense in the Asthma Field is incurred by a Party and shall initially continue until [\*\*\*\*] after the First Commercial Sale of Licensed Product in the Asthma Field in the U.S. Territory, subject to any early termination in the U.S. Territory or the Territory pursuant to Section 17.2, 17.3, 17.4, 17.6, or 17.7. At the end of this initial term and each extension thereof, [\*\*\*\*] may, at its option, elect to extend the co-promotion for an additional year, provided that [\*\*\*\*] makes such election in writing to [\*\*\*\*] no later than [\*\*\*\*] prior to the end of the initial term or extension term (as the case may be) and provided further that [\*\*\*\*] for [\*\*\*\*] prior to such election [\*\*\*\*]. The initial term of co-promotion and any extensions thereof (in each case, taking into account any early termination in the U.S. Territory or the Territory pursuant to Section 17.2, 17.3, 17.4, 17.6, or 17.7) shall be referred to herein as the **“Asthma Co-Promotion Term.”**

**(b)** The Parties’ co-promotion of the Licensed Products in the Transplant Field in the U.S. Territory shall commence on the date that the first Operating Expense in the Transplant Field is incurred by a Party and shall initially continue until [\*\*\*\*] after the First Commercial Sale of Licensed Product in the Transplant Field in the U.S. Territory, subject to any early termination in the U.S. Territory or the Territory pursuant to Section 17.2, 17.3, 17.5, or 17.6. At the end of this initial term and each extension thereof, [\*\*\*\*] may, at its option, elect to extend the co-promotion for [\*\*\*\*], provided that [\*\*\*\*] makes such election in writing to [\*\*\*\*] no later than [\*\*\*\*] prior to the end of the initial term or extension term (as the case may be) and provided further that [\*\*\*\*] (as applicable) for the [\*\*\*\*] prior to such election [\*\*\*\*]. The initial term of co-promotion and any extensions thereof (in each case, taking into account any early termination in the U.S. Territory or the Territory pursuant to Section 17.2, 17.3, 17.5, or 17.6) shall be referred to herein as the **“Transplant Co-Promotion Term.”**

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## 6.5 Sales Force Training.

**(a) Asthma Field.** During the Asthma Co-Promotion Term, each Party's relevant U.S. Territory operating entities shall be responsible for the development and conduct of training programs specifically relating to the co-promoted Licensed Products in the Asthma Field for the sales representatives of such Party. The Parties participating in Detailing agree to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy. The costs of transporting, housing and maintaining personnel of a Party for such training shall be treated as Sales Force Expenses of such Party and shall be borne [\*\*\*\*] pursuant to Section 6.3. The Parties shall establish joint training programs as specified by the Asthma JDC (which shall include a combined launch meeting attended by both Parties' sales representatives) and shall share the direct incremental cost of such training [\*\*\*\*] [\*\*\*\*]. Information transmitted pursuant to this Section 6.5(a) shall be treated as Confidential Information of both Parties.

**(b) Transplant Field.** If both Parties are Detailing in the Transplant Field pursuant to Section 6.2(c), then during the Transplant Co-Promotion Term, each Party's relevant U.S. Territory operating entities shall be responsible for the development and conduct of training programs specifically relating to the co-promoted Licensed Products in the Transplant Field for the sales representatives of such Party. If [\*\*\*\*] is the Promoting Party (as defined in Section 6.2(c)), then during the Transplant Co-Promotion Term [\*\*\*\*] shall be [\*\*\*\*] responsible for such development and conduct. If [\*\*\*\*] is the Promoting Party, then during the Transplant Co-Promotion Term [\*\*\*\*] shall be [\*\*\*\*] responsible for such development and conduct. The Parties participating in Detailing agree to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy. The costs of transporting, housing and maintaining personnel of a Party for such training shall be treated as Sales Force

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Expenses of such Party. If both Parties are Detailing in the Transplant Field pursuant to Section 6.2(c), then the Parties shall establish joint training programs as specified by the Transplant JCC (which shall include a combined launch meeting attended by both Parties' sales representatives) and shall [\*\*\*\*] cost of such training [\*\*\*\*]. Information transmitted pursuant to this Section 6.5(b) shall be treated as Confidential Information of both Parties.

**6.6 Joint U.S. Marketing Subcommittee.** The joint U.S. marketing subcommittee of the Asthma JDC shall specify in detail each Party's obligations, consistent with Sections 6.1 through 6.5, with respect to Licensed Product Promotion and Detailing in the Asthma Field in the U.S. Territory during the Asthma Co-Promotion Term.

**6.7 Negative Covenant.** Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee [\*\*\*\*] Licensed Products in the U.S. Territory [\*\*\*\*], except as expressly permitted by any other written agreement between the Parties which is currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties. PDL acknowledges and understands that Roche cannot control [\*\*\*\*] and that the purpose of the foregoing covenant is to prevent Roche and its Affiliates and sublicensees from [\*\*\*\*].

## ARTICLE 7

### COMMERCIALIZATION IN ROW TERRITORY AND WORLDWIDE TRACKING OF SALES

**7.1 Commercialization by Roche in ROW Territory.** Except as expressly

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set forth in this Article 7, Roche shall have sole responsibility and decision-making authority for the marketing, promotion, medical activities, sale and distribution of the Licensed Product in the Collaborative Fields in the ROW Territory (collectively, the “**ROW Commercialization Activities**”), including post-registration clinical and marketing studies that are not conducted in order to obtain, expand (as mutually agreed with PDL) and/or maintain Regulatory Approval of a Licensed Product in the Collaborative Fields in the U.S. Territory or European Union. Roche shall be responsible for all costs and expenses associated with the ROW Commercialization Activities. Roche’s sales force shall promote the Licensed Product in the ROW Territory in a manner that reflects Roche’s capacities and that is consistent with Roche’s promotional efforts for its own products of similar market potential.

**7.2 Roche Diligence in ROW Territory.**

(a) At least [\*\*\*\*] prior to the first expected launch date in the ROW Territory of the Licensed Product in each Collaborative Field, Roche will provide PDL with its draft plan for Roche’s, its Affiliates’ and sublicensees’ commercialization of the Licensed Products in such Collaborative Field in the ROW Territory. PDL shall have the opportunity to comment on such draft plan, and Roche shall take such comments into account when finalizing the plan. Roche shall comply and ensure the compliance of its Affiliates and sublicensees with such finalized plan. Roche shall provide PDL, upon PDL’s request, with reasonable documentation of such compliance.

(b) Roche, directly or through its Affiliates and/or sublicensees, shall use Diligent Efforts to commercialize the Licensed Products in both the Asthma Field and the Transplant Field in each country in the ROW Territory. Roche shall provide PDL, upon PDL’s request (such request not to be made more than once per calendar year), with a written summary specifying in reasonable detail, on a country-by-country basis, how it has used such Diligent Efforts.

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**7.3 Negative Covenant.** Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to, [\*\*\*\*] Licensed Products in the ROW Territory [\*\*\*\*], except as expressly permitted by any other written agreement between the Parties which is currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties. PDL acknowledges and understands that Roche cannot control [\*\*\*\*] and that the purpose of the foregoing covenant is to prevent [\*\*\*\*].

**7.4 [\*\*\*\*].** Subject to Section 13.1, Roche and PDL shall cooperate fully under [\*\*\*\*] to [\*\*\*\*] and [\*\*\*\*] for the U.S. Territory and the ROW Territory in order to optimize global penetration of the Licensed Product in the Collaborative Fields.

**7.5 [\*\*\*\*].** In order to most effectively establish a [\*\*\*\*] for the Licensed Product with the benefit of the Parties' experience in the areas of [\*\*\*\*], the Parties may participate in discussions regarding the [\*\*\*\*] the Licensed Product within and outside the Collaborative Fields to the extent [\*\*\*\*].

**7.6 Tracking of Sales in the Territory.** The Parties recognize that PDL has the right to market Licensed Products for indications outside the Collaborative Fields. As a result, Licensed Products marketed by PDL or its collaborators in the future for indications outside the Collaborative Fields may nonetheless be sold in the Collaborative Fields, and Licensed Products marketed by PDL and/or Roche in the future for indications in the Collaborative Fields may nonetheless be sold outside the Collaborative Fields (collectively, "**Cross-Field Sales**"). In order to detect and account for these Cross-Field Sales of Licensed Products, the Parties agree as follows:

(a) If at any time during the term of this Agreement, PDL, its Affiliate, or licensee is marketing a Licensed Product for an indication outside the Collaborative Fields that is approved by the relevant regulatory authority in such territory (a "**Non-**

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**Collaborative Field Product**) and PDL or Roche is at the same time in the same territory marketing a Licensed Product for an indication in the Collaborative Fields that is approved by the relevant regulatory authority in such territory (an **“Collaborative Field Product”**), and a Party believes that (i) sales of a Non-Collaborative Field Product are occurring or will occur for use in the Collaborative Fields; or (ii) sales of the Collaborative Field Product are occurring or will occur for use outside the Collaborative Fields, then such Party may provide notice to the other Party of its desire to track sales of Licensed Product for the relevant indications in such territory.

(b) Upon receipt of notice under Section 7.6(a), PDL and Roche shall meet and agree upon a method of tracking sales of each such product for use in its respective indications (a **“Sales Tracking Methodology”**) including (i) the acquisition of one or more [\*\*\*\*] (including, by way of example, [\*\*\*\*] [\*\*\*\*]) or other [\*\*\*\*] (including, for example, [\*\*\*\*]) generally recognized in the pharmaceutical industry as having [\*\*\*\*] in the tracking of sales of pharmaceutical products that have a similar nature as and are prescribed by similar physicians as the Collaborative Field Product and the Non-Collaborative Field Product in the U.S. Territory and, if applicable, outside the U.S. Territory (the **“Data Services”**), and (ii) the methodology for applying any [\*\*\*\*] to determine the extent of Cross-Field Sales in the relevant territory. At the request of either Party, any meeting held under this Section 7.6(b) shall [\*\*\*\*] in the relevant territory, provided any such [\*\*\*\*] is or agrees to be bound by confidentiality provisions similar to those contained in this Agreement.

(c) In the event that PDL, Roche, and [\*\*\*\*] (as applicable) are unable to agree on a Sales Tracking Methodology pursuant to Section 7.6(b), then the following default methodologies shall apply:

(i) With respect to each Major Regulatory Jurisdiction [\*\*\*\*] in which a Collaborative Field Product and a Non-Collaborative Field Product have received Regulatory Approval and in which [\*\*\*\*], sales in the Collaborative Fields in such country and sales outside the Collaborative Fields in such country shall be calculated for each Collaborative Field Product and each Non-Collaborative Field Product [\*\*\*\*]. For clarity, the [\*\*\*\*]d ([\*\*\*\*]) shall always be [\*\*\*\*] for such product in the relevant country.

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**(ii)** With respect to each country in which a Collaborative Field Product and a Non-Collaborative Field Product have received Regulatory Approval and to which Section 7.6(c)(i) is inapplicable, the percentage of sales of each Collaborative Field Product attributable to use outside the Collaborative Field and the percentage of sales of each Non-Collaborative Field Product attributable to use in the Collaborative Field shall be calculated from [\*\*\*\*] based on [\*\*\*\*] are evaluated pursuant to Section 7.6(c)(i). In the event that there are [\*\*\*\*] are evaluated pursuant to Section 7.6(c)(i), then [\*\*\*\*] shall apply unless and until the Parties agree on a Sales Tracking Methodology pursuant to Section 7.6(b).

**(d)** All costs associated with the acquisition and application of such Data Services and Sales Tracking Methodology shall be shared [\*\*\*\*] and [\*\*\*\*] participating in the negotiations contemplated by Section 7.6(b). In addition, the Parties and any [\*\*\*\*] shall also meet and confer with respect to: (i) how to account for prescriptions to patients with multiple afflictions (e.g. transplant patients with multiple sclerosis), both within and outside the Collaborative Fields; (ii) the right for each Party to audit, on a periodic basis, the [\*\*\*\*]; and (iii) a mechanism for addressing [\*\*\*\*].

**(e)** If in the course of applying the foregoing [\*\*\*\*] to track sales of the Collaborative Field Product and Non-Collaborative Field Product pursuant to this

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Section 7.6, or in the course of performing an audit of such application by the other Party, a Party determines that Cross-Field Sales are occurring at [\*\*\*\*], the Parties shall utilize the [\*\*\*\*] mechanism for Cross-Field Sales established by the JSC (as set forth in Section 3.3(1)) to compensate any affected Party for the economic effects thereof. That reimbursement mechanism shall be designed to place each Party in the same economic position it would have occupied had no Cross-Field Sales occurred and that accomplishes such goal by avoiding the unjust enrichment of the selling party on account of such Cross-Field Sales. Such a [\*\*\*\*] mechanism shall take into account any agreement (if an agreement exists) entered into by both Parties and a Third Party. Such a [\*\*\*\*] mechanism shall also take into account the [\*\*\*\*], the [\*\*\*\*] [\*\*\*\*] in conjunction with such sale and/or [\*\*\*\*] (for example, the [\*\*\*\*]).

(f) In the event of any unresolved issues, dispute or disagreement under this Section 7.6, the Parties will submit such dispute, issue or disagreement for resolution pursuant to Article 18.

**7.7 Distribution Outside the Collaborative Fields.** If a Non-Collaborative Field Product is approved for sale in a particular country in the ROW Territory under the same trademark as a Collaborative Field Product, then the Parties shall discuss such situation in good faith, including whether to enter a separate agreement whereby Roche would distribute such Non-Collaborative Field Product in such country for use outside the Collaborative Fields. If a Non-Collaborative Field Product is approved for sale in the U.S. Territory under the same trademark as a Transplant Branded Product for which Roche is then booking sales in the U.S. Territory pursuant to Section 6.2(a), then the Parties shall discuss such situation in good faith, including whether to enter a separate agreement whereby Roche would distribute such Non-Collaborative Field Product in the U.S. Territory for use outside the Collaborative Fields until the earlier of the end of the Transplant Co-Promotion Term or Regulatory Approval in the Asthma Field in the U.S. Territory.

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**8.1 Clinical Supply.**

(a) With respect to Licensed Product, PDL shall supply the Active Pharmaceutical Ingredient (“API”), Investigational Medicinal Product (“IMP”), Drug Product (“DP”) and placebo for Development purposes in the Asthma Field in accordance with the Asthma Development Plan and for Development purposes in the Transplant Field in accordance with the Transplant Development Plan. The Asthma Development Plan and Transplant Development Plan shall each set forth appropriate milestones to ensure conformance therewith. These milestones, in general, will be based on [\*\*\*\*] to conduct the planned clinical trials in accordance with the projected schedule at each stage in the Asthma Development Plan or Transplant Development Plan (as applicable). A milestone based on [\*\*\*\*] should include the [\*\*\*\*] to be supplied by [\*\*\*\*] for Development purposes and an approximate delivery schedule therefor. [\*\*\*\*] should include, but are not limited to, [\*\*\*\*] [\*\*\*\*]. Material that is not [\*\*\*\*] shall be replaced by [\*\*\*\*] at [\*\*\*\*]. PDL shall review current and proposed manufacturing subcontractors for clinical supply with the Asthma JDC and the Transplant JDC. The Asthma JDC and Transplant JDC shall consider using Roche as a subcontractor for various clinical manufacturing steps, including formulation, filling, finishing, and distribution. This consideration of Roche as the formulation, filling, finishing and/or distribution subcontractor for the clinical supply shall be based on capacity, quality, compliance, cost, capability, distribution, and the strategic needs of the Parties, and subject to the normal supplier qualification process at PDL. If Roche is selected as a subcontractor, the Parties shall negotiate in good faith to enter into an appropriate toll manufacturing agreement.

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(b) The cost associated with supplying all API, IMP, and placebo for the Asthma Development Plan, as it existed on the Effective Date, pursuant to this Section 8.1 for the purposes of obtaining Regulatory Approval in the U.S. Territory and the European Union, shall be [\*\*\*\*] and shall be [\*\*\*\*] (assuming no change in the non-manufacturing aspects of the initial Asthma Development Plan, as it existed on the Effective Date, that would affect the quantities of API, IMP, or placebo required to be manufactured), consisting of [\*\*\*\*] for such clinical supplies for the phase I and phase II clinical program of the Asthma Development Plan (the “Phase I/II [\*\*\*\*] Price for Asthma”) and [\*\*\*\*] for such clinical supplies for the phase III clinical program of the Asthma Development Plan (the “Phase III [\*\*\*\*] Price for Asthma”). These costs shall be included as a Development Expense as follows:

(i) The Phase I/II [\*\*\*\*] Price for Asthma shall be included as a Development Expense in [\*\*\*\*] [\*\*\*\*] (i.e., [\*\*\*\*] [\*\*\*\*]) in the [\*\*\*\*] calendar quarters beginning with the quarter beginning [\*\*\*\*].

(ii) No later than [\*\*\*\*], the Parties shall determine the aggregate quantity of additional IMP to be manufactured from [\*\*\*\*] for use in clinical trials in the Collaborative Fields. To the extent such quantity does not exceed [\*\*\*\*], the cost for such material will be calculated based on the [\*\*\*\*] set forth in the following table:

Cost	[****]
[****]	

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(iii) For IMP ordered after [\*\*\*\*] from [\*\*\*\*], or in aggregate quantities of additional IMP exceeding [\*\*\*\*] from [\*\*\*\*], the Parties shall negotiate a price in good faith, as such material may or may not require [\*\*\*\*].

(iv) The Phase III [\*\*\*\*] Price for Asthma shall be included as a Development Expense in [\*\*\*\*] (i.e., [\*\*\*\*]) in the [\*\*\*\*] calendar quarters beginning with [\*\*\*\*] after Roche decides to proceed with phase III development in the Asthma Field (i.e., such decision is currently identified as the Roche “Full Development Decision Point [FDDP]” determination as approved by the “Life Cycle Committee [LCC]”). Roche shall promptly inform PDL of its decision whether or not to proceed with phase III development.

(v) If the API output from the production campaign for the initial IMP that is contemplated in Section 8.1(b)(iv) exceeds the needs of the Asthma Development Plan as it existed on the Effective Date, the excess material will be used to supply any additional needs of the then current Asthma Development Plan or needs of the then current Transplant Development Plan at no additional cost except for any incremental costs associated with fill/finish or other clinical manufacturing activities beyond those planned in the Asthma Development Plan as it existed on the Effective Date.

(vi) The cost of additional material needed beyond the API output from the production campaign for the initial IMP that is contemplated in Section 8.1(b)(iv) (whether for use in clinical trials in the Asthma Field or the Transplant Field) shall be the applicable Target Price described in Section 8.3 or 8.4 (with respect the same quantities for commercial supply). If any such additional material is ordered in time to be manufactured as part of the production campaign for the initial IMP that is

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contemplated in Section 8.1(b)(iv), the quantity used to determine the applicable Target Price for such additional material will include the quantity of initial IMP in such production campaign. The applicable Target Price for subsequent orders for additional material supplied will be based on [\*\*\*\*].

(c) With respect to API, IMP, or placebo supplied by PDL to Roche pursuant to this Section 8.1 for use in any Development activities not required to obtain Regulatory Approval in the U.S. Territory or the European Union, Roche shall pay PDL, within the later of [\*\*\*\*] of acceptance of the shipment or [\*\*\*\*] of receipt of the applicable invoice, a transfer price equal to (i) [\*\*\*\*] as the case may be, minus (ii) [\*\*\*\*] for the production of such material. Such amount shall be deemed an Incremental Development Expense.

**8.2 Commercial Supply.** Roche and PDL shall negotiate in good faith a definitive commercial supply agreement (“Commercial Supply Agreement”) that will govern the exact terms and conditions of the commercial supply of API or other finished form of Licensed Product by PDL to Roche for sale in the ROW Territory for use in the Collaborative Fields and, if there is a Transplant Branded Product, for sale in the U.S. Territory during the Transplant Co-Promotion Term for use in the Transplant Field for so long as there is a Branded Transplant Product. The Parties acknowledge and agree that the Commercial Supply Agreement will address Roche’s remedies in the event that PDL is unable to supply or have supplied API or other finished form of Licensed Product in quantities desired by Roche (“**Failure to Supply**”). All such remedies set forth in the Commercial Supply Agreement shall be Roche’s sole remedies with respect to a Failure to Supply. The Parties shall propose a more detailed timeframe for finalizing the Commercial Supply Agreement to the JSC. In any event, the Parties agree to initiate the negotiation of the Commercial Supply Agreement at the latest upon the enrollment of the last patient in the phase IIb dose ranging study and conclude the negotiation

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within [\*\*\*\*] of the enrollment of the last patient in the phase IIb dose ranging study. The Parties acknowledge and agree that the terms and conditions for commercial supply of Licensed Product with respect to the Asthma Field and the terms and conditions for commercial supply of Licensed Product with respect to the Transplant Field may be addressed in a single Commercial Supply Agreement or may alternatively be addressed in separate agreements. The Parties shall negotiate and enter into a quality agreement at the same time as the Commercial Supply Agreement. If a second Commercial Supply Agreement is entered into, the Parties shall decide whether the existing quality agreement is sufficient to address both Commercial Supply Agreements and, if it is not, whether to amend such quality agreement or enter into a separate quality agreement.

### 8.3 Transfer Price for Commercial Supply of API.

(a) If Roche desires to perform the fill/finish step of the manufacturing process of Licensed Product for sale in the Collaborative Fields in the ROW Territory or for sale in the U.S. Territory during the Transplant Co-Promotion Term for use in the Transplant Field (provided and for so long as there is a Transplant Branded Product), it shall notify PDL of its desire and commitment based on capacity, quality, compliance, cost, capability and the strategic needs of the Parties. The Parties shall discuss and agree upon the amounts which Roche would [\*\*\*\*] for the fill/finish step under different reasonably contemplated supply requirements if Roche were to perform such fill/finish (the **“Roche Fill/Finish Cost”**). If [\*\*\*\*] provides a corresponding fill/finish cost that is [\*\*\*\*], based on the same assumptions with respect to the calculations of such cost, then [\*\*\*\*] shall perform such fill/finish step and the Parties shall agree upon the appropriate commitment for continued fill/finish by [\*\*\*\*] (including the frequency and lead times with which [\*\*\*\*]) with a view to ensuring uninterrupted supply of Licensed Product in the ROW Territory and in the U.S. Territory for use in the Transplant Field during the Transplant Co-Promotion Term with respect to a Transplant Branded Product.

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(b) Roche will pay PDL a Transfer Price [\*\*\*\*] calculated as follows: Transfer Price = [\*\*\*\*], where the Target Price is determined based on the [\*\*\*\*] as shown below. The [\*\*\*\*] is determined by combining [\*\*\*\*] with [\*\*\*\*][\*\*\*\*]. For [\*\*\*\*] intermediate to those shown below, [\*\*\*\*] will be used to determine the Target Price. If [\*\*\*\*] are [\*\*\*\*] or [\*\*\*\*], the Target Price will [\*\*\*\*]. PDL shall supply up to [\*\*\*\*] per year in the Collaborative Field as follows. PDL's current [\*\*\*\*] facility contains [\*\*\*\*], and is viewed to have [\*\*\*\*] (representing a capacity of [\*\*\*\*]). This facility is capable [\*\*\*\*][\*\*\*\*], with an [\*\*\*\*] (representing nearly [\*\*\*\*]). Such an expansion would require between [\*\*\*\*] to complete (from initial design to approval to supply commercially). PDL's plan would be to assess Licensed Product demand forecasts following a decision to move to phase III development (FDDP), which would then allow adequate time to expand the capacity of [\*\*\*\*] if required.

<b>Target Price</b>	[****]
[****]	[****]

The Transfer Price for API will be fixed [\*\*\*\*] as described in the Commercial Supply Agreement to be negotiated between the Parties.

**8.4 Transfer Price for Commercial Supply of Finished Product.** If PDL or its subcontractor performs the fill/finish step, then Roche will pay PDL a Transfer Price based on [\*\*\*\*][\*\*\*\*] calculated as follows: Transfer Price = [\*\*\*\*], where the Target Price is determined based on the [\*\*\*\*] as shown below. The [\*\*\*\*] is determined by

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combining [\*\*\*\*] with [\*\*\*\*]. For [\*\*\*\*] intermediate to those shown below, [\*\*\*\*][\*\*\*\*] will be used to determine the Target Price. If [\*\*\*\*] are [\*\*\*\*] [\*\*\*\*] or [\*\*\*\*], the Parties will [\*\*\*\*]. For the purpose of all calculations under this Section 8.4, finished Licensed Product [\*\*\*\*] [\*\*\*\*] shall be handled separately from finished Licensed Product [\*\*\*\*].

[\*\*\*\*]

TARGET PRICE FOR

TARGET PRICE [\*\*\*\*]

[\*\*\*\*]

For the purpose of this Section 8.4:

(a) the term [\*\*\*\*] indicates a [\*\*\*\*] that contains [\*\*\*\*], which would be labeled and bulk packaged for shipment only;

(b) the term [\*\*\*\*] indicates a [\*\*\*\*] that contains [\*\*\*\*] (exact package to be determined), which would be labeled and bulk packaged for shipment only.

(c) In the event that the [\*\*\*\*] configurations differ from those specified above, the Parties shall negotiate in good faith a new Target Price table.

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(d) The Transfer Price for finished Licensed Product will be fixed annually in accordance with the procedure described in the Commercial Supply Agreement to be negotiated between the Parties.

**8.5 Transfer Price Following Expiration of Royalty Obligations.** Following expiration of Roche's royalty obligations with respect to a Collaborative Field (the "Expiring Field") in a given country in the ROW Territory pursuant to Section 10.3(d), PDL will continue to supply Licensed Product to Roche for sale in the ROW Territory under the terms of the Commercial Supply Agreement, except that the Transfer Price shall be [\*\*\*\*]. If Drug Approval Applications with respect to both the Transplant Field and the Asthma Field have been approved in such country and Roche's royalty obligations with respect to one of the Collaborative Fields have not expired, then this Section 8.5 shall only apply to that fraction of Licensed Product allocable to the Expiring Field, which shall be calculated in a manner consistent with Section 10.3(b).

**8.6 Delivery Terms.** The Parties acknowledge and agree that the Target Prices set forth in Sections 8.3 and 8.4, and the Transfer Price set forth in Section 8.5, (a) are based on PDL delivering API or other finished form Ex Works (Incoterms 2000) PDL's or its Third Party manufacturer's facilities and (b) do not include the cost of any shipping fees, freight charges, insurance, import and export compliance fees, consumption taxes, withholding taxes, customs, duties and other taxes imposed by any government taxing authority in connection with API or other finished form supplied by PDL for the ROW Territory or the U.S. Territory.

**8.7 Transition Services After Expiration.** If Roche or its Affiliate or sublicensee is still selling the Licensed Product in the ROW Territory in the Collaborative Fields at the time of expiration of this Agreement and Roche wishes to assume the responsibility for supplying the Licensed Product for such sales, then Roche

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shall notify PDL in writing at least [\*\*\*\*] prior to the expiration of this Agreement and PDL for a reasonable transition period thereafter shall supply Licensed Product to Roche and provide Roche with certain transition services related to the transfer of manufacturing from PDL to Roche or its designee, all under the terms of (and subject to the execution of) a separate written agreement to be negotiated by the Parties in good faith.

## ARTICLE 9

### R&D REIMBURSEMENT PAYMENT AND DEVELOPMENT PAYMENTS

#### 9.1 R&D Reimbursement Payments.

(a) Prior to the Amendment Effective Date, Roche paid PDL a non-refundable, non-creditable payment of Seventeen Million Five Hundred Thousand Dollars (\$17,500,000) ([\*\*\*\*]).

(b) Roche shall pay to PDL a non-refundable, non-creditable payment of [\*\*\*\*] within [\*\*\*\*] after (i) [\*\*\*\*] or (ii) [\*\*\*\*].

**9.2 Asthma Development Payments.** Roche shall pay to PDL the following non-refundable and non-creditable amounts no later [\*\*\*\*] after the later of (i) first occurrence of the indicated event with respect to a Licensed Product or (ii) receipt by Roche of an invoice for such amount:

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<u>Event</u>	<u>Payment</u>
(a) [****] (as defined and specified in Exhibit [****])	[****]
(b) [****] (as defined and specified in Exhibit [****])	[****]
(c) [****] (as described in Exhibit [****]) prior to [****]	[****]
(d) [****]	[****]
(e) [****]	[****]
(f) [****]	[****]
(g) [****]	[****]

If Roche is responsible for achieving an event listed in this Section 9.2, then Roche shall provide PDL with written notice of the first occurrence of such event within [\*\*\*\*] of such occurrence. If Roche fails to provide such notice within such [\*\*\*\*] period, then Roche's associated payment shall be due no later than [\*\*\*\*] after such event. If any of the payments specified in [\*\*\*\*] have not been made at the time the payment specified in [\*\*\*\*] becomes due and payable, then Roche shall make all such unpaid payments no later than the due date for the payment specified in [\*\*\*\*] [\*\*\*\*], regardless of whether the events specified in [\*\*\*\*] have occurred.

**9.3 Transplant Development Payments.** Roche shall pay to PDL the following non-refundable and non-creditable amounts no later than [\*\*\*\*] after the later of (i) first occurrence of the indicated event with respect to a Licensed Product or (ii) receipt by Roche of an invoice for such amount:

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<u>Event</u>	<u>Payment</u>
(a) [****] [****]	[****]
(b) [****] (as described in Exhibit [****]) [****]	[****]
(c) [****]	[****]
(d) [****]	[****]
(e) [****]	[****]
(f) [****]	[****]
(g) [****]	[****]

For clarity, Roche shall owe a single payment upon achievement of the event specified in [\*\*\*\*], which payment shall satisfy Roche's obligations with respect to such event both under this [\*\*\*\*] and under [\*\*\*\*]. If Roche is responsible for achieving an event listed in this [\*\*\*\*], [\*\*\*\*] of such occurrence. [\*\*\*\*].

**ARTICLE 10**  
**PAYMENTS BASED ON SALES OF PRODUCTS**

**10.1 Profit Share in the U.S. Territory.**

(a) PDL shall pay Roche, within [\*\*\*\*] after the end of each calendar quarter during the Asthma Co-Promotion Term, an amount equal to [\*\*\*\*] of the [\*\*\*\*] in the Asthma Field for such calendar quarter.

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(b) With respect to Transplant Branded Product Roche shall pay PDL, within [\*\*\*\*] after the end of each calendar quarter during the Transplant Co-Promotion Term, an amount equal to [\*\*\*\*] of the [\*\*\*\*] in the Transplant Field for such calendar quarter.

(c) If there is no Transplant Branded Product, then PDL shall pay Roche, within [\*\*\*\*] after the end of each calendar quarter during the Transplant Co-Promotion Term, an amount equal to [\*\*\*\*] of the [\*\*\*\*] in the Transplant Field for such calendar quarter.

**10.2 [\*\*\*\*] in the U.S. Territory.**

(a) For each of the [\*\*\*\*] following the [\*\*\*\*], PDL shall pay to Roche [\*\*\*\*] on a quarterly basis on PDL Net Sales, in the Asthma Field, of the Licensed Product [\*\*\*\*], at the following rates:

<u>Year</u>	<u>[****]</u>
For the [****] following [****]	[****]
For the [****] following [****] Term	[****]
For the [****] following [****]	[****]

If in the U.S. Territory, sales in the Asthma Field of units of Generic Products in the aggregate total at least [\*\*\*\*] of the aggregate sales in the Asthma Field of units of all Generic Products and Licensed Products as measured [\*\*\*\*], then PDL shall have the right to [\*\*\*\*] due under [\*\*\*\*] by [\*\*\*\*] in the [\*\*\*\*], [\*\*\*\*] in the [\*\*\*\*], and [\*\*\*\*] in the [\*\*\*\*] (in each case rounded to the nearest [\*\*\*\*]). For clarity, if such [\*\*\*\*] are applicable, then the actual [\*\*\*\*] paid by PDL shall be [\*\*\*\*] in the [\*\*\*\*], [\*\*\*\*] in the [\*\*\*\*], and [\*\*\*\*]

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in the [\*\*\*\*] year. Any [\*\*\*\*] pursuant to this [\*\*\*\*] shall only apply to [\*\*\*\*]. The JFC shall work to develop and implement an agreed upon procedure for tracking such Generic Products.

(b) For each of the [\*\*\*\*] following the end of the [\*\*\*\*], PDL shall pay to Roche [\*\*\*\*] on a quarterly basis on PDL Net Sales, in the Transplant Field, of the Licensed Product [\*\*\*\*], at the following rates:

<u>Year</u>	<u>[****]</u>
For the [****] following [****] [****]	[****]
For the [****] following [****]	[****]
For the [****] following [****]	[****]

If in the U.S. Territory, sales in the Transplant Field of units of Generic Products in the aggregate total at least [\*\*\*\*] of the aggregate sales in the Transplant Field of units of all Generic Products and Licensed Products as measured [\*\*\*\*], then PDL shall have the right to [\*\*\*\*] due under [\*\*\*\*] by [\*\*\*\*] in the [\*\*\*\*], [\*\*\*\*] in the [\*\*\*\*] year, and [\*\*\*\*] in the [\*\*\*\*] year (in each case rounded to the nearest [\*\*\*\*]). For clarity, if such [\*\*\*\*] are applicable, then the [\*\*\*\*] paid by PDL shall be [\*\*\*\*] in the [\*\*\*\*], [\*\*\*\*] in the [\*\*\*\*], and [\*\*\*\*] in the [\*\*\*\*]. Any [\*\*\*\*] pursuant to this [\*\*\*\*] shall only apply to [\*\*\*\*]. The JFC shall work to develop and implement an agreed upon procedure for tracking such Generic Products.

(c) For clarity, the [\*\*\*\*] specified in Sections 10.2(a) and 10.2(b) are [\*\*\*\*] the first of which commences on the [\*\*\*\*] [\*\*\*\*] or [\*\*\*\*], as applicable.

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**10.3 Royalties in the ROW Territory.**

(a) Royalties for Approval(s) in One Collaborative Field. Subject to Section 10.3(b), for each calendar year or portion thereof during the term specified in Section 10.3(d), Roche shall pay to PDL incremental royalties on Roche Net Sales in the ROW Territory, at a royalty rate determined by annual Roche Net Sales in the ROW Territory of all Licensed Products as follows:

<u>Annual Roche Net Sales in ROW Territory (US\$)</u>	<u>Royalty Rate</u>
Up to and including [****]	[****]
Above [****] but not exceeding [****]	[****]
Above [****]	[****]

As an example, if annual Roche Net Sales in the ROW Territory for a given year are [\*\*\*\*], Roche would pay royalties equal to [\*\*\*\*], calculated as [\*\*\*\*] multiplied by [\*\*\*\*] plus [\*\*\*\*] [\*\*\*\*] plus [\*\*\*\*].

(b) Royalties for Approvals in Both Collaborative Fields. The following provisions shall apply to any country in the ROW Territory in which Drug Approval Applications with respect to both the Transplant Field and the Asthma Field have been approved, for so long as such approvals remain in force:

(i) Roche shall owe two separate quarterly royalties, each calculated pursuant to the schedule in Section 10.3(a), one based on Roche Net Sales in the ROW Territory in the Asthma Field and one based on Roche Net Sales in the ROW Territory in the Transplant Field. Roche Net Sales in the ROW Territory shall be

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allocated between the Asthma Field and the Transplant Field in accordance with the remainder of this Section 10.3(b), or in accordance with any other procedure unanimously approved by the JSC.

(ii) Within [\*\*\*\*] after the First Commercial Sale in the second Collaborative Field, the JSC shall prepare and approve a written report containing (A) the aggregate Global Net Sales for the most recently ended calendar year in those Major Regulatory Jurisdictions ([\*\*\*\*]) in which the Licensed Product has received Regulatory Approval in both Collaborative Fields; and (B) the percentage of such Global Net Sales attributable to use of the Licensed Product in the Transplant Field, calculated based on the reasonable methodologies consistently applied by Roche for the purpose of tracking its sales of other products in the Transplant Field (such percentage, the “**Transplant Percentage**”). The cost of implementing the methodology for tracking sales of Licensed Product in the Transplant Field shall be [\*\*\*\*]. The JSC shall prepare and approve an updated Transplant Percentage within [\*\*\*\*] after the end of each subsequent calendar year.

(iii) For the purpose of calculating royalties under Section 10.3, Roche Net Sales in the ROW Territory in the Transplant Field shall be deemed to be equal to Roche Net Sales in the ROW Territory multiplied by the Transplant Percentage, and the remainder of the Roche Net Sales in the ROW Territory shall be deemed to be Roche Net Sales in the ROW Territory in the Asthma Field.

(c) Roche shall have the right to deduct from any royalties payable under Section 10.3 the following: (i) [\*\*\*\*] for Licensed Products sold in the ROW Territory (on a first-in, first-out basis) during the royalty reporting period for which such royalties are due; and (ii) any [\*\*\*\*] for Licensed Product sold in the ROW Territory (on a first-in, first-out basis) during the royalty reporting period for which such royalties are due.

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(d) Roche's obligation to pay a royalty under Section 10.3 for a particular Licensed Product in a particular Collaborative Field shall expire, on a country-by-country basis, on the later of (i) [\*\*\*\*] following the First Commercial Sale of such Licensed Product in Collaborative Field, in such country and (ii) the last date on which the making, using, selling, or importing of Licensed Product, but for the licenses granted herein, would infringe a Valid Claim. If required by law, the First Commercial Sale in the European Union will be considered the First Commercial Sale in each country of the European Union.

#### 10.4 Adjustments Related to Third Party Competition.

(a) If in a country of the ROW Territory sales in the Asthma Field of units of Generic Products in aggregate total at least [\*\*\*\*] of the aggregate sales in the Asthma Field of units of all Generic Products and Licensed Products as measured at [\*\*\*\*], then Roche shall have the right [\*\*\*\*] any royalties due under Section 10.3 (after the applicable [\*\*\*\*] if applicable) by: (a) [\*\*\*\*] in the [\*\*\*\*] in which such Generic Product sales achieve such sales levels; (b) [\*\*\*\*] in the [\*\*\*\*], and (c) [\*\*\*\*] in the [\*\*\*\*] and all [\*\*\*\*] (in each case rounded to the nearest [\*\*\*\*]). Any royalty [\*\*\*\*] pursuant to this Section 10.4(a) shall only apply to royalties on Roche Net Sales in the ROW Territory in the Asthma Field. The JFC shall work to develop and implement an agreed upon procedure for tracking such Generic Products.

(b) If in a country of the ROW Territory sales in the Transplant Field of units of Generic Products in aggregate total at least [\*\*\*\*] of the aggregate sales in the Transplant Field of units of all Generic Products and Licensed Products as measured at the end of a full calendar year, then Roche shall have the right to [\*\*\*\*] any royalties due under Section 10.3 (after the applicable [\*\*\*\*], if applicable) by: (a) [\*\*\*\*] in the [\*\*\*\*] in which such Generic Product sales achieve such sales levels; (b) [\*\*\*\*] in the [\*\*\*\*], and

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(c) [\*\*\*\*] in the [\*\*\*\*] and [\*\*\*\*] (in each case rounded to the nearest [\*\*\*\*]). Any royalty [\*\*\*\*] pursuant to this Section 10.4(b) shall only apply to royalties on Roche Net Sales in the ROW Territory in the Transplant Field. The JFC shall work to develop and implement an agreed upon procedure for tracking such Generic Products.

**10.5 Adjustments for Third Party Licenses.** Roche and PDL shall share all costs associated with Third Party Licenses in ROW Territory as set forth in this Section 10.5. For the ROW Territory, Roche shall be responsible for [\*\*\*\*] of all payments under Third Party Licenses that are not included in the Transfer Price and are allocable to the use, development, sale, manufacture, or import of Licensed Products in the ROW Territory, including without limitation all payments under Third Party Licenses (a) calculated based on sales of Licensed Products in the ROW Territory; (b) made on account of the achievement of particular events relating to development or commercialization of Licensed Products in the ROW Territory; and (c) as consideration for a grant of a license or other rights in the ROW Territory (collectively, **“ROW License Payments”**). PDL shall be responsible for the remaining [\*\*\*\*] of ROW License Payments. The Parties shall, within [\*\*\*\*] after the end of each [\*\*\*\*], reimburse each other to effect the sharing of ROW License Payments set forth in this Section 10.5. For each license agreement that is included in Third Party Licenses pursuant to Section 1.88(b) and that is also necessary for the use, manufacture, sale, offering for sale, or importation of products outside the Collaborative Fields, the Parties will [\*\*\*\*] of payments under such license agreement to determine the portion of such payments [\*\*\*\*], which portion alone shall be includable in ROW License Payments. This Section 10.5 shall supersede Section 7.3 of the Worldwide Daclizumab Agreement to the extent Section 7.3 of the Worldwide Daclizumab Agreement is applicable to any ROW License Payments.

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**10.6 [\*\*\*\*] Payments.** Roche shall pay to PDL the following one-time, non-refundable and non-creditable amounts within [\*\*\*\*] after the later of (i) the first achievement of the indicated events with respect to [\*\*\*\*] of all Licensed Products in the Territory, and (ii) receipt by Roche of an invoice for such amount:

<u>Event</u>	<u>Payment</u>
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

For clarity, if more than one of the indicated [\*\*\*\*] events occurs in the same twelve (12) month period, then Roche shall pay PDL the sum of all payments corresponding to such [\*\*\*\*] events. Roche shall provide PDL with written notice of the first achievement of each event listed in this Section 10.6 within [\*\*\*\*] of such achievement. If Roche fails to provide such notice within such [\*\*\*\*], then Roche's associated payment shall be due no later than [\*\*\*\*] after such event.

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**ARTICLE 11**

**PAYMENT; REPORTS; AUDITS**

**11.1 Roche Quarterly Royalty Payments and Reports.**

(a) Until the expiration of Roche's royalty obligations under Section 10.3, Roche agrees to make payments and written reports to PDL within [\*\*\*\*] after the end of each calendar quarter covering all sales of the Licensed Products in the ROW 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 Licensed Products disposed of by sale, the description of Licensed Products and the calculation of Roche Net Sales in the ROW Territory,

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

(iii) the calculation of the amount due to PDL for such quarter pursuant to Sections 10.3, 10.4, 10.5 and 10.6.

(b) The information contained in each report under Section 11.1(a) shall be considered Confidential Information of Roche. Concurrent with the delivery of each quarterly report, Roche shall make the payment due PDL hereunder for the calendar quarter covered by such report.

(c) It is understood that only one royalty payment under Article 10 shall be payable on a given unit of Licensed Product disposed of under this Agreement. In

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the case of transfers or sales of any Licensed Product between Roche and an Affiliate sublicensee of Roche, 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.

### **11.2 PDL Quarterly Royalty Payments and Reports.**

(a) During the [\*\*\*\*] period of PDL's royalty obligations under Section 10.2(a) and the three (3) year period of PDL's royalty obligations under Section 10.2(b), PDL agrees to make payments and written reports to Roche within [\*\*\*\*] after the end of each calendar quarter covering all sales of the relevant Licensed Product in the Asthma Field or the Transplant Field (as applicable) in the U.S. 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 sublicensee. Each report shall state for the period in question:

- (i) for such Licensed Products disposed of by sale, the description of Licensed Products and the calculation of PDL Net Sales therefor,
- (ii) for such Licensed Products disposed of other than by sale, the description and nature of the disposition, and
- (iii) the calculation of the amount due to Roche for such quarter pursuant to Section 10.2.

(b) The information contained in each report under Section 11.2(a) shall be considered Confidential Information of PDL. Concurrent with the delivery of each quarterly report, PDL shall make the payment due Roche hereunder for the calendar quarter covered by such report.

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(c) It is understood that only one royalty payment under Section 10.2 shall be payable on a given unit of Licensed Product disposed of under this Agreement. In the case of transfers or sales of any Licensed Product between PDL and an Affiliate sublicensee of PDL which is subject to royalties under Section 10.2, 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.

**11.3 Gross Margin Reports.** Along with each of the payments specified in Sections 10.1(a) and 10.1(c), PDL shall provide Roche with a written report containing the PDL Adjusted Gross Sales and COGS figures relevant to the calculation of the PDL Gross Margin in the applicable field, and the calculation of the amount due to Roche. Along with each of the payments specified in Section 10.1(b), Roche shall provide PDL with a written report containing the Roche Adjusted Gross Sales, Target Price, Transfer Price and Roche Fill/Finish Costs figures relevant to the calculation of the Roche Gross Margin, and the calculation of the amount due to PDL. The information contained in each report under this Section 11.3 shall be considered Confidential Information of the Parties.

**11.4 Other Reports.** The Parties' reporting obligations with respect to Development Expenses, Operating Expenses and Sales Force Expenses are set forth in Sections 4.6(c) and 6.3(c). The information contained in such reports shall be considered Confidential Information of both Parties.

## 11.5 Accounting.

**(a) Product Sales Records.** Each Party (the “**Royalty Paying Party**”) agrees to keep full, clear and accurate records for a period of at least [\*\*\*\*] after the relevant payment is owed pursuant to this Agreement, setting forth the manufacturing, sales and other disposition of Licensed Products sold or otherwise disposed of 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 Section 11.1, 11.2, or 11.3. 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 global accounting firms. Such audit shall not be performed more frequently than [\*\*\*\*] 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.

**(b) Expense Records.** Each Party (the “**Expense Incurring Party**”) agrees to keep full, clear and accurate records for a period of at least [\*\*\*\*] after the relevant report is made pursuant to Section 4.6(c) or 6.3(c) setting forth its Development Expenses or Operating Expenses, as applicable, incurred in sufficient detail to enable royalties and compensation payable to the other Party (the “**Expense Reimbursing Party**”) hereunder to be determined. Each Expense Incurring Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the Expense Reimbursing Party to verify reports made pursuant to Section 4.6(c) or 6.3(c), as applicable. Unless the Expense Reimbursing Party obtains the prior written consent of the Expense Incurring Party, such accounting firms must be selected

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from among the four largest global accounting firms. Such audit shall not be performed more frequently than [\*\*\*\*] 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 Expense Reimbursing Party, except in the event that the results of the audit reveal a discrepancy in favor of the Expense Incurring Party of [\*\*\*\*] or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Expense Incurring Party.

**11.6 Methods of Payments.** All payments due to either PDL or Roche under this Agreement shall be paid in Dollars by wire transfer to a bank in the U.S. designated in writing by the Party to which the payment is due.

**11.7 Taxes.** If provision is made in law or regulation of any country of the Territory for withholding of taxes of any type, levies or other charges with respect to the any amounts payable hereunder to a Party or its Affiliates, the other Party or its Affiliates (“**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.

**11.8 Currency.** All payments under this Agreement shall be in Dollars.

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**11.9 Late Payments.** Any amount owed by one Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the [\*\*\*\*] as reported by Bloomberg (or a successor or similar organization).

## ARTICLE 12

### PATENTS AND KNOW-HOW

**12.1 PDL Technology.** Ownership of the PDL Know-How and PDL Patents shall remain vested at all times in PDL.

**12.2 Joint Inventions and Joint Roche-PDL Patents.** Subject to Section 12.6(e), ownership of Joint Inventions and Joint Roche-PDL Patents shall be vested jointly in PDL and Roche. Except where such activities would conflict with an exclusive license granted to a Party in this Agreement or in the Worldwide Daclizumab Agreement, 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 under any Joint Roche-PDL Patent, and neither Party shall be obligated to account to the other. 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.

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**12.3 Roche Technology.** Except as expressly provided in this Agreement or the Worldwide Daclizumab Agreement, ownership of the Roche Know-How, Roche Patents and Roche Inventions shall remain vested at all times in Roche.

**12.4 Disclosure of New Inventions.** At a regular interval to be agreed by the Parties (but no less than quarterly), the Parties shall disclose to each other any Joint Inventions, Roche Inventions, or other inventions that constitute or will constitute new PDL Know-How, Roche Know-How, PDL Patents (if a patent application is filed), or Roche Patents (if a patent application is filed), to extent that any of the foregoing were conceived or reduced to practice since the previous new invention disclosure.

**12.5 Prosecution of Sole PDL Patents and Sole Roche Patents.**

(a) PDL agrees to prosecute and reasonably maintain all of the patents and applications included within the Sole PDL Patents (except for [\*\*\*\*]), to the extent it has the rights to do so, consistent with the patent strategy developed by the JPC, and Roche agrees to prosecute and reasonably maintain the Sole Roche Patents, to the extent it has the rights to do so from any co-owner of such Sole Roche Patents, consistent with the patent strategy developed by the JPC. The costs and expenses for such prosecution and maintenance shall be allocated between the Parties as set forth in Section 12.7.

(b) The Party responsible for such patent (“**Responsible Party**”) shall provide the other Party with a reasonable opportunity to comment on all draft filings prior to their submission to the relevant patent authority. 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 Sole 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

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(except for [\*\*\*\*]) or Sole Roche 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 Collaborative Fields, PDL and its Affiliates shall have a worldwide immunity from suit thereunder. If Roche's interest in any Sole Roche Patent is assigned to PDL, PDL will thereafter prosecute and reasonably maintain such Sole Roche Patent at PDL's own cost to the extent that PDL desires to do so, provided that to the extent such Sole Roche Patent contains claims outside the Collaborative Fields, Roche and its Affiliates shall have a worldwide immunity from suit thereunder.

**12.6 Prosecution of Joint Inventions.**

(a) PDL will have the first right of election to file priority patent applications for Joint Inventions in any country in the Territory. If PDL declines to file such applications then Roche may do so. Such filings and all subsequent prosecution and maintenance shall be consistent with the patent strategy developed by the JPC.

(b) The Party not performing the priority patent filings for Joint Inventions pursuant to this Section 12.6 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.

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(c) The Party performing the priority patent filings for Joint Inventions pursuant to this Section 12.6 undertakes to perform the corresponding convention filings from case to case, after having discussed the countries for foreign filings with the other Party.

(d) The costs and expenses for prosecution and maintenance of Joint Roche-PDL Patents shall be allocated between the Parties as set forth in Section 12.7.

(e) 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 and the Parties shall discuss whether the Responsible Party shall assign such Joint Roche-PDL Patent 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 Collaborative Fields, 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 Collaborative Fields, Roche and its Affiliates shall have a worldwide immunity from suit thereunder.

**12.7 Allocation of Patent Prosecution Expenses.** The costs incurred by the Parties with respect to the prosecution and maintenance of PDL Patents and Roche Patents in the U.S. Territory and the European Union, or in connection with the international phase of PCT applications that designate the U.S. and/or European Union countries, shall be included in [\*\*\*\*] and shall be shared [\*\*\*\*] by the Parties until the end of the [\*\*\*\*]. Thereafter, [\*\*\*\*] shall be solely responsible for such costs in the [\*\*\*\*] or in connection with the international phase of PCT applications that designate the [\*\*\*\*], and [\*\*\*\*] shall be solely responsible for such costs in the [\*\*\*\*] or in connection

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with the international phase of PCT applications that designate [\*\*\*\*]. PDL shall bear [\*\*\*\*] of the costs incurred by the Parties with respect to the post-issuance maintenance of PDL Patents in the ROW Territory (except for the European Union). Except as set forth in the preceding sentence, Roche shall bear [\*\*\*\*] of the costs incurred by the Parties with respect to the prosecution and maintenance of PDL Patents and Roche Patents in the ROW Territory (except for the European Union) until the termination of Roche's royalty obligations under Section 10.3. Thereafter, PDL will be solely responsible for such costs with respect to the PDL Patents and Roche shall be solely responsible for such costs with respect to Sole Roche Patents. Notwithstanding anything to the contrary set forth above, PDL will be solely responsible for all costs with respect to the prosecution and maintenance of the [\*\*\*\*].

### **12.8 Enforcement and Defense of Sole Patents.**

(a) 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 Sole Roche 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. In the [\*\*\*\*] Territory, [\*\*\*\*] shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the [\*\*\*\*] in a Collaborative Field, in its own name and entirely under its own direction and control. The Parties shall share [\*\*\*\*] all expenses associated with such action or proceeding, provided it is commenced prior [\*\*\*\*]. [\*\*\*\*] shall bear all costs associated with any such action or proceeding commenced after [\*\*\*\*]. In the [\*\*\*\*] Territory, [\*\*\*\*] shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the [\*\*\*\*] (other than [\*\*\*\*] [\*\*\*\*]) in a Collaborative Field at [\*\*\*\*], 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 [\*\*\*\*] at [\*\*\*\*], in its own name and entirely under its own direction and control.

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(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 [\*\*\*\*] (other than [\*\*\*\*] and those [\*\*\*\*] for which [\*\*\*\*]) in a Collaborative Field or [\*\*\*\*] (other than those [\*\*\*\*]), 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, provided however, that the Parties shall [\*\*\*\*] all expenses associated with (i) actions or proceedings brought in the U.S. Territory prior to [\*\*\*\*] with respect to [\*\*\*\*] in the Asthma Field and (ii) actions or proceedings brought in the U.S. Territory [\*\*\*\*] with respect to [\*\*\*\*] in the Transplant Field. After [\*\*\*\*], [\*\*\*\*] shall not have any right to bring any action or defend any proceeding in the U.S. Territory with respect to a [\*\*\*\*] in the Asthma Field. After the [\*\*\*\*], [\*\*\*\*] shall not have any right to bring any action or defend any proceeding in the U.S. Territory with respect to a [\*\*\*\*] in the Transplant Field.

(c) In any event, the Party bringing an action (“**Acting Party**”) pursuant to this Section 12.8 shall solicit, and seriously consider in good faith the input of the other Party (“**Assisting Party**”) 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 Assisting Party promptly and fully informed of the status of any such action, and the Assisting Party shall have the right to review and comment on the Acting Party’s activities related thereto.

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(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 Assisting 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 Sole Roche 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), [\*\*\*\*].

(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 12.8 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 12.8 shall be reversed.

(f) Notwithstanding the foregoing, at PDL's request [\*\*\*\*], Roche shall assist PDL with respect to enforcement or revocation actions outside the Collaborative Fields with respect to a Sole PDL Patent claiming the composition of matter of a Licensed Product.

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**12.9 Enforcement and Defense of 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 [\*\*\*\*] shall have the exclusive right to bring such action or defend such proceeding, in its own name and entirely under its own direction, and at [\*\*\*\*] request, [\*\*\*\*] shall participate in such action or proceeding at [\*\*\*\*]. 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 12.9 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.

**12.10 Distribution of Proceeds.** In the event either Party exercises the rights conferred in Section 12.8 or 12.9 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

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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 be allocated as follows:

(a) With respect to actions or proceedings commenced hereunder in the U.S. Territory prior to the end of the Asthma Co-Promotion Term regarding one or more Sole PDL Patents or Sole Roche Patents infringed in the Asthma Field or prior to the end of the Transplant Co-Promotion Term regarding one or more Sole PDL Patents or Sole Roche Patents infringed in the Transplant Field, the Parties shall [\*\*\*\*] share such remaining recovery;

(b) With respect to actions or proceedings commenced hereunder in the U.S. Territory after the end of the Asthma Co-Promotion Term regarding one or more Sole PDL Patents or Sole Roche Patents infringed in the Asthma Field or after the end of the Transplant Co-Promotion Term regarding one or more Sole PDL Patents or Sole Roche Patents infringed in the Transplant Field, [\*\*\*\*] shall retain such remaining recovery in its entirety;

(c) With respect to actions or proceedings commenced hereunder in the ROW Territory regarding one or more Sole PDL Patents or Sole Roche Patents, [\*\*\*\*] shall retain such remaining recovery in its entirety, provided that if [\*\*\*\*] is the acting Party, then such remaining recovery shall be deemed [\*\*\*\*] and [\*\*\*\*] shall pay [\*\*\*\*] a royalty based thereon in accordance with the terms set forth in Section [\*\*\*\*];

(d) With respect to actions or proceedings commenced by PDL hereunder with respect to a Joint Roche-PDL Patent, such remaining recovery shall be divided between the Parties [\*\*\*\*]; and

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(e) With respect to actions or proceedings commenced by Roche hereunder with respect to a Joint Roche-PDL Patent, such remaining recovery shall be divided [\*\*\*\*] between the Parties.

#### **12.11 Defense of Infringement Actions.**

(a) If Roche and/or PDL are named as defendant(s) in a patent infringement suit filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of Licensed Products in a Collaborative Field in the ROW Territory, then Roche shall defend such suit at its own cost 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) If Roche and/or PDL are named as defendant(s) in a patent infringement suit filed by a Third Party concerning the methods or products used by or on behalf of PDL during the manufacture of Licensed Products for sale in a Collaborative Field in the U.S. Territory, and PDL had not previously disclosed to Roche that it was using such methods or products during such manufacture, then PDL shall defend such suit at its own cost and hold Roche harmless against any such patent or

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other infringement suits, and any claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and costs, that may be incurred by either Party therein or in settlement thereof. Any and all settlements must be approved by both Parties, 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.

(c) If Roche and/or PDL are named as defendant(s) in a patent infringement suit not covered by Section 12.11(b) that is filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of Licensed Products in the Asthma Field in the U.S. Territory prior to the end of the Asthma Co-Promotion Term or in the Transplant Field in the U.S. Territory prior to the end of the Transplant Co-Promotion Term, then the Parties shall share [\*\*\*\*] all costs associated with such suit including all claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and costs, that may be incurred by either Party therein or in settlement thereof. Any and all settlements must be approved by both Parties, such approval not to be unreasonably withheld. Neither Party shall be required to approve any settlement that does not include as a condition thereof the granting to such Party of a full and unconditional release of claims.

(d) During the term of this Agreement, each Party shall bring to the attention of the other Party all information regarding potential infringement of Third Party intellectual property rights via the development, manufacture, production, use, importation, offer for sale, or sale of Licensed Products in a Collaborative Field in the ROW Territory or the U.S. Territory. The Parties shall discuss such information and decide how to handle such matter.

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(e) This Section 12.11 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

**12.12 Right to Counsel.** Each Party to this 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 Agreement.

**12.13 Conflicts.** If the terms set forth in this Article 12 conflict with or are inconsistent with any terms set forth in the Worldwide Daclizumab Agreement, then the terms set forth in this Article 12 shall prevail to the extent necessary to overcome such conflict or inconsistency.

## ARTICLE 13

### TRADEMARKS

**13.1 Selection and Procurement of Trademarks.** The JSC shall select a single trademark (other than the Zenapax Trademark) to be used to market the Licensed Product in the Asthma Field throughout the Territory and a separate trademark (other than the Zenapax Trademark and the trademark selected for the Asthma Field) to be used to market the Licensed Product in the Transplant Field in each regulatory jurisdiction in the Territory in which different trademarks may be used to market the Licensed Product in the Asthma Field and the Transplant Field. Such separate trademark, once it becomes registered in the U.S. Territory and is approved by the FDA for use in the U.S. Territory with respect to the Licensed Product in the Transplant Field, shall be referred to herein as the **“Transplant Trademark.”** Each selected trademark shall be deemed a PDL Trademark and shall be owned by PDL. PDL shall be responsible for procurement and maintenance of trademark registrations for the PDL Trademarks in the Territory, except that PDL may cease trademark registration procurement activities for any PDL Trademark in any country in the ROW

Territory provided it first offers Roche the opportunity to assume such activities at its own expense. Those expenses incurred by PDL with respect to PDL Trademarks in the U.S. Territory shall be included in Operating Expenses.

**13.2 Use of the Trademarks.** Roche and its Affiliates and sublicensees shall use the PDL Trademarks only in connection with the development, use, marketing, promotion, detailing, sale, and offer for sale of Licensed Product in the Territory in accordance with the licenses granted in Sections 2.1(a)(iii)(2) and 2.1(b)(ii). It is understood and agreed by PDL that, in the ROW Territory, Roche shall have the right to use the corporate names of Roche and its Affiliates, and associated logos and designs, in conjunction with the PDL Trademarks, and shall identify PDL on all packaging and labeling as the manufacture and co-developer of the Licensed Product. It is also understood and agreed that, during the Asthma Co-Promotion Term in the U.S. Territory, the Parties shall have the right to use the corporate names of the Parties and their Affiliates, and all associated logos and designs, in conjunction with the PDL Trademarks with respect to the Asthma Field and that, during the Transplant Co-Promotion Term in the U.S. Territory, the Parties shall have the right to use the corporate names of the Parties and their Affiliates, and all associated logos and designs, in conjunction with the PDL Trademarks with respect to the Transplant Field.

**13.3 PDL House Marks.** Roche acknowledges the goodwill and reputation associated with the PDL House Marks and shall use the PDL House Marks in a manner that maintains and promotes such goodwill and reputation. Roche shall take all reasonable precautions and actions to protect the goodwill and reputation that has inured to the PDL House Marks, shall refrain from doing any act that is reasonably likely to impair the reputation of the PDL House Marks, and shall cooperate fully to protect the PDL House Marks.

**13.4 Quality Control.** Roche's use of the PDL Trademarks and the PDL House Marks must comply with PDL's style and branding guidelines, and Roche shall provide all materials (including without limitation advertising or promotional materials) that incorporate the PDL Trademarks or PDL House Marks to the Asthma JDC or Transplant JCC (as applicable) for prior review and approval.

**13.5 Acknowledgement of Ownership Rights.** Roche undertakes to conduct its activities in such a way so as not to jeopardize or compromise in any way the PDL Trademarks or rights therein. Roche shall not use the PDL Trademarks or PDL House Marks, as the case may be, as all or part of any corporate name, trade name, trademark, service mark, certification mark, collective membership mark, domain name, or any other designation confusingly similar to the PDL Trademarks or PDL House Marks in any way that damages the PDL Trademarks or PDL House Marks. If Roche or its Affiliates challenge or, directly or indirectly, assert any right, title or interest in or to the PDL Trademarks, PDL House Marks, or any registrations or applications for registration thereof, or seek to register the PDL Trademarks or PDL House Marks in any country for any goods and services, then PDL shall have the right to give written notice to Roche of such conduct and Roche shall immediately cease such conduct.

**13.6 Use of Trademark Designations.** The <sup>TM</sup> designation may be used in conjunction with each PDL Trademark within the Territory. Once registrations issue, the <sup>®</sup> designation may be used in connection with the PDL Trademarks. An appropriate statutory notice of trademark ownership shall be affixed to or imprinted on any material wherever the PDL House Marks or PDL Trademarks are used. PDL's ownership of such marks shall be identified on all materials on which they appear. The exact language for identification of ownership shall be in accordance with branding and implementation guidelines to be agreed on by the Parties.

**13.7 Infringement of Trademarks.**

**(a) Procedure.** In the event that either Party becomes aware of (i) actual infringement of a PDL Trademark in the ROW Territory; (ii) a mark or name confusingly similar to a PDL Trademark in the ROW Territory; or (iii) any unfair trade practices, trade dress imitation, passing off, or like offenses, in the ROW Territory that relate to the PDL Trademarks, such Party shall promptly so notify the other Party in

writing. [\*\*\*\*] shall have the right, but not the obligation, at its [\*\*\*\*], to initiate, prosecute, and control an infringement action or file any other appropriate action or claim related to such infringement of the PDL Trademark against any Third Party. If [\*\*\*\*] fails to bring any such infringement action within a period of ninety (90) days after delivery of the notice set forth above, then [\*\*\*\*] shall have the right, but not the obligation, at its [\*\*\*\*], to initiate, prosecute, and control an infringement action or file any other appropriate action or claim related to such infringement of the PDL Trademark against any Third Party. In either event, the Party not bringing any such action (i) shall have the right (at its own expense) to participate in such action and to be represented by counsel of its own choice, and (ii) agrees, at the request [\*\*\*\*] of the Party bringing such action, to be joined as a Party to the suit and to provide reasonable assistance in any such action. The Party controlling such action shall take all reasonable and appropriate steps to protect, defend, and maintain the PDL Trademarks for use by the Parties and shall have the right to control settlement of such action; provided, however, that no settlement shall be entered into without the written consent of the other Party, not to be unreasonably withheld.

**(b) Costs.** Any damages or monetary award recovered shall be applied first to reimburse the reasonable costs and expenses of the Party bringing such action in connection with such litigation, with the balance being allocated to the Parties [\*\*\*\*].

### **13.8 Third Party Trademark Claims.**

**(a) Claims Based on Use of the PDL Trademarks.** If a claim is brought by a Third Party that the Parties' use of the PDL Trademarks infringes such Third Party's trademarks, the Party against which (or against whose Affiliate, as the case may be) the action is brought will give prompt written notice to the other Party of

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such claim. If the JSC or Executive Officers selected such trademark for the Licensed Product by consensus, then (i) [\*\*\*\*] shall defend any such claim and any resulting suit brought in the ROW Territory at its expense and shall indemnify [\*\*\*\*] and its Affiliates against any resulting final judgments and settlements, provided that [\*\*\*\*] shall not settle any claim or suit in a manner that would adversely affect [\*\*\*\*] without obtaining [\*\*\*\*] prior written consent, which shall not be unreasonably withheld, and (ii) [\*\*\*\*] shall defend any such claim and any resulting suit brought in the U.S. Territory with respect to use of the trademark in the Asthma Field during the Asthma Co-Promotion Term or in the Transplant Field during the Transplant Co-Promotion Term provided that the costs associated with such defense shall be Operating Expenses (and therefore shared equally by the Parties) and [\*\*\*\*] shall not settle any claim or suit in a manner that would adversely affect [\*\*\*\*] without obtaining [\*\*\*\*] prior written consent, which shall not be unreasonably withheld. If the JSC and Executive Officers did not reach consensus regarding the selection of a trademark for use on the Licensed Product and [\*\*\*\*] selected such trademark pursuant to Section 3.5(b), then [\*\*\*\*] shall defend such claim and any resulting suit at its expense and shall indemnify [\*\*\*\*] and its Affiliates against any resulting final judgments and settlements, provided that [\*\*\*\*] shall not settle any claim or suit in a manner that would adversely affect [\*\*\*\*] without obtaining [\*\*\*\*] prior written consent, which shall not be unreasonably withheld. If the JSC and Executive Officers did not reach consensus regarding the selection of a Transplant Trademark and [\*\*\*\*] selected such trademark pursuant to Section 3.5(b)(iv), then [\*\*\*\*] shall defend such claim and any resulting suit at its expense and shall indemnify [\*\*\*\*] and its Affiliates against any resulting final judgments and settlements, provided that [\*\*\*\*] shall not settle any claim or suit in a manner that would adversely affect [\*\*\*\*] without obtaining [\*\*\*\*] prior written consent, which shall not be unreasonably withheld.

**(b) Claims Based on Use of the PDL House Marks.** If a claim is brought by a Third Party that the use of the PDL House Marks by Roche or its Affiliates

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in the ROW Territory infringes such Third Party's trademarks, Roche shall give prompt written notice to PDL of such claim. [\*\*\*\*] shall defend such claim and any resulting suit at its expense and shall indemnify [\*\*\*\*] and its Affiliates against any resulting final judgments and settlements, provided that [\*\*\*\*] shall not settle any claim or suit in a manner that would adversely affect [\*\*\*\*] without obtaining [\*\*\*\*] prior written consent, which shall not be unreasonably withheld.

## ARTICLE 14

### REPRESENTATIONS, WARRANTIES, AND COVENANTS

**14.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party:

(a) Such Party is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

(b) The execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

(c) Such Party has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any agreement of such Party with a Third Party;

(d) To the best of its knowledge, such Party has the right to grant the rights and licenses described in this Agreement; and

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(e) PDL and Roche each covenant to timely make any required application pursuant to the HSR Act. Each party shall cooperate fully and promptly in any required HSR notification process as well as any other applicable governmental or regulatory filing required by the HSR Act.

**14.2 Disclaimer.** EXCEPT AS EXPRESSLY SET FORTH IN SECTION 14.1, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY ARE PROVIDED “AS IS” AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OR DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

**14.3 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, EACH PARTY’S PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT FOR DAMAGES ARISING FROM A BREACH OF SECTION 2.3 OR 15.1. THE FOREGOING SHALL NOT LIMIT EITHER PARTY’S INDEMNIFICATION OBLIGATIONS HEREUNDER.

## ARTICLE 15

### CONFIDENTIALITY

**15.1 Nondisclosure of Confidential Information.** All Information disclosed by one Party to the other Party under this Agreement shall be subject to the nondisclosure and nonuse provisions set forth in Article XIV of the Worldwide

Daclizumab Agreement (as amended by this Agreement). The Parties hereby amend Section 14.1(a) of the Worldwide Daclizumab Agreement to permit, in addition to any rights already granted under the Worldwide Daclizumab Agreement, (a) the use by a Party of any trade secrets or proprietary information disclosed to such Party by the other Party (“**Confidential Information**”) for those purposes permitted by this Agreement; and (b) the further disclosure by such Party of such trade secrets or proprietary information disclosed to such Party by the other Party to those of its Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents or subcontractors as necessary in connection with such Party’s performance under this Agreement.

The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to investment bankers, investors, and potential investors, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 15. In addition, a copy of this Agreement may be filed by PDL with the Securities and Exchange Commission. In connection with any such filing, PDL shall endeavor to obtain confidential treatment of economic and trade secret information.

In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information except as permitted hereunder.

**15.2 Publicity.** The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as Exhibit E. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties; provided, however, that any disclosure which is required by law as advised by the disclosing Party’s counsel may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure and to the extent practicable shall provide the other Party an opportunity to comment on the proposed disclosure.

**15.3 Publications.** Prior to public disclosure or submission for publication of a document describing the results of any scientific activity or collaboration between PDL and Roche in a Collaborative Field, the Party disclosing or submitting such a document (“Disclosing Party”) shall send the other Party (“Responding Party”) a copy of the document. The term “document” includes all manifestations of idea expression, including but not limited to graphic (e.g. text, charts, and other visual presentations) and electromagnetic (e.g. CD, floppy disk, e-mail, video tape, DVD, and other forms of memory). The Responding Party shall have a reasonable time period not to exceed [\*\*\*\*] from its confirmed date of receiving the document (“Review Period”) to determine (i) whether the document contains Confidential Information belonging to the Responding Party and (ii) whether the document discloses an invention for which patent protection should be sought (prior to publication of such document) for the purpose of protecting an invention. If the Responding Party does not object in writing to publication of the document within the Review Period, then the Disclosing Party may submit such document for publication or otherwise disclose to the public such results of the scientific activity or collaboration. If the Responding Party determines that the document contains Confidential Information or a patentable invention for which patent protection will be sought, then the Responding Party shall notify in writing the Disclosing Party during the Review Period of its determination. If the document contains [\*\*\*\*], then the Disclosing Party shall [\*\*\*\*] before public disclosure or submission for publication. If the document contains subject matter for which patent protection should be sought, then the Disclosing Party shall delay public disclosure or submission of the document for a period of at least [\*\*\*\*] from the date it receives written notice from the Responding Party, so as to permit preparation and filing of a patent application on the disclosed subject matter. [\*\*\*\*] after the date the Disclosing Party receives notice from the Responding Party, the Disclosing Party may submit for publication or publicly disclose such invention. Authorship for any document shall be determined in accordance with

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accepted scientific practice. If a question of authorship arises, then the authorship shall be determined by good faith consultation between the respective heads of research for each Party.

## ARTICLE 16

### INDEMNIFICATION

**16.1 Indemnification by PDL.** Unless otherwise provided herein, PDL agrees to indemnify, hold harmless and defend Roche and its directors, officers, employees and agents (the “**Roche Indemnitees**”) from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or losses (including without limitation attorneys’ fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) (“**Losses**”) to the extent that such Losses arise out of (a) a breach of a representation or warranty or covenant by PDL under Article 14 or (b) the distribution, manufacture, use, testing, promotion, marketing or sale of a Licensed Product by or on behalf of PDL, its Affiliates or sublicensees (except for Roche), but only to the extent the Losses described in “(b)” result from (i) any violation of applicable law by PDL with respect to co-promotion activity in a Collaborative Field in the U.S. Territory under Article 6, (ii) the failure of Licensed Products manufactured by PDL to conform to cGMP or the written specifications for such products or (iii) the negligence or misconduct or failure to act of PDL, its agents or sublicensees in connection with PDL’s obligations under this Agreement. The indemnification obligation set forth in (b) above with respect to the manufacture of Licensed Product shall be automatically superseded by the execution of a Commercial Supply Agreement; after such execution Roche shall be entitled only to such manufacturing-related indemnification from PDL as may be specified in such Commercial Supply Agreement. Notwithstanding the foregoing, PDL shall not have any obligation to indemnify the Roche Indemnitees with respect to any Losses arising out of the negligence or misconduct or failure to act of Roche, its Affiliates, or sublicensees (except for PDL).

**16.2 Indemnification by Roche.** Unless otherwise provided herein, Roche shall indemnify, hold harmless and defend PDL and its directors, officers, employees and agents (the “**PDL Indemnitees**”) from and against any and all Losses, to the extent that such Losses arise out of (a) a breach of a representation or warranty or covenant by Roche under Article 14 or (b) the distribution, use, testing, promotion, marketing, or sale of a Licensed Product by or on behalf of Roche, its Affiliates or sublicensees (except for PDL), but only to the extent that the Losses described in “(b)” result from (i) any violation of applicable law by Roche with respect to co-promotion activity in a Collaborative Field in the U.S. Territory under Article 6, (ii) any ROW Commercialization Activities, or (iii) the negligence or misconduct or failure to act of Roche, its agents or sublicensees in connection with Roche’s obligations under this Agreement. Notwithstanding the foregoing, Roche shall not have any obligation to indemnify the PDL Indemnitees with respect to any Losses arising out of the negligence or misconduct or failure to act of PDL, its Affiliates, or sublicensees (except for Roche).

**16.3 Procedure.** In the event of a claim by a Third Party against a Party entitled to indemnification under this 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 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.

**16.4 Certain Losses.** Any Losses resulting from Third Party suits, claims, or actions in the U.S. with respect to which neither Party owes an indemnification

obligation under this Article 16 shall be [\*\*\*\*]. In addition, notwithstanding anything to the contrary, all Losses arising from latent defects in the Licensed Products shall [\*\*\*\*] and [\*\*\*\*] shall have any indemnification obligations with respect thereto.

#### **16.5 Insurance.**

(a) PDL, at its own expense, shall maintain product liability insurance in an amount consistent with industry standards for a company of similar standing during the term of this Agreement. PDL shall provide [\*\*\*\*] prior written notice to any cancellation of its insurance program. PDL shall designate Roche as an additional insured under its applicable insurance policies.

(b) The Parties acknowledge that Roche, as of the Effective Date, self-insures. If during the term of this Agreement Roche [\*\*\*\*], Roche shall [\*\*\*\*] under its applicable insurance policies and shall provide PDL with [\*\*\*\*] prior written notice of any [\*\*\*\*].

**16.6 Relationship to Worldwide Daclizumab Agreement.** Solely to the extent that either Party has a Loss recoverable under this Article 16, the Parties' rights and obligations under this Article 16 shall supersede any rights or obligations of the Parties granted under Section 17.6 of the Worldwide Daclizumab Agreement.

### **ARTICLE 17**

#### **TERM AND TERMINATION**

**17.1 Term.** The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article 17, will expire on

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the date on which neither Party has nor will have any additional payment obligations to the other Party under this Agreement. Upon expiration of the Agreement, provided that there has been [\*\*\*\*] in at least [\*\*\*\*], Roche shall have a fully paid-up license with respect to the licenses granted under Section 2.1(b) [\*\*\*\*]. Upon expiration of the Agreement, provided that there has been a [\*\*\*\*] in at least [\*\*\*\*], Roche shall have a fully paid-up license with respect to the licenses granted under Section 2.1(b) ([\*\*\*\*]).

#### 17.2 Termination for Breach.

(a) A Party (“**non-breaching Party**”) shall have the right, in addition to any other rights and remedies, to terminate this Agreement in the event the other Party (“**breaching Party**”) is in breach of any of its material obligations under this Agreement, provided that any such termination shall only be effective with respect to the particular Region(s) and the particular Collaborative Field to which such breach amounted to a material breach, except that (i) [\*\*\*\*], and (ii) [\*\*\*\*], each of which shall be subject to the terms of Section 17.2(e). The non-breaching Party shall provide written notice to the breaching Party, which notice shall identify the breach and the Region(s) and the Collaborative Field with respect to which the non-breaching Party intends to have this Agreement terminate. With respect to breaches of any payment provision hereunder, the breaching Party shall have a period of [\*\*\*\*] after such written notice is provided to cure such breach; provided, however, if there is a dispute as to whether a development event or commercialization event referenced in Section 9.2, 9.3 or 10.6, respectively, has occurred (thereby triggering a payment obligation under such sections), Roche shall not be obliged to make such payment until such dispute is resolved in accordance with Article 18. With respect to all other breaches, the breaching Party shall have a period of [\*\*\*\*] after such written notice is provided to cure such breach. If such breach is not cured within the applicable period set forth above, this Agreement shall terminate immediately with respect to the applicable Region and

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applicable Collaborative Field, upon written notice provided by the non-breaching Party of such termination. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach. Termination for a breach occurring in one or more Regions in the ROW Territory shall not affect any rights or obligation hereunder relating to the U.S. Territory, and vice versa, except as otherwise provided above. Termination for a breach occurring with respect to the Asthma Field shall not affect any rights or obligation hereunder relating to the Transplant Field, and vice versa.

**(b)** For clarity and without limiting the generality of the foregoing, any breach of a material obligation relating to co-promotion of Licensed Product under this Agreement in a particular Collaborative Field shall be treated as a breach with respect to the U.S. Territory and may therefore give rise to a right, pursuant to Section 17.2(a), to terminate this Agreement with respect to such Collaborative Field solely as to the U.S. Territory.

**(c) Consequences of Termination for Roche's Breach.**

**(i)** If Roche breaches the Agreement with respect to a Region in the ROW Territory and with respect to a Collaborative Field, and PDL terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to such Region and such Collaborative Field, then the following shall apply:

**(1)** Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and

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information, in each case to the extent in Roche's control and to the extent related to the affected Collaborative Field and related to the Licensed Products in the affected Region, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be [\*\*\*\*];

(2) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under the Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the affected Collaborative Field in the affected Region;

(3) All licenses granted to Roche under Section 2.1(b) shall terminate with respect to the affected Region, but only with respect to the affected Collaborative Field; and

(4) The Parties' respective co-development and co-promotion rights and obligations in the U.S. Territory, and the Parties' rights and obligations in any other Region in the ROW Territory and in any other Collaborative Field shall not be affected by any termination of this Agreement with respect to a Collaborative Field and a Region in the ROW Territory.

(ii) If Roche breaches the Agreement with respect to the U.S. Territory and with respect to a Collaborative Field, and PDL terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to the U.S. Territory and such Collaborative Field, then the following shall apply:

(1) If the affected Collaborative Field is the Asthma Field, then the Asthma Co-Promotion Term, if started, shall end and, if not yet started, shall not commence;

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(2) If the affected Collaborative Field is the Transplant Field, then the Transplant Co-Promotion Term, if started, shall end and, if not yet started, shall not commence;

(3) Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to the affected Collaborative Field and related to the Licensed Products in the U.S. Territory, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be borne [\*\*\*\*];

(4) All licenses granted to PDL in Sections 2.2(a) and 2.2(c) shall become exclusive, perpetual, irrevocable, and fully paid, but only with respect to the affected Collaborative Field;

(5) All licenses granted to Roche under Section 2.1(a) shall terminate with respect to the affected Collaborative Field, and Roche shall cease to have any right or obligation to Develop, sell or co-promote Licensed Products in the affected Collaborative Field in the U.S. Territory or to participate in any other commercialization- or development-related activities ([\*\*\*\*]) with respect to Licensed Products in the affected Collaborative Field in the U.S. Territory; and

(6) The Parties' respective rights and obligations with respect to the ROW Territory (and all Regions therein) or any other Collaborative Field shall not be affected by any termination of this Agreement with respect to the affected Collaborative Field in the U.S. Territory.

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(iii) Notwithstanding the foregoing Sections 17.2(c)(i) and (ii), in the event that Roche breaches the Agreement with respect to the [\*\*\*\*], then PDL shall have the right to terminate this Agreement in its entirety with respect to the affected Collaborative Field and such termination shall have the consequences set forth in Section 17.2(e)(ii).

**(d) Consequences of PDL's Breach.**

(i) If PDL breaches the Agreement with respect to a Region in the ROW Territory and with respect to a Collaborative Field, and Roche terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to such Region, then the following shall apply:

(1) Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to the affected Collaborative Field and related to the Licensed Products in the affected Region. The costs of such transfers shall be borne [\*\*\*\*]. At Roche's reasonable request, PDL shall allow Roche to access such regulatory filings, Regulatory Approvals, clinical trial agreements, and data as required for Roche to satisfy its obligations under applicable law or to prepare a defense against Third Party litigation;

(2) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under the Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the affected Collaborative Field in the affected Region;

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(3) All licenses granted to Roche under Section 2.1(b) shall terminate with respect to such affected Region, but only with respect to the affected Collaborative Field; and

(4) The Parties' respective co-development and co-promotion rights and obligations in the U.S. Territory, and the Parties' rights and obligations in any other Region in the ROW Territory and in any other Collaborative Field shall not be affected by any termination of this Agreement with respect to the affected Collaborative Field in the affected Region in the ROW Territory.

(ii) If PDL breaches the Agreement with respect to a Collaborative Field and a Region in the ROW Territory and Roche has the right to terminate the Agreement with respect to such Collaborative Field in such Region as a result, Roche may elect the following as an alternative remedy to termination:

(1) The Parties' respective rights and obligations with respect to the ROW Territory shall remain unchanged, except that Roche shall be relieved of any diligence obligations in the affected Collaborative Field with respect to the affected Region for so long as PDL's breach in such affected Collaborative Field and affected Region prevents Roche from satisfying such diligence obligations; and

(2) The Parties' respective co-development and co-promotion rights and obligations in the U.S. Territory, and the Parties' rights and obligations in all other Regions in the ROW Territory and in other Collaborative Fields shall not be affected.

(iii) If PDL breaches the Agreement with respect to the U.S. Territory and with respect to a particular Collaborative Field, and Roche terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to the U.S. Territory and such Collaborative Field, then the following shall apply:

(1) If the affected Collaborative Field is the Asthma Field, then:

(a) the Asthma Co-Promotion Term shall end;

(b) all licenses granted PDL in Section 2.2(a) (but only with respect to the Asthma Field) shall be suspended until [\*\*\*\*];

(c) PDL shall grant to Roche, under the PDL Technology, an exclusive license to use, import, offer for sale and sell Licensed Products in the Asthma Field in the U.S. Territory until [\*\*\*\*], provided that if PDL or its Third Party licensee has filed for regulatory approval in an indication outside of the Collaborative Fields in the U.S. Territory for Licensed Product having the same formulation and mode of administration as Licensed Product being developed or commercialized for the Asthma Field, then the Parties shall discuss in good faith the feasibility of two parties simultaneously booking sales of Licensed Product;

(d) PDL shall cease to have any right or obligation to Develop or co-promote Licensed Products in the Asthma Field in the U.S. Territory or to actively participate in any other commercialization- or development-related activities with respect to Licensed Products in the Asthma Field in the U.S. Territory until [\*\*\*\*], provided that PDL shall retain the right of access to information, meetings and planning reasonably required to ensure effective transition, manufacturing support and return to PDL following the [\*\*\*\*];

(e) the Parties shall share [\*\*\*\*] Operating Expenses, Roche's Sales Force Expenses and Roche Gross Margin (all with respect to the Asthma Field, with the understanding that the meaning of such terms shall be modified as necessary to accomplish the intended purpose) until [\*\*\*\*], provided that any payments [\*\*\*\*] may be offset by the amount of [\*\*\*\*], as set forth in a final non-appealable judgment or award granted in accordance with the dispute resolution procedures of Article 18; and

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(f) on [\*\*\*\*], the licenses to Roche set forth in Sections 2.1(a), 2.1(b) and 17.2(d)(iii)(3)(c) shall terminate with respect to the Asthma Field, the licenses set forth in Section 2.2(a) shall come back into force with respect to the Asthma Field and become exclusive, and PDL shall have sole responsibility and decision-making authority for the Detailing, marketing, Promotion, sale and distribution of Licensed Product in the Asthma Field in the U.S. Territory. Except as explicitly provided in Section 10.2, PDL shall owe Roche no consideration in respect to sales of Licensed Product in the Asthma Field in the U.S. Territory [\*\*\*\*], except for [\*\*\*\*] provided for hereinabove;

(2) If the affected Collaborative Field is the Transplant Field and there is a Transplant Branded Product, then the Transplant Co-Promotion Term and the Parties' rights and obligations during such period with respect to the Transplant Field shall continue as before termination except that:

(a) PDL shall cease to have any right or obligation to Develop or co-promote Licensed Products in the Transplant Field in the U.S. Territory or to actively participate in any other commercialization- or development-related activities with respect to Licensed Products in the Transplant Field in the U.S. Territory [\*\*\*\*], provided that PDL shall retain the right of access to information, meetings and planning reasonably required to ensure effective transition, manufacturing support and return to PDL following the [\*\*\*\*];

(b) Roche [\*\*\*\*], from [\*\*\*\*], the amount of damages caused by PDL's breach, as set forth in a final non-appealable judgment or award granted in accordance with the dispute resolution procedures of Article 18; and

(c) [\*\*\*\*], the licenses to Roche set forth in Sections 2.1(a) and 2.1(b) shall terminate with respect to the Transplant Field, the

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licenses set forth in Section 2.2(a) shall come back into force with respect to the Transplant Field and become exclusive, the provisions of Section 5.1(b)(iii) shall apply, and PDL shall have sole responsibility and decision-making authority for the Detailing, marketing, Promotion, sale and distribution of Licensed Product in the Transplant Field in the U.S. Territory. Except as explicitly provided in Section 10.2, PDL shall owe Roche no consideration in respect to sales of Licensed Product in the Transplant Field in the U.S. Territory after [\*\*\*\*], except for the [\*\*\*\*] for hereinabove;

(3) If the affected Collaborative Field is the Transplant Field and there is no Transplant Branded Product, then the Transplant Co-Promotion Term and the Parties' rights and obligations during such period with respect to the Transplant Field shall be affected as set forth in Section 17.2(d)(iii) (1) *mutatis mutandis* as if the Asthma Field were the Transplant Field; and

(4) The Parties' respective rights and obligations with respect to the ROW Territory (including all Regions therein) or with respect to any other Collaborative Field shall not be affected by any termination of this Agreement with respect to the affected Collaborative Field in the U.S. Territory.

**(e) Consequences of Material Breach of Development Plan.** Notwithstanding the applicability of Sections 17.2(c) or 17.2(d), if a Party breaches a material obligation related to the Asthma Development Plan or Transplant Development Plan, the non-breaching Party shall have the following alternatives;

(i) Continue the Agreement in effect and pursue any and all remedies available in law or at equity, including the right to seek specific performance of the Parties' respective performance and payment obligations under the Asthma Development Plan or Transplant Development Plan (as applicable) as well as the right to seek appropriate damages; or

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(ii) Terminate the Agreement in its entirety, pursuant to the procedure outlined in Section 17.2(a), in which case the following shall apply:

(1) Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to both the affected Collaborative Field and the Licensed Products in the Territory, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be borne [\*\*\*\*];

(2) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the affected Collaborative Field in the Territory; and

(3) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate with respect to the affected Collaborative Field and Roche shall cease to have any rights with respect to the Licensed Products in the affected Collaborative Field in the Territory.

**17.3 Termination at Will.** Commencing [\*\*\*\*], Roche shall have the right to terminate this Agreement without cause (but solely with respect to the [\*\*\*\*]) in accordance with subsections (a) and (b) below. Commencing upon [\*\*\*\*], Roche shall have the right to terminate this Agreement without cause (but solely with respect to the [\*\*\*\*]) in accordance with subsections (a) and (b) below. For clarity, Roche's

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forementioned right to terminate this Agreement with respect to the [\*\*\*\*] is separate from its aforementioned right to terminate this Agreement with respect to the [\*\*\*\*], and Roche may exercise one, both or neither of these rights, each in accordance with the terms and conditions that apply to such termination.

**(a) During Development.** Prior to the receipt of Regulatory Approval in a particular Collaborative Field in the U.S. Territory or the European Union, termination under this Section 17.3 in such Collaborative Field shall pertain to both the ROW Territory and the U.S. Territory and such termination shall become effective [\*\*\*\*] after PDL's receipt of Roche's written termination notice. During the period between Roche's termination notice and the effective date of such termination (the "**Termination Notice Period**"), the Parties shall continue to perform all of their obligations under this Agreement with respect to the affected Collaborative Field, including sharing Development Expenses and other costs required to be shared under this Agreement; provided, however, that no payments shall become due or payable for any development or commercialization events in the affected Collaborative Field that are first achieved during the applicable Termination Notice Period. Termination of this Agreement with respect to a Collaborative Field pursuant to this Section 17.3(a) shall have the following effects:

**(i)** Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to both the affected Collaborative Field and the Licensed Products in the Territory, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be borne [\*\*\*\*];

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(ii) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the affected Collaborative Field in the Territory;

(iii) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate with respect to the affected Collaborative Field and Roche shall cease to have any rights with respect to the Licensed Products in the affected Collaborative Field in the Territory; and

(iv) During an additional [\*\*\*\*] following the effective date of such termination, Roche shall continue to pay its share any non-cancelable Development Expenses and any other non-cancelable costs that are required to be shared under this Agreement, in each case solely with respect to the ROW Territory and solely with respect to the Collaborative Field, and in each case subject to PDL's obligation to use reasonable efforts to mitigate such non-cancelable expenses and costs. In addition, Roche shall provide, [\*\*\*\*], transition services to ensure effective transition to PDL or a Third Party designated by PDL for a period not to exceed [\*\*\*\*] following the effective date of such termination, all on terms to be agreed upon by the Parties.

**(b) After Regulatory Approval.** After the receipt of Regulatory Approval in the U.S. Territory or the European Union in a particular Collaborative Field, termination under this Section 17.3 in such Collaborative Field shall be on a Region-by-Region basis in the ROW Territory and shall become effective [\*\*\*\*] after PDL's receipt of Roche's written termination notice. During the period between Roche's termination notice and the effective date of such termination (the "**Termination Notice Period**"),

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the Parties shall continue to perform all of their obligations under this Agreement with respect to the affected Collaborative Field, including sharing costs required to be shared under this Agreement; provided, however, that no payments shall become due or payable for any development or commercialization events in the affected Collaborative Field that are first achieved during the Termination Notice Period that apply solely to terminated Regions. Termination of this Agreement pursuant to this Section 17.3(b) with respect to a Collaborative Field shall have the following effects:

(i) Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to both the Collaborative Field and the Licensed Products in the terminated countries, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be [\*\*\*\*];

(ii) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the affected Collaborative Field in the terminated countries;

(iii) All licenses granted to Roche under Section 2.1(b) (and Section 2.1(a) if the U.S. Territory is terminated) with respect to the Collaborative Field shall terminate with respect to the terminated Region; and

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(iv) The Parties' respective co-promotion rights and obligations in the U.S. Territory shall not be affected by any termination of this Agreement pursuant to this Section 17.3(b) with respect only to Regions that are part of the ROW Territory.

**17.4 Termination of Asthma Co-Promotion Term by Roche.** In the event that, any anytime after [\*\*\*\*]but before [\*\*\*\*], [\*\*\*\*] falls below [\*\*\*\*], Roche shall have the right, within [\*\*\*\*] after the end of such [\*\*\*\*], to provide written notice to PDL of Roche's intent to terminate the Asthma Co-Promotion Term, which termination shall be effective at the end of such [\*\*\*\*] period. In the event that Roche terminates the Asthma Co-Promotion Term pursuant to this Section 17.4, then the following shall apply:

(a) All licenses granted to Roche under Section 2.1(a) shall terminate with respect to the Asthma Field, and Roche shall cease to have any right or obligation to co-promote Licensed Products in the Asthma Field in the U.S. Territory or to participate in any other commercialization- or development-related activities (including sharing of Operating Expenses) with respect to Licensed Products in the Asthma Field in the U.S. Territory;

(b) [\*\*\*\*], PDL shall pay royalties to Roche at the rate of [\*\*\*\*] of PDL Net Sales in the Asthma Field. PDL will not have any obligation to pay royalties to Roche pursuant to Section 10.2 with respect to PDL Net Sales in the Asthma Field; and

(c) The Parties' respective rights and obligations with respect to the ROW Territory or with respect to the Transplant Field shall not be affected by any termination of the Asthma Co-Promotion Term pursuant to this Section 17.4.

**17.5 Termination of Transplant Co-Promotion Term by Roche.** In the event that, any anytime after the [\*\*\*\*] but before [\*\*\*\*], [\*\*\*\*] or [\*\*\*\*] (as applicable) [\*\*\*\*] falls below [\*\*\*\*], Roche shall have the right, within [\*\*\*\*] after the end of such [\*\*\*\*], to

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provide written notice to PDL of Roche's intent to terminate the Transplant Co-Promotion Term, which termination shall be effective at the end of such [\*\*\*\*] period. In the event that Roche terminates the Transplant Co-Promotion Term pursuant to this Section 17.5, then the following shall apply:

(i) Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to both the Transplant Field and the Licensed Products in the U.S. Territory, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be [\*\*\*\*];

(b) All licenses granted to Roche under Section 2.1(a) shall terminate with respect to the Transplant Field, and Roche shall cease to have any right or obligation to co-promote Licensed Products in the Transplant Field in the U.S. Territory or to participate in any other commercialization- or development-related activities (including sharing of Operating Expenses or Sales Force Expenses) with respect to Licensed Products in the Transplant Field in the U.S. Territory;

(c) [\*\*\*\*], PDL shall pay royalties to Roche at the rate of [\*\*\*\*] of PDL Net Sales in the Transplant Field. PDL will not have any obligation to pay royalties to Roche pursuant to Section 10.2 with respect to PDL Net Sales in the Transplant Field; and

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(d) The Parties' respective rights and obligations with respect to the ROW Territory or with respect to the Asthma Field shall not be affected by any termination of the Transplant Co-Promotion Term pursuant to this Section 17.5.

**17.6 Change of Control Termination.** In the event of a Change of Control of a Party (the "**Acquired Party**") in which the Acquired Party is acquired by or becomes an Affiliate of a Major Pharmaceutical Company (the "**Acquiror**"), the other Party (the "**Non-Acquired Party**") shall have the following rights:

(a) If the Acquiror does not have a product that has received regulatory approval for [\*\*\*\*] in the U.S. or the European Union, or the Acquired Party and the Acquiror have agreed to divest any such product, then the Non-Acquired Party shall have the right to request in writing to and thereafter discuss face-to-face with the Executive Officer of the Acquired Party the future plans of the Acquired Party for the development and commercialization of Licensed Product in the [\*\*\*\*]. If the Acquiror does not have a product that has received regulatory approval [\*\*\*\*] in the U.S. or the European Union, or the Acquired Party and the Acquiror have agreed to divest any such product, then the Non-Acquired Party shall have the right to request in writing to and thereafter discuss face-to-face with the Executive Officer of the Acquired Party the future plans of the Acquired Party for the development and commercialization of Licensed Product in the [\*\*\*\*]. Any request for a face-to-face discussion pursuant to the preceding two (2) sentences shall be referred to herein as a "**Status Request.**" The right to make a Status Request shall commence on the date of a public announcement (the "**Announcement Date**") by the Acquired Party of its intention to undergo such a Change of Control ("**Transaction**") and expire [\*\*\*\*] after the close of the Transaction.

If, following a Status Request, the Non-Acquired Party believes in good faith the Acquired Party is either (i) failing to progress the development and/or commercialization

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of the Licensed Product in the applicable Collaborative Field in either the U.S. or European Union because of the Transaction or (ii) not expeditiously proceeding with the divestiture, then the Non-Acquired Party may give the Acquired Party written notice of such alleged failure, identifying the issues and specific reasons for such allegation. The Acquired Party shall have [\*\*\*\*] to provide the Non-Acquired Party a written response specifying details of (1) why the Transaction has not negatively impacted the development and/or commercialization of the Licensed Product in the applicable Collaborative Field or (2) how it is expeditiously proceeding with the divestiture.

If the Acquired Party fails to timely provide such written response, or has failed within the [\*\*\*\*] period to remedy such allegations, then the Non-Acquired Party shall have the right to terminate this Agreement in its entirety with respect to the affected Collaborative Field in accordance with Section 17.6(d).

**(b)** If the Acquiror has a product that has received regulatory approval for [\*\*\*\*] in the U.S. or the European Union that will not be divested, the Non-Acquired Party may, upon prior written notice delivered within [\*\*\*\*] following the Announcement Date, either (i) elect to proceed with the Agreement under the terms of Section 17.6(a), or (ii) terminate this Agreement with respect to the [\*\*\*\*] effective [\*\*\*\*] after the consummation of the closing of the Transaction. If no election is made under this Section 17.6(b), then the Non-Acquired Party shall be deemed to have elected to proceed with the Agreement under the terms of Section 17.6(a).

**(c)** If the Acquiror has a product that has received regulatory approval for [\*\*\*\*] in the U.S. or the European Union that will not be divested, the Non-Acquired Party may, upon prior written notice delivered within [\*\*\*\*] days following the Announcement Date, either (i) elect to proceed with the Agreement under the terms of

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Section 17.6(a), or (ii) terminate this Agreement with respect to the [\*\*\*\*] effective [\*\*\*\*] after the consummation of the closing of the Transaction. If no election is made under this Section 17.6(c), then the Non-Acquired Party shall be deemed to have elected to proceed with the Agreement under the terms of Section 17.6(a).

**(d)** In the event of any termination of this Agreement pursuant to this Section 17.6, then the following shall apply:

**(i)** Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to both the affected Collaborative Field and the Licensed Products in the Territory, except that Roche may keep one copy of all such information for archival purposes. The costs of such transfers shall be borne [\*\*\*\*];

**(ii)** Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the affected Collaborative Field in the Territory; and

**(iii)** All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate with respect to the affected Collaborative Field and Roche shall cease to have any rights with respect to the Licensed Products in the affected Collaborative Field in the Territory.

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**17.7 Termination for Material Delay.** If the JSC adopts a revised Asthma Development Plan that sets forth an anticipated commercial launch date for the Licensed Product in the Asthma Field in the U.S. Territory that is at least [\*\*\*\*] later than the anticipated commercial launch date set forth in the Asthma Development Plan attached to the Original Asthma Agreement on the Effective Date as Exhibit D of such agreement, then Roche shall have the right to terminate this Agreement with respect to both the ROW Territory and the U.S. Territory (but in each case only with respect to the Asthma Field) by providing written notice of such intent to PDL between [\*\*\*\*]. Such termination would become effective [\*\*\*\*] after PDL's receipt of such notice, and would have the following effect:

(a) Roche shall, at PDL's written request, promptly (and in any event within [\*\*\*\*] after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related to both the Asthma Field and the Licensed Products in the Territory. The costs of such transfers shall be borne [\*\*\*\*]. At Roche's reasonable request, PDL shall allow Roche to access such regulatory filings, Regulatory Approvals, clinical trial agreements, and data as required for Roche to satisfy its obligations under applicable law or to prepare a defense against Third Party litigation;

(b) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Roche Inventions and patents claiming Roche Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the Territory;

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(c) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate with respect to the Asthma Field and Roche shall cease to have any rights with respect to the Licensed Products in the Asthma Field in the Territory; and

(d) During an additional [\*\*\*\*] period following the effective date of such termination, Roche shall continue to pay its share any non-cancelable Development Expenses and any other non-cancelable costs that are required to be shared under this Agreement, in each case solely with respect to the Asthma Field and the ROW Territory and subject to PDL's obligation to use reasonable efforts to mitigate such non-cancelable expenses and costs. In addition, Roche shall provide, at cost, transition services to ensure effective transition to PDL or a Third Party designated by PDL for a period not to exceed [\*\*\*\*] following the effective date of such termination, all on terms to be agreed upon by the Parties.

**17.8 Survival; Accrued Rights.** The rights and obligations of the Parties with respect to a Collaborative Field under the following provisions of this Agreement shall survive expiration of this Agreement or termination of this Agreement with respect to such Collaborative Field: Sections 2.2, 6.2(d), 8.7, 11.5, 11.9, 12.1, 12.2, 12.3, 12.6, 12.9, 12.10 (solely with respect to Joint Roche-PDL Patents), 12.13, 14.3, 15.1, 15.3, 16.1, 16.2, 16.3, 16.6, 17.1, 17.2(c), 17.2(d)(i), 17.2(d)(iii), 17.2(e)(ii), 17.3, 17.6(d), 17.7, 17.8, and 19.4 and Article 18 (except for Section 18.4). In any event, expiration or termination of this Agreement with respect to a Collaborative Field shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

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**17.9 Termination Covers All Indications in the Affected Collaborative Field.** For clarity, all terminations described in this Article 17 shall involve all indications within the Collaborative Field to which such termination pertains. Neither Party shall have the right to terminate its rights or the rights of the other Party with respect solely to a subset of indications within a particular Collaborative Field.

## ARTICLE 18

### DISPUTE RESOLUTIONS; GOVERNING LAW; CONDITIONS SUBSEQUENT TO CLOSING

**18.1 Disputes.** Unless otherwise set forth in this Agreement, in the event of any dispute arising under this Agreement between the Parties (including without limitation any dispute under Article 17), the Parties shall refer such dispute to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute.

**18.2 Arbitration.** If the Parties are unable resolve a given dispute pursuant to Section 18.1 within sixty (60) days of referring such dispute to the Executive Officers, either Party may have the given dispute settled by binding arbitration in the manner described below:

**(a) Arbitration Request.** If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the “**Arbitration Request**”) to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods as to which Party must cure a breach of this Agreement becomes suspended as to the subject matter of the dispute.

**(b) Additional Issues.** Within ten (10) business days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

**(c) No Arbitration of Patent Issues.** Unless otherwise agreed by the Parties, disputes relating to patents shall not be subject to arbitration, and shall be submitted to a court of competent jurisdiction.

**(d) Arbitration Procedure.** Except as expressly provided herein, the sole mechanism for resolution of any claim, dispute or controversy arising out of or in connection with or relating to this Agreement or the breach or alleged breach thereof shall be arbitration by the American Arbitration Association (“AAA”) in [\*\*\*\*], under the commercial rules then in effect for the 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 [\*\*\*\*], whether or not the [\*\*\*\*] is deemed to apply to said arbitration. Nothing in this 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.

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**18.3 Choice of Law.** The validity, performance, construction, and effect of this Agreement shall be governed by the laws of the [\*\*\*\*], U.S.A., without regard to conflicts of law principles that would provide for application of the law of a jurisdiction outside [\*\*\*\*] and excluding the United Nations Convention on Contracts for the International Sales of Goods.

**18.4 Conditions Subsequent.** If the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") or any other applicable governmental law applies to the transactions contemplated by this Agreement but not by the Original Asthma Agreement, then the effectiveness of this Agreement and such transactions shall be subject to and contingent upon the satisfaction under the following condition subsequent to the execution of this Agreement. The condition subsequent shall be the earlier to occur of [\*\*\*\*] following (a) approval of the transaction by the Federal Trade Commission or any other applicable governmental authority having jurisdiction with respect to the HSR Act or such other applicable law, or (b) expiration or termination of all applicable waiting periods, and requests for information (and any extensions thereof) under the HSR Act or such other applicable law. Subject to the terms and conditions of this Agreement, each Party shall use commercially reasonable efforts to take, or cause to be taken, all reasonable actions, and to do, or cause to be done, all things necessary and appropriate, in each case to satisfy the condition subsequent and to consummate the transactions contemplated by this Agreement but not by the Original Asthma Agreement. Each Party shall cooperate with the other Party in the preparation, execution and filing of all documents that are required or permitted to be filed on or before the Closing Date for the purpose of consummating such transactions, including, filings pursuant to the HSR Act or other governmental filing. Each Party shall bear its own costs (including counsel or other expert fees) with respect to preparing, executing and filing such documents. Either Party may terminate this Agreement in its entirety,

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upon [\*\*\*\*] prior written notice to the other Party if the condition subsequent under this Section 18.4 has not been fulfilled within [\*\*\*\*] after the Amendment Effective Date, in which case, upon termination, there shall be no liabilities for obligations on the part of either Party except if there has been a breach of this Section 18.4. For clarity, in the event of a termination pursuant to this Section 18.4, the Original Asthma Agreement shall remain in full force and effect.

## ARTICLE 19

### MISCELLANEOUS

**19.1 Assignment.** Either Party may assign this Agreement and the licenses herein granted (a) to any Affiliate of such Party without the prior written 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) without the prior written consent of the other Party, to any Third Party purchaser of all or substantially all of the business unit to which this Agreement relates, which in the case of PDL, shall mean PDL's therapeutic antibody business, and in the case of Roche, shall mean Roche's therapeutic antibody business. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment in violation of this Section 19.1 shall be null and void. This Agreement shall be binding on and shall inure to the benefit of the permitted successors and assigns of the Parties hereto.

**19.2 Force Majeure.** 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

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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 19.2 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.

**19.3 Entire Agreement.** This Agreement, together with the side letter to which the initial Transplant Development Plan is attached, constitutes the entire agreement between the Parties hereto with respect to the subject matter herein and, effective as of the Amendment Effective Date, supersedes all previous agreements, whether written or oral, including the Original Asthma Agreement. Notwithstanding the foregoing, the terms of the Worldwide Daclizumab Agreement shall remain in force and effect (including but not limited to Section 17.3 thereof), except to the extent this Agreement indicates otherwise by specific reference in Sections 10.5, 15.1, and 16.6, and Article 12 herein. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both Parties.

**19.4 Severability.** If a Party receives notification of any investigation, inquiry or proceeding regarding the legality, validity or enforceability of any provision under this Agreement, the Parties shall promptly meet to discuss the provision in question and discuss in good faith the appropriate actions, if any, to be taken in response to such notification. If any provision of this Agreement is declared illegal, invalid or unenforceable by an arbitrator pursuant to Article 18 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 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 Agreement, in

all other respects and all other jurisdictions, will remain in force; provided, however, that 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 Article 18.

**19.5 Notices.** Any notice or report required or permitted to be given under this 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 94555  
U.S.A.  
Attention: Chief Executive Officer

and Protein Design Labs, Inc.  
34801 Campus Drive  
Fremont, California 94555  
U.S.A.  
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

**19.6 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 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 Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

**19.7 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.

**19.8 Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Roche or PDL are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, will be promptly delivered to them (a) upon any such commencement of a bankruptcy proceeding upon their written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

**19.9 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 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.

**19.10 No Strict Construction.** This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party.

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

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

[Rest of page intentionally blank]

IN WITNESS WHEREOF, the Parties have executed this Amended and Restated Co-Development and Commercialization Agreement through their duly authorized representatives to be effective as of the Amendment Effective Date.

PROTEIN DESIGN LABS, INC.

By: /s/ Mark McDade  
Name: Mark McDade  
Title: Chief Executive Officer

HOFFMANN-LA ROCHE INC.

By: /s/ Frederick C. Kantz III  
Name: Frederick C. Kantz III  
Title: Vice President

F. HOFFMANN-LA ROCHE LTD

By: /s/ St. Arnold  
Name: St. Arnold  
Title: \_\_\_\_\_

By: /s/ Dr. Peter Hug  
Name: Dr. Peter Hug  
Title: Executive Vice President, Pharma Partnering

**SIGNATURE PAGE**

**EXHIBIT A**

**FINANCIAL APPENDIX**

This Financial Appendix is a supplement to the definitions and procedures provided in Articles 1 and 11 and Sections 4.6 and 6.3 of this Agreement. References to Articles and Sections are references to the articles and sections of the Agreement. This Appendix sets forth the principles for capturing, reporting and consolidating Operating Expenses, Development Expenses, royalties and gross margin profit sharing. Further, it describes the accounting (i.e. the frequency of reporting, currency, taxes, methods of determining payments between the Parties, auditing of accounts, etc.) and the definitions of Sales Force Expenses, Development Expenses and Operating Expenses.

**REPORTING AND CONSOLIDATION**

During the applicable period in which such revised budgets are required under the Agreement, preparation of revised annual budgets associated with the Development Plan or the Commercialization Plan (as the case may be) will be initiated in each [\*\*\*\*] during such period and a preliminary budget should be presented for review by the JSC before end of each [\*\*\*\*] during such period. The completed annual budget should be endorsed by the JSC between the Parties by the end of each [\*\*\*\*] during such period. Reporting by each Party will be performed as follows (with copies provided to the JSC and to the other Party):

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

A-1.

**CONFIDENTIAL TREATMENT**

<b>Reporting Event (calendar basis)</b>	<b>Frequency</b>	<b>Submission Deadline</b>
[****] actuals	end of quarter	[****] after end of quarter
[****]	end of quarter	[****] after end of quarter
Accruals	end of quarter	[****] of last month of the quarter
Preliminary annual budget	annually	[****]
Final annual budget	annually	[****]
Forecasts (rolling [****] except [****])	quarterly	[****]
		[****]

The JFC may change the reporting timelines according to the needs of the alliance. The JFC should also evaluate the possibility to have a common system to consolidate joint development expenses & marketing activities (e.g. co-development system).

Responsibility for approving the annual budgets associated with the Development Plan and the Commercialization Plan will rest with the JSC.

The JFC shall be responsible for the preparation of consolidated reporting (actuals, budgets and forecasts) for the Operating Expenses and Development Expenses as well as determination of the cash settlement. The JFC shall provide the JSC (and the Party not preparing the consolidated reporting on behalf of the JFC) within forty-five working days after the submission date shown above, a statement showing the consolidated results, forecasts and cash settlements required in a format agreed to by the Parties.

The JFC will be responsible for monitoring and agreeing upon appropriate controls to ensure reasonable and consistent calculation and allocation of Sales Force Expenses, Operating Expenses and Development Expenses under the Agreement. More specifically, the JFC shall review the projected versus actual FTE's per quarter and the process by which Third Parties are retained to provide services in the

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performance by the Parties under the Agreement. In any event, the JFC shall review use of FTE resources on a quarterly basis. The Parties shall also use commercially reasonable efforts to provide access to available discounts and discount programs available from existing vendors for the benefit of the Parties under the Agreement.

Reports of actual results compared to budget will be made by the JFC. The Parties will work together to keep actual spending within the approved budget. The Parties shall discuss in good faith the adoption of additional control measures to address deviations from the approved budget on an aggregate annual basis above [\*\*\*\*]. In any event, if a Party contemplates that an expenditure will increase the annual budget in excess of [\*\*\*\*], the Parties shall review the expenditure with the JFC prior to commitment to that expenditure. The JFC will meet as appropriate to review and approve the reporting events (actuals, accruals, budgets and forecasts).

Each Party will use its applicable project cost system with the goal of tracking and reporting costs on a project/product indication/work package basis consistent with its other projects/products in development.

### ACCOUNTING

**1. Audits.** Each Party (the “**Audited Party**”) agrees to keep full, clear and accurate records for a period of at least [\*\*\*\*] after the relevant report is made pursuant to Section 4.6(c), 6.3(c) or 11 setting forth its Development Expenses, Operating Expenses, Sales Force Expenses or Net Sales, as applicable, incurred in sufficient detail to enable royalties and compensation payable to the other Party (the “**Auditing Party**”) hereunder to be determined. Each Audited Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the Auditing Party to verify reports made pursuant to Section 4.6(c) or 6.3(c), as applicable. Unless the Auditing Party obtains the prior written consent of the Audited Party, such

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accounting firms must be selected from among the four largest global accounting firms. Such audit shall not be performed more frequently than [\*\*\*\*] 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 Auditing Party, except in the event that the results of the audit reveal a discrepancy in favor of the Audited Party of [\*\*\*\*] or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Audited Party.

**2. Methods of Payments.** All payments due to either PDL or Roche under this Agreement shall be paid in Dollars by wire transfer to a bank in the U.S. designated in writing by the Party to which the payment is due.

**3. Taxes.** If provision is made in law or regulation of any country of the Territory for withholding of taxes of any type, levies or other charges with respect to 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.

**4. Currency.** All payments under this Agreement shall be in Dollars. Whenever payments require conversion from a foreign currency, then this shall be converted using the average daily exchange rate for the period to be reported based on Roche Swiss Franc Sales Statistics, which shall be based on exchange rate information obtained from the Reuters system.

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**5. Late Payments.** Any amount owed by one Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the [\*\*\*\*] as reported by Datastream (or a successor or similar organization).

**6. General.** As a general matter, the Parties do not intend that expenses paid for or credited under this Agreement will be charged or credited more than once.

## DEFINITIONS

### A. SALES FORCE EXPENSES

Sales Force Expenses shall mean all direct and/or allocated (on a fully utilized basis) costs directly associated with the efforts of field sales representatives with respect to Licensed Products in the U.S. Territory, including direct costs associated with field sales forces, field sales offices, and home offices staffs directly involved in the management of and the performance of the selling functions. All direct costs shall be fully documented, and all allocations shall be based on a Party's then current standard practices and in any event discussed and agreed upon prior to being considered Sales Force Expenses.

### B. DEVELOPMENT EXPENSES

Development Expenses shall mean the expenses incurred by a Party or for its account that are consistent with the Development Plan and specifically are attributable to the Development of a Licensed Product. Development Expenses shall include amounts paid by a Party to Third Parties involved in the Development of Licensed Products, and all internal costs incurred by a Party in connection with the Development of Licensed Products. Notwithstanding anything to the contrary herein, Development

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Expenses shall not include any Incremental Development Expenses. Development Expenses for manufacturing of clinical supplies shall be as set forth in Article 8.

Development Expenses shall include but are not limited to the cost of the development of research plans and programs, screening, lead optimization, in vitro and in vivo testing, studies on the toxicological, pharmacokinetic, metabolic or clinical aspects of such Product conducted internally or by individual investigators, or consultants necessary for the purpose of obtaining and/or maintaining approval of such Product by a governmental organization in a country, and costs for preparing, submitting, reviewing or developing data or information for the purpose of a submission to a governmental authority to obtain and/or maintain approval of Product in a country as well as costs of process development and scale-up costs and recovery (including plant costs). Development Expenses shall further include costs of Phase IV Trials and Post-Launch Product R&D Expenses. Development Expenses shall not include patent costs, pre-Registration marketing costs (e.g. trademark costs, advertising agency selection costs, pre-marketing studies), post-Registration clinical studies which are not enabling for Registration of the Product and post-Registration marketing studies.

Development Expenses constitute of two main accounting elements, variable costs and fixed costs.

Variable costs are external costs invoiced from Third Parties.

Fixed costs include the amounts expended for personnel, relocation, travel, entertainment and training incurred by the functions directly operating the program. The work scope of these functions include activities within the areas of development operations, clinical quality insurance, medical science, genetics integrated medicine, drug regulatory and technical development. To these primary fixed costs should be added the secondary fixed costs which are attributable to a Party's costs for IT software and hardware, IT external costs, depreciation, occupancy costs, corporate bonus (to the extent not charged directly), and its payroll, information systems, human relations or purchasing functions. These secondary fixed costs are allocated to company departments based on space occupied or headcount or other activity-based method.

The secondary fixed costs further include costs attributable to general corporate activities for executive management, investor relations, business development, legal affairs and finance. In determining all these fixed costs, the Parties have agreed on an FTE-rate that will be charged for the resources allocated to the programs from the functions directly operating the programs on a fractional FTE-basis. The Parties have agreed on a FTE rate which will be used for calculating FTE's in the performance of Development activities under the Agreement. The Parties contemplate that this rate captures total actual personnel and fixed costs attributable to the performance of the Joint Development Plan under this Agreement.

All FTE expenditures shall be included in Development Expenses based on a rate of [\*\*\*\*]. Each calendar year beginning [\*\*\*\*], the FTE rate will be [\*\*\*\*] compared to previous calendar year.

Time-recording will be used by all people within these functions to record actual time spent on the activities under the programs. For clarity, FTE time recording should be made on a fractional basis. Each Party will also use its applicable project cost system with the purpose of tracking and reporting costs on a project/product indication/work package level.

### **C. POST-LAUNCH PRODUCT R&D EXPENSES**

Post-Launch Product R&D Expenses shall include certain research and development costs incurred by a Party in relation to a Licensed Product after the first commercial launch and shall exclude administrative expenses and costs that are included within Costs of Goods Sold. Such post-launch research and development costs shall include, to the extent relating to a Licensed Product:

- Phase IV Trials.

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- Ongoing medical affairs (PDL) and the counterpart for Roche.
- Preclinical research.
- Contract R&D costs performed by others for a particular project that have no alternative future uses in other R&D projects or otherwise.
- Fees and expenses of outside counsel in respect of regulatory affairs unrelated to obtaining Regulatory Approval.

#### **D. OPERATING EXPENSES**

Operating Expenses means those expenses incurred by a Party which are generally consistent with the Commercialization Plan (and associated budget) and are specifically attributable to Licensed Products in the U.S. Territory, and shall consist of (i) Marketing Expenses, (ii) Distribution Expenses, (iii) Third Party License Expenses, (iv) Allocated Administration Expenses, (v) Medical Activities, and (vi) Patent and Legal Expenses. Operating Expenses shall exclude Development Expenses and Sales Force Expenses. Notwithstanding the foregoing, Patent and Legal Expenses need not be consistent with the Commercialization Plan (and associated budget) as long as they have been approved by the JSC. Each Party shall allocate its Operating Expenses and each of the expenses listed in subsections (i) through (v) above between the Transplant Field and the Asthma Field, either based on the field-specific nature of the expenses in question or, in the case of expenses lacking a clear association with a particular field, based on reasonable accounting methodologies consistently applied throughout such Party's organization.

#### **1. MARKETING EXPENSES**

Marketing Expenses means the costs incurred by a Party, excluding Allocated Administration Expenses and Sales Force Expenses, which are generally consistent with the Commercialization Plan (and associated budget) and are specifically attributable to the sale, promotion, and/or marketing of a Licensed Product in the U.S. Territory. Marketing Expenses shall be the sum of Marketing Management, Market and

Consumer Research, Advertising, Trade Promotion, and Consumer Promotion (each of which is specified below), and the cost of performing Non-Registrational Trials (as defined in Section 1.49).

**1.1 “Marketing Management”** shall include product management and sales promotion management compensation and departmental expenses. This shall include costs associated with developing overall sales and marketing strategies and planning for Licensed Products. In addition, payments to Third Parties in connection with trademark selection, filing, prosecution and enforcement shall be included in this category.

**1.2 “Market and Consumer Research”** shall include compensation and departmental expenses for market and consumer research personnel and payments to Third Parties related to conducting and monitoring professional and consumer appraisals of existing, new or proposed Licensed Products such as market share services (e.g., IMS data), special research testing, and focus groups. Costs incurred pursuant to Section 7.6 shall not be included in Market and Consumer Research, but shall be shared in accordance with the terms set forth in Section 7.6.

**1.3 “Advertising”** shall include all media costs associated with Licensed Product advertising as follows: production expense/artwork including set up; design and art work for an advertisement; the cost of securing print space, air time, etc. in newspapers, magazines, trade journals, television, radio, billboards, etc.

**1.4 “Trade Promotion”** shall include the allowances given to retailers, brokers, distributors, hospital buying groups, etc. for purchasing, promoting, and distribution of Licensed Products. This shall include purchasing, advertising, new distribution, and display allowances as well as free goods, wholesale allowances and reasonable field sales samples. To the extent multiple products are involved and some of such products are not Licensed Products, then such allowances shall be allocated on a *pro rata* basis based upon net sales of each respective product by such operating unit during the most recent quarter.

**1.5 "Consumer Promotion"** shall include the expenses associated with programs to promote Licensed Products directly to the end user. This category shall include expenses associated with promoting products directly to the professional community such as professional samples, professional literature, promotional material costs, patient aids and detailing aids. To the extent multiple products are involved and some of such products are not Licensed Products, then such allowances shall be allocated on a *pro rata* basis based upon net sales of each respective product by such operating unit during the most recent quarter.

**1.6 "Education"** shall include expenses associated with professional education with respect to Licensed Products through any means not covered above, including articles appearing in journals, newspapers, magazines or other media; seminars, scientific exhibits, and conventions; and symposia, advisory boards and opinion leader development activities.

## **2. DISTRIBUTION EXPENSES**

Distribution Expenses shall be the sum of Stock and Shipping expenses and Transportation expenses, each as specified below.

**2.1 "Stock and Shipping"** shall include the portion of distribution costs for the warehousing of Licensed Product finished goods from the point of completion of production to the time the goods are turned over to a carrier for delivery as follows: order filling/assembly functions; reasonable order billing and customer service functions; reasonable portion of company owned/leased facilities relating to warehousing of finished products; storage of products at public warehouses.

**2.2 "Transportation"** shall include the portion of distribution costs relating to moving Licensed Product goods from a warehouse to the customer as follows: outbound transportation costs; costs of moving goods from a manufacturing point to a warehouse at another location from which it is ultimately to be distributed to a customer; the costs of the traffic department where there is a separate department that has responsibility for administration of freight costs.

### **3. THIRD PARTY LICENSE EXPENSES**

Third Party License Expenses means all payments by a Party under Third Party Licenses that are allocable to the use, development, sale, manufacture, or import of Licensed Product in the U.S. Territory, including without limitation all payments by a Party under Third Party Licenses (a) calculated based on sales of Licensed Product in the U.S. Territory; (b) made on account of achievement of particular events relating to development or commercialization of Licensed Product in the U.S. Territory; and (c) as consideration for a grant of a license or other rights in the U.S. Territory.

### **4. ALLOCATED ADMINISTRATION EXPENSES**

Allocated Administration Expenses means the administration expenses incurred by a Party or any of its operating units that are actually directly engaged in the commercialization of Licensed Products in the U.S. Territory pursuant to the Commercialization Plan, to be calculated in the manner set forth below. In view of the manner in which Allocated Administration Expenses are calculated, administration expenses shall be excluded from the definition of each of the other elements which make up Operating Expenses.

The costs recoverable as Allocated Administration Expenses are the costs of finance, management information services, human resources, legal, and employees engaged in general management functions for the operating units in question. Cost categories included within Allocated Administration Expenses shall not be included in any other cost recoverable under this Agreement.

Recoverable administration expenses shall include the direct costs of employees performing such functions, the costs of supporting such individuals in the performance of their job (e.g., occupancy costs, travel, computers, and telephones), and outside services (e.g., consulting and audit services). Such costs shall be calculated in accordance with the customary accounting methodology of the Party incurring such expenses, consistently applied throughout such organization. Such costs shall be allocated based on a percentage determined by sales of Licensed Product supported by

such operating unit(s) divided by the total product sales supported by such operating unit(s) during the relevant quarter. Total Allocated Administrative Expenses of a Party shall not exceed [\*\*\*\*] of the Operating Expenses incurred by such Party (less Allocated Administrative Expense), on an annualized basis.

#### **5. PATENT AND LEGAL EXPENSES**

Patent and Legal Expenses means (a) the fees and expenses of outside counsel and payments to Third Parties incurred after the Effective Date in connection with the preparation, filing, prosecution and maintenance of PDL Trademarks and those patent fees and expense set forth in Section 12.7, (b) all expenses associated with Third Party claims in the U.S. Territory for which neither Party has an indemnification obligation pursuant to Article 16, and (c) all expenses associated with latent defects in the Licensed Product in the U.S. Territory for which neither Party has an indemnification obligation pursuant to Article 16. For clarity, no internal legal costs shall be included in Patent and Legal Expenses.

**EXHIBIT B**

**GMP AUDIT**

Pursuant to the Original Asthma Agreement, the Parties have formed an advisory group, consisting of qualification experts from both PDL and Roche. This group has advised, and will continue to advise, PDL on the qualification and validation activities (including a discussion of the PDL process evaluation and process validation plan for Daclizumab) required to license PDL's manufacturing facility. This group has coordinated an initial, informal audit by Roche of the PDL manufacturing facility project following mechanical completion, which included a review of the Impact Assessment, the System Boundary Drawings, the Commissioning Documents, and sample IQ, OQ, and PQ Documents (which is consistent with the ISPE Baseline Guide for Commissioning and Qualification Activities, the qualification approach currently being applied by PDL). This initial audit was advisory only, and as such, did not trigger any development event payment.

Roche will perform a formal GMP Audit after the completion of PQ by PDL. This audit will include a review of PDL's PQ Plans and Reports, and their overall Quality Management System, using the standards set forth in ICH Q7A and the US and EMEA Regulations. For clarity, PQ, Process Qualification, is the documented verification that premises and equipment perform effectively, reliably, and meeting predetermined acceptance criteria. The PQ of process support and utility systems involves the operation, sampling, and monitoring of the system under specified conditions over a relevant period of time. Therefore, PQ is mandatory for the critical process support and utility systems, as determined in the PDL Impact Assessment.

PDL should keep Roche directly informed as to their progress toward completion of the PQ, informing Roche of any significant issues that arise. When nearing the completion of PQ, PDL should supply Roche with advance copies of their PQ procedures, plans, and other related documents, and determine, with Roche, an appropriate timeline for the GMP Audit, which allows both Parties to prepare properly.

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**CONFIDENTIAL TREATMENT**

The GMP Audit will be successful if (a) the PQ Plans, PQ Reports, and Quality Management System are in compliance with cGMP guidelines and (b) there are no observations which (i) will lead to a significant delay of Phase III clinical development or the anticipated launch of the product, (ii) present a significant risk of non-acceptance of the site by regulatory authorities for clinical and/or commercial supplies, or (iii) may place clinical material or commercial supplies “at risk”.

Following the completion of [\*\*\*\*] [\*\*\*\*], but prior to [\*\*\*\*], the payment described in 9.2(c) or 9.3(b), as applicable, will be due.

If PDL, based upon the Licensed Product demand forecasts, decides to expand the capacity of its 610 Manufacturing Facility to supply Licensed Product, then Roche shall have the right, but not the obligation to perform both an informal audit and a formal GMP Audit of such capacity expansion. The purpose, timing, and coordination of such audits would be similar to those described above, except that no development payment would be due pursuant to Section 9.2(c) or 9.3(b) on account of the successful completion of these audits.

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**CONFIDENTIAL TREATMENT**

**EXHIBIT C**

**THIRD PARTY LICENSES**

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To the extent that one or more additional agreements entered into by a Party prior to the Effective Date are necessary for the use, manufacture, sale, offering for sale, or importation of Licensed Products in the Collaborative Fields in the Territory (or to the extent that one or more of the agreements listed on this Exhibit C as of the Effective Date are not necessary therefor), the Parties agree to discuss in good faith the amendment of this Exhibit C to include (or to remove, as appropriate) any such agreements that a Party may reasonably suggest to the other Party in writing during the thirty (30) days immediately following the Effective Date.

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**CONFIDENTIAL TREATMENT**

**EXHIBIT D**

**[\*\*\*\*] TESTING PLAN**

Roche and PDL recognize that the ideal assessment of Daclizumab [\*\*\*\*] would accurately determine clinically relevant [\*\*\*\*] responses to Daclizumab for the proposed asthma indication within this particular patient population. Clinically relevant responses reflect issues related to [\*\*\*\*].

The [\*\*\*\*] plan should be discussed on a regular basis with regulatory authorities especially at the end of phase II meeting.

**I. Assay outline:**

Samples from clinical study subjects in the asthma development program will be tested for the presence of [\*\*\*\*]. The primary [\*\*\*\*] assessment methods will comprise:

[\*\*\*\*]

**II. [\*\*\*\*] definition:**

For the purposes of identifying [\*\*\*\*] response, a [\*\*\*\*] is defined as one of the following:

[\*\*\*\*]

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**III. [\*\*\*\*] and Patient testing:**

Throughout the development of the compound, [\*\*\*\*] will be done.

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**IV. Deliverables:**

End of Phase 1:

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Interim analysis of [\*\*\*\*] [\*\*\*\*]

The JDC will assess the possibility and desirability of [\*\*\*\*] for testing [\*\*\*\*].

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**V. Development Events:**

For the purposes of this Agreement, the rate of [\*\*\*\*] as determined by step 3 [\*\*\*\*] will be used for certain development payments and project decisions.

**Phase 1 Development Event:**

(1) Not more than [\*\*\*\*] and (2) an acceptable [\*\*\*\*]

**Phase 2 Development Event:**

Not more than [\*\*\*\*]

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## PRESS RELEASE

**Roche and PDL to Jointly Develop Daclizumab in Transplant Maintenance Therapy**

Nutley, NJ and Fremont, CA

Roche and Protein Design Labs, Inc. (PDL) (NASDAQ: PDLI) today announced an expansion to their partnership to co-develop and commercialize daclizumab for organ transplant patients on long-term, maintenance therapy. Roche currently markets daclizumab for induction transplant therapy as Zenapax®. Roche and PDL are developing a new subcutaneous daclizumab (daclizumab s.c.) formulation, manufactured by PDL, for use in Phase II clinical trials expected to start in 2006.

Currently, transplant patients are treated with the combination therapy of Roche's CellCept® (mycophenolate mofetil) with a calcineurin inhibitor such as cyclosporine and steroids to prevent organ rejection. However, the long-term use of the current calcineurin inhibitors can cause kidney toxicity, diabetes and cardiovascular disorders. Using daclizumab s.c. as maintenance treatment in combination with CellCept may allow for the reduction, and potential elimination, of the more toxic drugs from transplant patient maintenance regimens.

Mark McDade, Chief Executive Officer, PDL, said, "We are enthusiastic about the opportunity to develop daclizumab s.c. with our longstanding partner Roche. Today's agreement builds upon our existing collaboration with Roche in asthma, as we continue to explore development of daclizumab s.c. in other indications."

"Roche and PDL are highly committed to daclizumab, our partnership, and in developing better treatments to improve long-term outcomes for transplant patients," said Peter Hug, Roche's Global Head of Pharma Partnering. "With the potential to use CellCept® and daclizumab s.c. as the centerpiece for long-term transplant therapy, we could offer patients a safer, more tolerable option."

Roche and PDL have amended their current agreements to reflect the scope of daclizumab s.c.'s further development. Under the terms of this agreement, PDL will receive a \$10 million upfront payment and may be eligible to receive payments up to \$145 million if certain milestones are satisfied and if the indication is successfully developed. Roche will continue to manufacture and promote Zenapax® exclusively on a worldwide basis. Roche and PDL will share equally global development costs, and PDL has the option to co-promote daclizumab s.c. for transplant maintenance in the United States. Outside the United States, PDL will receive royalties on net sales of the product in transplant maintenance. As part of this arrangement, the parties agree that PDL will not exercise its option to promote Zenapax® for prevention of acute kidney transplant rejection and PDL is no longer required to make the payment which would otherwise be due in 2007 for such right. PDL and Roche will continue with the co-development of daclizumab s.c. in respiratory disorders, as announced in September 2004.

#### **About the Roche - PDL partnership**

In 1989, Roche acquired the worldwide rights to daclizumab, a product approved in 1997 as Zenapax® for the prevention of renal allograft rejection. In October 2003, Roche returned to PDL all rights to daclizumab, except in transplantation where PDL retained the option until 2007 to re-acquire development rights. In September 2004, PDL and Roche announced the continued co-development of daclizumab s.c. in respiratory disorders.

#### **Roche in Transplantation**

Roche is strongly committed to improving the long-term outcomes of transplantation and enhancing the quality of life of transplant recipients. Roche has developed innovative therapies that improve graft and post-transplant health. CellCept is the cornerstone of current immunosuppressant therapies for transplant recipients and is the largest selling branded immunosuppressive in North America. Zenapax® prevents acute rejection of the newly transplanted organ. Valcyte® (valganciclovir) was developed for the

prevention of cytomegalovirus, a dangerous viral infection associated with transplantation. In addition, Roche supports basic research in transplantation with its funding of the independent Roche Organ Transplantation Research Fund (**ROTRF**), which directly supports innovative research projects attracting new researchers with innovative and novel scientific ideas to meet unmet medical needs in solid organ transplantation.

#### **About Protein Design Labs**

PDL is a biopharmaceutical company focused on the research, development and commercialization of novel therapies for inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several products in the United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products. Further information on PDL is available at [www.pdl.com](http://www.pdl.com).

#### **About Roche – More Than a Century in the U.S. and the World**

Founded in 1896 and headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is one of the world's leaders in diagnostics, the leading supplier of pharmaceuticals for cancer, as well as a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on many fronts to improve people's health and quality of life. Roche employs roughly 65,000 people in 150 countries, including approximately 15,000 in the United States.

For further information, please visit our worldwide and U.S. website (Global: [www.roche.com](http://www.roche.com) and U.S.: [www.roche.us](http://www.roche.us)).

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## Facts About Zenapax, CellCept and Valcyte

**Zenapax** is a humanized monoclonal antibody that blocks interleukin-2 (IL-2) receptors and acts as an immunosuppressant. It is used just before and/or at the time of kidney transplantation in combination with cyclosporine and corticosteroids to prevent early rejection. The recommended dose of Zenapax is 1.0 mg/kg. Based on clinical trials, the standard course of Zenapax therapy is five doses. Zenapax received U.S. Food and Drug Administration (FDA) approval in December 1997.

The most frequently reported adverse events associated with Zenapax were constipation, nausea, diarrhea and vomiting. Cellulitis and wound infections occurred more frequently in patients treated with Zenapax versus placebo. Severe hypersensitivity reactions following Zenapax administration have been reported rarely.

Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Zenapax. The physician responsible for Zenapax administration should have complete information requisite for the follow-up of the patient.

**CellCept** is an immunosuppressant or anti-rejection drug approved for use in combination with other immunosuppressive drugs (cyclosporine and corticosteroids) for the prevention of rejection in patients receiving kidney, heart and liver transplants.

There are no adequate and well-controlled studies in pregnant women. As CellCept (mycophenolate mofetil) has been shown to have teratogenic effects in animals at subclinical doses on a body surface area basis, it may cause fetal harm when administered to a pregnant woman. CellCept should not be used in pregnant women unless the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should have a negative serum or urine pregnancy test with a sensitivity of at least 50 mIU/mL within one week prior to beginning therapy even where there has been a history of infertility, unless due to hysterectomy.

Women of childbearing potential must use effective contraception before beginning CellCept therapy, during therapy and for six weeks following discontinuation of therapy.

Two reliable forms of contraception must be used simultaneously unless abstinence is the chosen method. If pregnancy occurs during treatment, the physician and patient should discuss the desirability of continuing the pregnancy (see complete product information).

Adverse events reported in >30% of renal, cardiac or liver transplant patients receiving CellCept (in combination with cyclosporine and corticosteroids) were pain, fever, headache, asthenia, anemia, leucopenia (patients should be monitored for neutropenia; dosing should be interrupted or the dose reduced if neutropenia develops), thrombocytopenia, leukocytosis, urinary tract infection, hypertension, hypotension, peripheral edema, hypercholesteremia, hypokalemia, hyperglycemia, creatinine, BUN and cough increased, hypomagnesemia, diarrhea, constipation, nausea, vomiting, respiratory infection, dyspnea, lung disorder, pleural effusion, tremor and insomnia.

Patients receiving immunosuppressant regimens are at increased risk of developing lymphomas and other malignancies, particularly of the skin.

**Warning:** Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

**Valcyte**, the oral pro-drug of Cytovene (ganciclovir), is the most widely prescribed anti-CMV medication in the United States. Valcyte is indicated for the prevention of CMV disease in kidney, kidney-pancreas and heart transplant patients at high risk. Valcyte is not approved for use in liver transplantation. The efficacy and safety of Valcyte in other solid organ transplants, such as lung transplant, have not been established.

The clinical toxicity of Valcyte, which is metabolized to ganciclovir, includes granulocytopenia, anemia and thrombocytopenia. In animal studies ganciclovir was

carcinogenic, teratogenic and caused aspermatogenesis. Valcyte tablets should not be administered if the absolute neutrophil count is less than 500 cells/ $\mu$ L, the platelet count is less than 25,000/ $\mu$ L or the hemoglobin is less than 8 g/dL. Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, bone marrow depression and aplastic anemia have been observed in patients treated with Valcyte tablets (and ganciclovir). Other adverse events reported with a frequency of <sup>3</sup> 5% included diarrhea, tremors, fever, nausea, headache, vomiting, insomnia and allograft rejection.

In liver transplant patients, there was a significantly higher incidence of tissue-invasive CMV disease in the Valcyte-treated group compared with the oral ganciclovir group (see CLINICAL TRIALS in the complete product information).

*For full prescribing information on CellCept, Zenapax and Valcyte, please visit: [www.rocheusa.com/products/transplantation.html](http://www.rocheusa.com/products/transplantation.html)*

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The information in these press releases should be considered accurate only as of the date of the release. PDL has no intention of updating and specifically disclaims any duty to update the information in these press releases. These press releases may contain forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those in the forward-looking statements. Factors that may cause such differences are discussed in PDL's filings with the Securities and Exchange Commission.

E-6.

**CONFIDENTIAL TREATMENT**

REGIONS

**1) United States of America**

**2) Canada**

**3) Japan**

**4) Western Europe**

The 15 pre May 1, 2004 EU member states

Switzerland

Turkey

Norway

Iceland

**5) Central and Eastern Europe**

Albania

Belarus

Bosnia-Herzegovina

Bulgaria

Croatia

Czech Republic

Estonia

Hungary

Latvia

Lithuania

Macedonia

Moldavia

Poland

Romania

Russia

Serbia & Montenegro

Slovakia

Slovenia

Ukraine

**6) Latin America**

34 countries from Mexico to Argentina including:

Argentina

Brazil

Chile

Colombia

Costa Rica

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Ecuador  
Mexico  
Peru  
Uruguay  
Venezuela

**7) Asia/Pacific**

Bangladesh  
Cambodia  
China (including Hong Kong)  
India  
Indonesia  
Korea  
Malaysia  
Pakistan  
Philippines  
Singapore  
Sri Lanka  
Taiwan  
Thailand  
Vietnam  
Australia  
New Zealand

**8) Pharma International**

All countries not listed above

**CONFIDENTIAL PROVISIONS REDACTED****SECOND AMENDED AND RESTATED WORLDWIDE AGREEMENT**

This Second Amended and Restated Worldwide Agreement is entered into as of October 28, 2005 (the "**Amendment 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**

PDL originally licensed to Roche, on an exclusive basis, rights to a humanized antibody now known by the generic name daclizumab, which binds to the interleukin-2 receptor ("**IL-2R**").

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

Roche and PDL are parties to that certain Amended and Restated Worldwide Agreement (the "**Agreement**"), dated October 1, 2003 (the "**Effective Date**"), under which PDL (1) reacquired all IL-2R antibody rights originally licensed by PDL to Roche, subject to Roche's continuing exclusive license to market and sell daclizumab for transplant indications throughout most of the world and to develop and to commercialize products based on [\*\*\*\*] that [\*\*\*\*] to the [\*\*\*\*] of [\*\*\*\*]; and (2) obtained the right to purchase, upon payment of an additional fee, 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 [\*\*\*\*].

Roche and PDL now desire to amend the Agreement to allow PDL to reacquire all remaining rights to daclizumab, subject to Roche's exclusive right to continue to commercialize Zenapax® in its current form for as long as Roche desires to do so.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

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 Agreement in this Second Amended and Restated Worldwide Agreement as follows:

## **I. DEFINITIONS**

For the purposes of this Second 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 Second Amended and Restated Worldwide Agreement, unless otherwise specified.

1.1 **"1989 Agreements"** means the agreements between Roche and PDL dated January 31, 1989, as amended.

1.2 **"1999 Agreements"** means the two agreements executed by Roche and PDL in 1999 to replace the 1989 Agreements. Such agreements, as amended, are known separately as the **"1999 PDL/Roche Agreement"** and the **"F. Roche Agreement,"** respectively.

1.3 **"1999 PDL/Roche Agreement"** has the meaning set forth in Section 1.2.

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

1.5 **"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, [\*\*\*\*].

1.6 **"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.

1.7 **"Asthma/Transplant Agreement"** means that certain Amended and Restated Co-Development and Commercialization Agreement, dated as of October 29, 2005.

1.8 **"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, polymyositis, Type I diabetes,

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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.

1.9 "**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.

1.10 "**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.

1.11 "**Commercialization Term**" means the period commencing on the Effective Date and ending on the date that Roche ceases to sell Nutley Dac throughout the Roche Territory, as permitted under this Second Amended and Restated Worldwide Agreement.

1.12 "**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.

1.13 "**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 Second Amended and Restated Worldwide Agreement, the Cost of Goods shall not exceed [\*\*\*\*].

1.14 "**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.

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1.15 “**Daclizumab**” means any product that contains humanized anti-Tac (as defined under “Field”).

1.16 “**Excluded Field**” means [\*\*\*\*] that (a) [\*\*\*\*], (b) [\*\*\*\*] and (c) [\*\*\*\*]. The parties agree that Daclizumab is not in the Excluded Field.

1.17 “**Excluded Product**” means any product in the Excluded Field, including any Combination Product, that contains an [\*\*\*\*]. [\*\*\*\*] shall be deemed to be an Excluded Product.

1.18 “**F. Roche Agreement**” has the meaning set forth in Section 1.2.

1.19 “**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.

1.20 “**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.

1.21 “**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.

1.22 “**JSC**” means the committee formed by the parties pursuant to Section 3.1 of the Asthma/Transplant Agreement.

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1.23 “**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 Second Amended and Restated Worldwide Agreement, infringe a Valid Claim of a Roche Patent. Daclizumab shall be deemed to be a Licensed Product.

1.24 “**Major Country**” means the [\*\*\*\*\*].

1.25 “**Nutley Dac**” shall mean the FDA-approved form of Daclizumab manufactured at Roche’s Nutley, New Jersey facility as of the Amendment Effective Date.

1.26 “**Other Indications**” means all indications other than Transplant Indications and Autoimmune Indications.

1.27 “**Other Licensed Products**” means all Licensed Products other than Daclizumab.

1.28 “**PDL Know-How**” means, except as otherwise set forth in this Section 1.28, 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 Second 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.

1.29 “**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 Second 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.

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1.30 “**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.

1.31 “**Product Operating Committee**” or “**POC**” means the product operating committee formed by the parties pursuant to Section 6.2(a) of the Agreement.

1.32 “**Queen et al. Patents**” means those Sole PDL Patents in the Territory claiming priority to U.S. Patent Application Serial No. 07/290,975, filed December 28, 1988.

1.33 “**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.

1.34 “**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.

1.35 “**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) [\*\*\*\*]; and (b) [\*\*\*\*].

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 [\*\*\*\*] by [\*\*\*\*]. 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.

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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, [\*\*\*\*], or [\*\*\*\*], shall be deemed the Roche Adjusted Gross Sales for such Daclizumab sold or otherwise transferred.

1.36 “**Roche Commercialization Activities**” has the meaning set forth in Section 4.1(a).

1.37 “**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 Second 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 as of the Effective Date are, specifically, those listed on Schedule 2.8(b).

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

1.39 “**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.

1.40 “**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 [\*\*\*\*].

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

1.41 “**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.

1.42 “**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.

1.43 “**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 Second 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).

1.44 “**Roche Patents**” means both the Roche Owned Patents and the Roche Controlled Patents.

1.45 “**Roche Products**” means Nutley Dac and any Excluded Products.

1.46 “**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**”).

1.47 “**Territory**” means all the countries of the world.

1.48 “**Third Party**” means any person or entity other than PDL, Roche, and their respective Affiliates.

1.49 “**Third Party License**” means any of the license agreements set forth on Appendix B.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

1.50 “**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 Nutley Dac in the Roche Territory.

1.51 “**Transplant JDC**” means the committee formed by the parties pursuant to Section 3.12 of the Asthma/Transplant Agreement.

1.52 “**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).

1.53 “**Transplant Induction**” shall mean the Transplant Indication involving the prophylaxis of acute organ rejection in patients receiving renal transplants and undergoing an immunosuppressive regimen that includes cyclosporine and corticosteroids.

1.54 “**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 [Reserved]

2.2 License Grant to PDL.

(a) Subject to the terms and conditions of this Second Amended and Restated Worldwide Agreement, Roche hereby 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 for use in all indications (but excluding, during the Commercialization Term, Nutley Dac for use in Transplant Induction). 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 [Reserved]

2.4 Transfer of Roche Licensed Know-How to PDL. Until the end of the Commercialization Term, if Roche develops or Controls Roche Licensed Know-How that it has not previously provided to PDL, Roche shall promptly provide such Roche Licensed Know-How to PDL through the parties' participation in the POC. Following the end of the Commercialization Term, 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 Second 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 Nutley Dac in the Roche Territory solely for use in Transplant Induction, and (ii) to sell and offer for sale Nutley Dac 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, use and import Nutley Dac, but only to the extent reasonably necessary for Roche to carry out its rights and obligations under this Second 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 [\*\*\*\*], or [\*\*\*\*]. 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 at the end of the Commercialization Term.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

(b) Subject to the terms and conditions of this Second 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 the [\*\*\*\*] shall be nonexclusive.

(c) PDL hereby covenants that, until the expiration of the [\*\*\*\*], it will not make, have made, use, sell, offer for sale or import any product in the Excluded Field Covered by the [\*\*\*\*] in the Roche Territory, and it will not grant to any Third Party any right or license under the [\*\*\*\*] 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 Second 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 Second 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 Second Amended and Restated Worldwide Agreement or any other written agreements in the Field between the parties currently in existence and not expressly superseded by this Second 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 Section 2.2.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

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 Second 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. 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. Roche further covenants that, [\*\*\*\*]. 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 [\*\*\*\*], [\*\*\*\*] shall not be responsible for any such royalty payments, and [\*\*\*\*] shall so notify [\*\*\*\*] in writing and [\*\*\*\*] shall have a period of [\*\*\*\*] to evaluate whether it desires that such [\*\*\*\*] be included within the [\*\*\*\*] licensed to [\*\*\*\*] under Section [\*\*\*\*] and if so, the mechanism for payment to [\*\*\*\*] thereunder. Where [\*\*\*\*] elects not to [\*\*\*\*] to such [\*\*\*\*], it [\*\*\*\*].

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

(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.

(h) Roche covenants that, in the event that Roche [\*\*\*\*], through whatever means, on PDL's request, Roche will within [\*\*\*\*] 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 Second Amended and Restated Worldwide Agreement to the extent deemed appropriate by both parties.

(i) To Roche's knowledge, neither Roche nor its Affiliates own any assets relevant solely to the development or commercialization of Daclizumab, other than the Daclizumab Assets (as defined in the Agreement), the Trademarks, and the Roche Owned Patents.

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.

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### III. DEVELOPMENT; REGULATORY ISSUES

#### 3.1 Development by Roche.

(a) Development of Daclizumab by Roche. Unless [\*\*\*\*], Roche shall have no right under this Second Amended and Restated Worldwide Agreement to [\*\*\*\*]. Roche shall have the right to continue to [\*\*\*\*] ongoing as of the Effective Date, which such [\*\*\*\*] shall be disclosed in writing by Roche to PDL within [\*\*\*\*] after the Effective Date. In addition, to the extent Roche receives any data or other results of any [\*\*\*\*] pursuant to [\*\*\*\*], Roche will update the POC with respect to such [\*\*\*\*]. 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 [\*\*\*\*] 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. Following the Amendment Effective Date, PDL shall be solely responsible, [\*\*\*\*] at its sole discretion, for the non-clinical, clinical, and regulatory development of Daclizumab (other than Nutley Dac) for all indications in the Territory, other than those trials referenced in Section 3.1(a) and except as otherwise provided in the Asthma/Transplant Agreement. All data and information generated by PDL development activities pursuant to this Section 3.2 shall be PDL Know-How.

3.3 Assistance by Roche. [\*\*\*\*] 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, [\*\*\*\*], 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). 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.

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3.4 Adverse Event Reporting. Subject to Section 3.7, 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 have each identified 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, shall continue exchanging information in accordance with the then current pharmacovigilance agreement. Upon the expiration or termination of the Asthma/Transplant Agreement, Roche and PDL shall promptly meet, together with any PDL licensee that is a party to the pharmacovigilance agreement then in effect, and negotiate in good faith an amendment to such pharmacovigilance agreement that takes into account the expiration or termination of the Asthma/Transplant Agreement. Such amended pharmacovigilance agreement (and any future amendments thereof) shall survive the end of the Commercialization Term.

3.5 Copies of Responses. Subject to Section 3.7, 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 [\*\*\*\*] of document finalization.

3.6 Regulatory Actions. Subject to Section 3.7, 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 Asthma/Transplant Agreement. During the term of the Asthma/Transplant Agreement, the terms of Sections 5.3, 5.4 and 5.5 of the Asthma/Transplant Agreement shall take precedence over the terms Sections 3.4, 3.5 and 3.6 of this Second Amended and Restated Worldwide Agreement. The terms of Sections 3.4, 3.5 and 3.6 of this Second Amended and Restated Worldwide Agreement shall regain full force and effect upon the expiration or termination of the Asthma/Transplant Agreement.

#### **IV. COMMERCIALIZATION AND MANUFACTURING**

##### **4.1 Commercialization By Roche**

(a) Commercialization of Nutley Dac by Roche. The parties intend that Roche will continue to market and sell Nutley Dac for Transplant Induction 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

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responsible, at its sole cost and as permitted by applicable law, for (i) the marketing, promotion, and detailing of Nutley Dac for use in Transplant Induction; (ii) accepting and filling orders for Nutley Dac received by it or its Affiliates, including the distribution of Nutley Dac to fill such orders; (iii) booking all sales of Nutley Dac attributable to such orders; and (iv) any other activities reasonably related to Nutley Dac 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. Roche may, in its sole discretion, discontinue marketing Nutley Dac at any time.

(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. 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 (other than Nutley Dac) for all indications and for all Other Licensed Products. In no event shall PDL owe under this Second Amended and Restated Worldwide Agreement any royalties or any other compensation to Roche on sales of Daclizumab 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 and Marketing Strategy.

(a) 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 Nutley Dac that it sells and distributes, subject to Sections 4.4(b)-(d).

(b) The parties desire to contribute their respective product and marketing expertise to best position Nutley Dac competitively. To that end, the parties agree [\*\*\*\*] in accordance with this Section 4.4. In order to facilitate these discussions, Roche shall, until the end of the Commercialization Term, provide PDL with [\*\*\*\*] and shall give due consideration to any recommendations or opinions offered by PDL regarding [\*\*\*\*] whether directly or through the POC.

(c) In addition, if Roche desires to implement a significant change in the existing marketing strategy (as defined in Section 4.4(c)(iii)) for Nutley Dac in the U.S. Territory, then the following procedures shall apply:

(i) Roche shall notify PDL immediately in writing and the parties shall meet in person within a reasonable time period following notification to discuss the proposed changes. Roche shall give due consideration to any recommendations or opinions offered by PDL regarding the impact of the proposed changes. The parties shall have a period of up to [\*\*\*\*] to further confer, but Roche shall have the right to effect such proposed change unless PDL notifies Roche in writing, supported by a rationale for such change, of its request for further consideration pursuant to subparagraph (ii) below.

(ii) If PDL notifies Roche in writing that it wishes further consideration of its views, then the parties shall refer the matter for discussion by a specially constituted subcommittee of the Transplant JDC consisting of [\*\*\*\*] from each of PDL and Roche with experience in sales and marketing in the Transplant Indications (the "JDC Special Committee"). The JDC Special Committee shall prepare an analysis of the impact on the Licensed Product of the proposed significant change in the existing marketing strategy for Nutley Dac. The JDC Special Committee shall have access to information and personnel from both parties reasonably required to prepare its analysis and assessment for review by the full Transplant JDC. The analysis shall be prepared as soon as practically feasible, in no event later than [\*\*\*\*] of the date of notification from Roche hereunder. The full Transplant JDC shall consider such analysis and assessment and agree upon a recommendation to the JSC within a reasonable period of time after receipt of such analysis and assessment. Thereafter, the JSC shall review and consider the recommendation of the Transplant JDC. If the JSC is unable to agree on the proposed significant change in the existing marketing strategy, then the matter shall be submitted for discussion and resolution by [\*\*\*\*] ([\*\*\*\*] The JSC shall within [\*\*\*\*] prepare an executive summary for submission to the Officers. The Officers shall then, within a reasonable period of time, meet to resolve the matter. If the Officers are unable to agree on appropriate resolution within [\*\*\*\*] thereafter, then [\*\*\*\*] shall have the sole right to effect the proposed significant change in the existing marketing strategy for Nutley Dac.

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(iii) The term "significant change in the existing marketing strategy" in this Section 4.4(c) shall mean proposals to: change the wholesale acquisition cost for the U.S. Territory by more than [\*\*\*\*], other than in response to a pricing move by a directly competitive product or in response to parallel importation or other governmental action; use a new trademark for Nutley Dac other than Zenapax; or change in marketing targeting a new indication or use outside of the Transplant Indications.

(d) In the event that [\*\*\*\*], the parties will promptly seek [\*\*\*\*] and, [\*\*\*\*], to [\*\*\*\*]e. The parties shall [\*\*\*\*] with such procedures until (i) [\*\*\*\*] or (ii) [\*\*\*\*].

#### 4.5 Manufacturing.

##### (a) Clinical Manufacturing.

(i) Supply. On January 1, 2005, 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.

(b) Commercial Manufacturing. PDL shall be solely responsible for the manufacturing of all Daclizumab, except that Roche shall be solely responsible for the manufacturing of all Nutley Dac, necessary to satisfy the commercial requirements of itself, its Affiliates and its sublicensees.

### **V. EFFECT OF END OF COMMERCIALIZATION TERM**

5.1 General. The parties intend that, subject to the terms and conditions of this Second Amended and Restated Worldwide Agreement, the commercialization of Nutley Dac for Transplant Induction in the Roche Territory will continue to be an exclusive Roche responsibility unless and until Roche decides to cease commercialization of Nutley Dac for Transplant Induction and thereby causes the Commercialization Term to end.

#### 5.2 Effect on Nutley Dac Rights. Effective immediately upon the expiration of the Commercialization Term:

(a) the license granted to Roche under Section 2.5(a) shall terminate, all such rights shall revert to PDL, and Roche shall no longer book sales of Nutley Dac for any indication or under any Trademark;

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

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(c) PDL may thereafter commence booking all sales of Nutley Dac in the Roche Territory purchased under (b) above, whether sold under a Trademark or the AI Trademark or any other trademark.

5.3 No Effect on Excluded Field and Excluded Products. The end of the Commercialization Term 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.

5.4 No Assumption of Liabilities. PDL shall assume no liabilities of Roche or its Affiliates as a result of any procedures or events set forth in this Article 5, 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 end of the Commercialization Term, of Daclizumab, and its manufacture of Daclizumab, including without limitation uncollected amounts, returns, recalls, and third party royalties (subject to Section 7.3) associated with such sales.

## **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) As of the Amendment Effective Date, the POC shall cease to be an independent body and shall be reconstituted as a subcommittee of the Transplant JDC. The POC shall remain a subcommittee of the Transplant JDC, unless and until the Asthma/Transplant Agreement is terminated with respect to the Transplant Field (as defined therein), at which point the POC shall once again become an independent body.

(b) The POC shall be 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(b)) by such party with the prior written consent of the other party in accordance with this Second 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.

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(c) 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.

(d) The POC shall be responsible for (i) exchanging information regarding the activities conducted by the parties, their sublicensees or their respective Affiliates under this Second Amended and Restated Worldwide Agreement, including without limitation, [\*\*\*\*] of [\*\*\*\*] with respect to [\*\*\*\*], (ii) making recommendations to the parties regarding the [\*\*\*\*] for [\*\*\*\*] for the [\*\*\*\*], (iii) discussing the [\*\*\*\*] and the potential for a [\*\*\*\*] to accomplish this goal, and (iv) such other activities as mutually agreed by Roche and PDL, [\*\*\*\*]. 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 end of the Commercialization Term.

(e) 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 [\*\*\*\*]. Each party's representatives shall have [\*\*\*\*]. In the event such representatives of each party are unable to agree:

(i) During any time period in which the POC is a subcommittee of the Transplant JDC, such dispute shall be referred to the Transplant JDC for resolution in good faith. If the Transplant JDC is unable to resolve such dispute, it will be handled in accordance with the dispute resolution procedures described in Sections 3.17(b) and 3.5(b) of the Asthma/Transplant Agreement, subject to Section 6.2(e)(ii); or

(ii) At any other time, such dispute shall be referred to the [\*\*\*\*] (the "[\*\*\*\*]") for resolution in good faith for a period of [\*\*\*\*].

(iii) In the event the [\*\*\*\*] are unable to resolve a dispute in the time frame set forth in Section 3.5(b) of the Asthma/Transplant Agreement or Section 6.2(e)(ii) (as applicable), [\*\*\*\*] shall have the final say on all such disputes related to [\*\*\*\*], except for disputes the resolution of which would take effect or continue to remain in effect, after [\*\*\*\*]; and [\*\*\*\*] shall have the final say on all other such disputes, including but not limited to those disputes related to d[\*\*\*\*].

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6.3 Dissolution of POC. The POC shall hold one final meeting after the end of the Commercialization Term and shall dissolve after such meeting.

## VII. COMPENSATION

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

### 7.2 Royalties.

#### (a) Royalties to PDL on Nutley Dac Sales.

(i) Roche shall pay PDL royalties on the sales of Nutley Dac prior to November 1, 2005 in accordance with the terms of this Agreement that were in effect prior to the Amendment Effective Date. The parties shall share Third Party License expenses arising from such sales in accordance with the provisions of this Agreement that were in effect prior to the Amendment Effective Date.

(ii) Commencing with sales of Nutley Dac on November 1, 2005 and continuing until the end of the Commercialization Term, Roche shall pay PDL royalties on Roche Net Sales at an incremental royalty rate determined by the annual (or annualized in the case of partial years) Roche Net Sales as follows:

<u>Annual Roche Net Sales (US\$)</u>	<u>Royalty Rate</u>
Up to and including [****]	[****]
Amount in excess of [****]	[****]

No adjustment will be made to the royalty rates specified in this Section 7.2(a)(ii) 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.

For example, if Roche Net Sales for a given year is fifty million dollars [\*\*\*\*], then Roche shall pay royalties on such sales equal to [\*\*\*\*].

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(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:

<u>Annual Roche Net Sales of Excluded Products (US\$)</u>	<u>Royalty Rate</u>
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.

7.3 Offset for Third Party Licenses.

(a) Appendix B sets forth the allocation between the parties of the costs associated with each Third Party License. Such costs include post-Amendment Effective Date license fees and any other post-Amendment Effective Date fixed costs associated with the Third Party License as well as any royalties incurred with respect to sales after the Amendment Effective Date.

(b) If after the Amendment Effective Date, either party obtains an additional license from a Third Party in order to manufacture, use, import, offer for sale or sell Daclizumab, the other party [\*\*\*\*]. This Section 7.3(b) shall not apply to the license agreement [\*\*\*\*]. Upon signing such agreement will be a Third Party License, [\*\*\*\*] will automatically have a sublicense under such agreement pursuant to Section 2.2, and the parties will allocate the costs associated with such agreement as specified in Appendix B.

(c) After the Amendment Effective Date, in each case where a party is responsible in accordance with this Section 7.3 for any amounts owed under a Third Party License to which the other party is the contracting party, such responsible party shall, within [\*\*\*\*] of the end of each quarter, pay such amount to such contracting party. In addition, each party shall

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submit to the other party, within [\*\*\*\*] after the end of each quarter, a written report setting forth the information set forth in Section 8.1(a) as well as any additional information needed to calculate the amounts owed under any Third Party License. For clarity, Roche may include information required by this Section 7.3(c) and by Section 8.1(a) in a single report, provided such report is delivered to PDL within [\*\*\*\*] of the end of each quarter. The information contained in each report under this Section 7.3(c) shall be considered confidential to the reporting party and the other party 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, regulation, or Third Party License.

(d) With respect to each payment timely received by a party pursuant to Section 7.3(c), such party shall timely pay such amount to the third party with which such party entered into the relevant Third Party License. With respect to each report timely received by a party pursuant to Section 7.3(c), such party shall timely submit, to the third party with which such party entered into the relevant Third Party License, either such report or a report that contains the relevant information contained in such report.

(e) Following the end of the Commercialization Term: (i) except as set forth in Section 7.3(d), Roche shall not have any further obligation pursuant to this Section 7.3 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, whether directly (if PDL is the party to the relevant Third Party License) or via Roche (if Roche is the party to the relevant Third Party License). The end of the Commercialization Term shall not have any effect on Roche's obligations to make Third Party License-related payments arising from sale or development of Excluded Products.

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

7.5 Sublicenses. 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 Second 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 Second 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).

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## VIII. PAYMENTS, REPORTS, AND ACCOUNTING

### 8.1 Roche Quarterly Royalty Payments and Reports.

(a) 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.

(b) The information contained in each report under Section 8.1(a) 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, regulation, or Third Party License. Concurrent with the making of each quarterly report, Roche shall include payment due PDL 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 Roche Product disposed of under this Second 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 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 Nutley Dac, stating in each such report the same information called for in each quarterly report by Section 8.1(a) for all Nutley Dac 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

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Products, stating in each such report the same information called for in each quarterly report by Section 8.1(a) for all Excluded Product made, sold or otherwise disposed of and which was not previously reported to PDL.

8.3 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 than [\*\*\*\*] 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.

8.4 Methods of Payments. All payments due to either PDL or Roche under this Second 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.

8.5 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.

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## **IX. CELL LINES**

### **9.1 Cell Lines.**

(a) 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.

(b) 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.

(c) 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 Second Amended and Restated Worldwide Agreement all rights to use the PDL Know-How, PDL’s rights under any Joint Roche-PDL Patents, and PDL Patents (i) to make, have made, use, import, offer to sell and sell anywhere in the world all products within the Field (but excluding Nutley Dac for use in Transplant Induction) and other than any Excluded Product or any other product in the Excluded Field; and (ii) for all uses outside of the Field. Following the end of the Commercialization Term, 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. Until the end of the Commercialization Term, 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. Following the expiration of the Commercialization Term, 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 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.

10.3 Roche Technology. PDL hereby acknowledges that, except as expressly provided herein, this Second 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 2.2 of this Second Amended and Restated Worldwide Agreement.

#### 10.4 Trademarks.

(a) Until the end of the Commercialization Term and except as otherwise agreed by the parties in writing, 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 Nutley Dac for Transplant Induction. 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.

(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.

### **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,

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among other things, that Roche undertake certain obligations in order to continue to maintain [\*\*\*\*] 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 either upon the expiration of the Commercialization Term or at some mutually agreed earlier date.

(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; provided, however, that Roche shall not have any rights to prosecute any Sole PDL Patent in any country in which Roche is not marketing Nutley Dac. 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 Excluded Field, 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, 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 5.2(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) [\*\*\*\*] will have the first right of election to file priority patent applications for Joint Inventions in any country in the world. If [\*\*\*\*] declines to file such applications then [\*\*\*\*] 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.

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(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 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 Inventions Outside the Field. Inventions and other intellectual property made by either party outside the Field shall be excluded from the provisions of this Second 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.

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

(b) [\*\*\*\*] Control. [\*\*\*\*] shall have full control over the strategy and decisions with respect to its filing of any patent applications and patents in the Territory. [\*\*\*\*] agrees to cooperate with and reasonably assist [\*\*\*\*] in the preparation of any patent applications and the maintenance of any patents.

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

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## 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 [\*\*\*\*] 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 [\*\*\*\*] 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.

(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.

(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 Second Amended and Restated Worldwide Agreement) or Roche without the prior consent of the other party hereto, [\*\*\*\*]. No settlement of any such action or

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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 Second Amended and Restated Worldwide Agreement), [\*\*\*\*].

(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.

(f) As of the Amendment Effective Date, Roche's right to prosecute an action under the Sole PDL Patents pursuant to Section 12.1(b) and any restrictions, obligations, or conditions on PDL's prosecution of actions under the Sole PDL Patents set forth in Section 12.1(c), (d), or (e) shall apply only with respect to [\*\*\*\*].

**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.

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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 Nutley Dac 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.

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12.5 Right to Counsel. Each party to this Second 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 Second Amended and Restated Worldwide Agreement; [\*\*\*\*].

### **XIII. TERM AND TERMINATION**

13.1 Term. The Parties' respective rights and obligations with respect to the time period between the Effective Date and the Second Amendment Effective Date shall be governed by the terms of the Agreement. This Second Amended and Restated Worldwide Agreement shall go into effect on the Amendment Effective Date and, unless earlier terminated pursuant to the terms of this Article XIII, 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. All licenses then in effect under any Roche Know-How or PDL Know-How shall survive the expiration of this Second Amended and Restated Worldwide Agreement and shall become fully-paid upon such expiration; provided, however, that any such licenses that were exclusive prior to expiration will convert to non-exclusive licenses upon such expiration.

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

13.3 Termination by PDL on Roche Default. If Roche defaults in the performance of, or fails to be in compliance with, any material agreement, condition or covenant of this Second Amended and Restated Worldwide Agreement with respect to the rights PDL grants to Roche under Article II of this Second Amended and Restated Worldwide Agreement, including royalties and consideration due from Roche to PDL under Article VII, then PDL may terminate any or all of the rights and licenses granted to Roche under Section 2.5 of this Second Amended and Restated Worldwide Agreement at its option, at which time Roche's right to promote, distribute and sell Nutley Dac in the Roche Territory shall terminate as though Roche had elected to end the Commercialization Term, with all the same effect as though that were the case. 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.

#### 13.4 Voluntary Termination Of License by Roche.

(a) Roche shall have the right to voluntarily terminate its licenses under Section 2.5(a), on six (6) months written notice to PDL. On notice of such voluntary termination, Roche shall notify PDL of the amount of Daclizumab that Roche, its Affiliates, sublicensees and

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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 Second 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 Second 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 2.2 (subject to Section 13.1), 2.7, 3.4, 5.4, 7.3, 7.4, 13.4, 13.5, 13.6, and Articles VIII, X, XI, XII, XIV, XV, and XVII (except for Section 17.1) shall survive the expiration or termination of this Second 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 Second Amended and Restated Worldwide Agreement and for a period of [\*\*\*\*] following expiration or termination of this Second 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

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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 Second 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 Second 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 Commercialization Term, 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 Second 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 Second 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 Second 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

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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 [\*\*\*\*] 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 [\*\*\*\*] 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 [\*\*\*\*] 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 [\*\*\*\*] 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. Unless the POC otherwise decides, PDL shall have the sole right to publish or otherwise publicly disclose, with or 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 Second 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 [\*\*\*\*], 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, [\*\*\*\*] within [\*\*\*\*] 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 [\*\*\*\*] of such failure. The award

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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 [\*\*\*\*], whether or not the [\*\*\*\*] is deemed to apply to said arbitration. Nothing in this Second 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 Second 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.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

17.2 Assignment. Either party may assign this Second 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 Second 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 Second Amended and Restated Worldwide Agreement to an entity, that is, as of the time of such proposed assignment, [\*\*\*\*] (in at least [\*\*\*\*] with [\*\*\*\*]), or [\*\*\*\*] in [\*\*\*\*] any [\*\*\*\*] for [\*\*\*\*] in any [\*\*\*\*]. This Second 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 Second 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 Agreement and 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 Second 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 Second 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 Second Amended and Restated Worldwide Agreement does not and will not supersede the Asthma/Transplant Agreement. In the event of a conflict or inconsistency between this Second Amended and Restated Worldwide Agreement and the Asthma/Transplant Agreement, the terms of the Asthma/Transplant Agreement shall take precedence over the terms of this Second Amended and Restated Worldwide Agreement. This Second 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 Second Amended and Restated Worldwide Agreement is declared invalid by an arbitrator pursuant to Section 15.1 or by a court of last

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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 Second 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 Second 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 Second 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 Second 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 Second 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 Second 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 Second 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 Second 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 Second 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 Second 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 Second Amended and Restated Worldwide Agreement shall be governed by the laws of the [\*\*\*\*], without regard to conflicts of law principles that would provide for application of the law of a jurisdiction outside [\*\*\*\*] 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 Second 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 Second 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 Second 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 Second 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 Second 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 Second Amended and Restated Worldwide Agreement), all as the other party may reasonably request for the purpose of carrying out the intent of this Second Amended and Restated Worldwide Agreement.

17.11 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.

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17.12 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 Second 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.

17.13 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.

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

17.15 Counterparts. This Second Amended and Restated Worldwide Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

[Rest of page intentionally blank]

IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Worldwide Agreement through their duly authorized representatives to be effective as of the Amendment Effective Date.

PROTEIN DESIGN LABS, INC.

By: /s/ Mark McDade  
Name: Mark McDade  
Title: Chief Executive Officer

HOFFMANN-LA ROCHE INC.

By: /s/ Frederick C. Kantz III  
Name: Frederick C. Kantz III  
Title: Vice President

F. HOFFMANN-LA ROCHE LTD

By: /s/ St. Arnold  
Name: St. Arnold  
Title: \_\_\_\_\_

By: /s/ Dr. Peter Hug  
Name: Dr. Peter Hug  
Title: Executive Vice President,  
Pharma Partnering

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.

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

		<u>Patent No.</u>	<u>Country</u>	<u>Title*</u>
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]

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[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]

	Country	Application No.	Title*
[****]	[****]		[****]
[****]	[****]		[****]
[****]	[****]		[****]
[****]	[****]		[****]
[****]	[****]		[****]
[****]	[****]		[****]
[****]	[****]		[****]
[****]	[****]		[****]

\* Exact titles may differ in different countries.  
1 and corresponding European national patents issued therefrom.  
2 registration date  
3 this is the application number; have not received patent yet.

\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

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**Appendix B**

**Third Party Licenses**

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**Appendix C**

**PDL Sole Territory: Countries or Jurisdictions in which All Rights Have Reverted to PDL**

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**Schedule 2.8(a)**

**Certain Roche Owned Patents**

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\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

**Schedule 2.8(b)**

**Certain Roche Controlled Patents**

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\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Notices of Third Party IP Rights

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\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Third Party Licenses

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\*\*\*\* Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

**AMENDED AND RESTATED  
CONSULTING AGREEMENT**

This Amended and Restated Agreement is between PROTEIN DESIGN LABS, INC., a Delaware corporation (“PDL”), and the PDL consultant who has signed this Agreement (“Consultant”). The original Agreement was effective as of January 2, 2004 and this Amended and Restated Agreement (the “Agreement”) is effective as of January 2, 2006 (the “Amended Effective Date”).

**1. ENGAGEMENT OF SERVICES.**

**1.1 Engagement.** PDL retains Consultant pursuant to the provisions of this Agreement to perform the consulting services specified in the Engagement attached as Exhibit A and any further Engagement that may be executed by the parties (the “Engagement”) in accordance with the schedule set forth in each such Engagement.

**1.2 No Delegation.** PDL selected Consultant to perform the services set forth in the Engagement based upon PDL receiving Consultant’s personal service. Therefore, Consultant may not subcontract or otherwise delegate or assigns its rights and obligations under this Agreement without PDL’s prior written consent. Consultant shall have the right and responsibility of controlling the manner and means of its completion of the Engagement. However, Consultant will perform such services at such place or places and at such times as PDL reasonably requests.

**2. COMPENSATION.**

**2.1 Fee.** PDL will pay the fee set forth in the Engagement for the services under this Agreement.

**2.2 Expenses.** PDL will reimburse Consultant for all out-of-pocket expenses (round trip economy class airfare for domestic travel and business class airfare for international travel, hotel, meals) reasonably incurred by Consultant and not otherwise reimbursed in connection with any trip made by Consultant at PDL’s specific request, for telephone toll charges, and for all other reasonable expenses actually incurred and not otherwise reimbursed which are incidental to the services performed under this Agreement.

**2.3 Payment.** PDL will pay for services and reimburse Consultant for reimbursable expenses within thirty (30) days of receipt of Consultant’s invoice provided Consultant has furnished documentation for the expenses as reasonably requested by PDL.

**2.4 Acceptance.** If the Engagement provides for a payment upon acceptance, PDL will have thirty (30) days to accept or reject the results of Consultant’s services after completion. If PDL rejects the results of Consultant’s services, or any significant portion thereof, PDL will so advise Consultant, and PDL will have the right and option (a) to extend the time for Consultant to complete the services upon such terms determined by PDL; or (b) to terminate this Agreement.

**3. INDEPENDENT CONTRACTOR.** Consultant’s relationship with PDL will be that of an independent contractor. Nothing in this Agreement will be construed to create an employer-employee relationship between the parties to this Agreement. Consultant will be solely responsible for and will maintain adequate records of expenses it will incur in the course of performing services under this Agreement and will be solely responsible for and will file, on a timely basis, all tax returns and payments required to be filed with or made to any federal, state or local tax authority with respect to its performance of services under this Agreement. Since Consultant will not be a PDL employee, Consultant will not be entitled to any of the benefits which PDL may make available to its employees, such as group insurance, profit-sharing, or retirement benefits, nor will any part of its compensation be subject to withholding by PDL for the payment of any social security, federal, state or any other employee payroll taxes.

**4. DISCLOSURE AND ASSIGNMENT OF INVENTIONS.**

**4.1 Disclosure and Assignment.** Consultant agrees to disclose promptly in writing to PDL every invention, discovery, improvement, copyrightable material, computer program, compound, micro-organism or other cell types, genetic or other biological material, process, manufacturing technique, trade secret, formula or know-how, whether or not patentable, conceived, made or reduced to practice or learned by Consultant in the course of any work that results from (1) any services performed for PDL or (2) use of trade secret information, equipment, supplies or facilities of PDL (collectively, “Inventions”). Consultant hereby assigns any such Inventions to PDL.

**4.2 Assistance.** With respect to any Inventions assigned to and owned by PDL pursuant to Section 4.1, Consultant agrees to assist PDL in any reasonable manner to obtain and enforce patents, copyrights, and other proprietary rights in any and all countries, and Consultant agrees to execute, when requested, patent applications and application assignments to PDL and any other lawful documents considered necessary by PDL to carry out the purpose of this Agreement, at PDL's expense. Consultant further agrees that the obligations and undertakings stated in this Section 4 will continue beyond the termination of this Agreement, but if called upon to render such assistance after the termination of Consultant's service to PDL, then Consultant will be entitled to a fair and reasonable per diem fee in addition to reimbursement of any expenses incurred at PDL's request.

#### **5. NO CONFLICT WITH PRIOR AGREEMENTS; INDEMNITY.**

**5.1 No Conflicts and Indemnity.** Consultant represents and warrants that Consultant is not obligated under any other agreement which would affect PDL's rights or Consultant's duties under this Agreement, and the performance of Consultant's duties as a consultant to PDL pursuant to the terms of this Agreement will not breach any agreement by which Consultant is bound, including (without limitation) any agreement limiting the use or disclosure of proprietary information acquired in confidence prior to engagement by PDL. Consultant agrees to indemnify PDL from any and all loss or liability incurred by reason of the alleged breach of any such agreement. Consultant also agrees that it will not bring to PDL or use in the performance of Consultant's responsibilities for PDL any materials or documents belonging to any current or former employer or other company that are not presently available to the public without the authorization of such former employer or company.

**5.2 Third-Party Rights.** Consultant further agrees not to disclose or make use of any information in the course of performing work for PDL which Consultant does not have the right to disclose, and which PDL is not free to use without liability of any kind. Consultant further agrees to inform PDL of any patents known to Consultant, which PDL may be in a position to violate as a result of information provided by Consultant.

#### **6. CONFIDENTIAL INFORMATION; NON-SOLICITATION.**

**6.1. Confidentiality and Nonuse.** Consultant will (a) hold PDL's Confidential Information in trust and in strictest confidence, (b) protect the Confidential Information from disclosure and in no event take or fail to take any action causing any Confidential Information disclosed to or developed by Consultant to lose its character as Confidential Information and (c) will not use, reproduce, disseminate or disclose the Confidential Information except as permitted under this Agreement. Any and all reproductions of the Confidential Information made by Consultant will prominently contain a confidentiality legend. "Confidential Information" means any and all data and information (a) which has value to PDL or to its affiliated companies, licensees, customers, suppliers, or other third parties and is not generally known by competitors and (b) which is treated by PDL as confidential. Confidential Information may include, but is not limited to, any portion of any scientific or technical information, process, data, biological material, software programs, and information relating to PDL's financial affairs, products, processes, business plans, employees, research and development, manufacturing, distribution and marketing, or information which any third party has disclosed to PDL in confidence.

**6.2 Exceptions.** Confidential Information will not include any information which is already known to Consultant free of any obligation of confidentiality at the time it is disclosed to Consultant by PDL, or which (a) has become generally known to the public through no wrongful act of Consultant; (b) has been rightfully received by Consultant from a third party without restriction on disclosure and without breach of an obligation of confidentiality running directly or indirectly to PDL; (c) has been approved for release to the general public by written authorization of PDL; (d) has been disclosed pursuant to a requirement of a governmental agency or of law without similar restrictions or other protections against public disclosure, or disclosure is required by operation of law; provided, however, that Consultant will first have given written notice of such required disclosure to PDL, made a reasonable effort to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which disclosure is required, and taken reasonable steps to allow PDL to seek to protect the confidentiality of the information required to be disclosed; or (e) is furnished to a third party by PDL without restrictions on the third party's right to disclose the information.

**6.3 Permitted Disclosures.** Disclosures of the Confidential Information will be made only to employees, agents or independent contractors of Consultant (a) who are directly involved in performing the Engagement for PDL and have a specific need to know such information, and (b) who have entered into written confidentiality agreements which impose, or are otherwise bound by, restrictions on the Confidential Information at least equivalent to those imposed under this Agreement.

**6.4 Nonsolicitation.** Consultant will not, during the term of this Agreement and for a period of one (1) year thereafter, either directly or indirectly, on Consultant's own behalf or in the service of, or on behalf of others, divert, solicit, or hire away, or attempt to divert, solicit, or hire away any person employed by PDL.

## **7. PDL PROPERTY.**

**7.1 Ownership.** Consultant acknowledges that all documents, including drawings, manuals, letters, notes, notebooks, reports, sketches, formulae, memoranda, records, files, data, financial information, development plans, employee lists, customer lists and the like, computer software, genetic and other biological material, compounds, and other PDL property in Consultant's custody or possession, whether delivered to it by PDL or made by Consultant in the performance of services under this Agreement, relating to the business activities of PDL and containing any information or data whatsoever, whether or not confidential, are the sole and exclusive property of PDL.

**7.2 Segregation and Return of Materials.** Consultant agrees to keep, separate and segregated from other work, all documents, records, notebooks, correspondence, cell lines and all products produced thereby, including (without limitation) compounds such as DNA, which directly relate to Consultant's work under this Agreement. All rights, title and interest to these items will be in PDL, and upon expiration or other termination of this Agreement for any reason whatsoever, all documents, records, notebooks, and similar repositories of or containing confidential information then in Consultant's control, whether prepared by Consultant or others, will be promptly turned over to PDL.

## **8. MISCELLANEOUS.**

**8.1 Assignment.** Consultant will not assign this Agreement or any part of this Agreement without PDL's prior written consent, and any such purported assignment will be void. This Agreement will be binding on Consultant's heirs, successors, executors, legal representatives, and permitted assigns and will inure to the benefit of PDL's successors and assigns.

**8.2 Term.** This Agreement is effective as of the date set forth above and continues for the term set forth in the Engagement (including such additional Engagements, if any, as the parties may enter into from time to time), unless earlier terminated in accordance with Section 8.3. The term of this Agreement may be extended by mutual agreement of the parties and by addendum to the original or any additional Engagements.

**8.3 Termination.** If payment for the services described in the Engagement is based upon a fixed price, either party may terminate this Agreement in the event of a material breach or default by the other party upon fifteen (15) days' prior written notice to the other party. If payment for Consultant's services described in the Engagement is other than a fixed price, either party may terminate this Agreement as to such Engagement for any reason, with or without cause, upon fifteen (15) days' prior written notice to the other party. On termination of this Agreement, PDL's obligation to pay any compensation (except for services or expenses already accrued or incurred) and Consultant's obligation to perform any further services pursuant to Section I of this Agreement will terminate; provided, however, that such termination will not affect Consultant's obligations under Section 4 (Disclosure and Assignment of Inventions), Section 5 (No Conflict with Prior Agreements; Indemnity), Section 6 (Confidential Information; Non-Solicitation) or Section 7 (PDL Property) of this Agreement, which obligations will continue for five (5) years from the date of termination.

**8.4 Notice.** Any notices permitted or required by this Agreement shall be in writing and shall be delivered personally or sent by telecopy, overnight courier, or certified or registered mail, return receipt requested to, if to PDL, PDL's principal offices (Attention: General Counsel) or, if to Consultant, the address set forth below

Consultant's signature, or to such other address as Consultant or PDL may designate by notice to the other. A notice will only be effective upon the earlier of actual receipt or three (3) business days after deposit in the United States mails.

**8.5 Entire Agreement, Amendments, Etc.** This Agreement, the exhibits to this Agreement, and the other documents contemporaneously executed or delivered constitute the full and entire understanding and agreement between the parties with respect to the subject matter of this Agreement, and supersede all prior understandings, negotiations and prior agreement between the parties. No waiver, amendment, or modification of any provision of this Agreement will be effective unless in writing and signed by the party against whom such waiver, amendment or modification is sought to be enforced. No failure or delay by either party in exercising any right, power or remedy under this Agreement will operate as waiver of any such right, power or remedy or of any other right, power or remedy under this Agreement.

**8.6 Applicable Law and Independence of Provisions.** This Agreement will be governed for all purposes by the law of the State of California as applied to transactions taking place wholly within California between California residents. If any provision of this Agreement is held invalid or unenforceable, the remaining provisions of this Agreement will continue in full force. PDL and Consultant agree to substitute for the invalid provisions a valid provision, which most closely approximates the intent and economic effect of the invalid provision.

**8.7 Authorization.** Each of the parties to this Agreement warrants that it has full authority and legal right to execute and deliver, and to perform its obligations under, this Agreement. Each of the individuals whose signature appears below warrants that he or she has full authority to execute this Agreement on behalf of the party on whose behalf he or she has affixed his or her signature to this Agreement.

**8.8 Attorney Fees.** The prevailing party shall be entitled to recover from the losing party its attorneys' fees and costs incurred in any action brought to enforce any right arising from this Agreement.

**8.9 Injunctive Relief.** Consultant acknowledges that money damages alone would be an inadequate remedy for the injuries and damage which would be suffered and incurred by PDL as a result of a breach of Sections 4, 5, 6 or 7. If Consultant breaches or threatens to breach any of such provisions, PDL, in addition to any other remedies it may have, will be entitled to a restraining order, injunction, or other similar remedy in order to specifically enforce such provisions. In the event that PDL seeks an injunction under this Agreement, Consultant waives any requirement that PDL post a bond or any other security.

PROTEIN DESIGN LABS, INC.:

By: /s/ Mark McDade  
Print Name: Mark McDade  
Title: CEO

CONSULTANT:

By: /s/ Cary Queen  
Print Name: Cary Queen  
Title: \_\_\_\_\_  
Address: [\*\*\*\*]  
                  [\*\*\*\*]  
SSN: [\*\*\*\*]

**EXHIBIT A**  
**ENGAGEMENT NO.1**

- A. Term: 3 years from the Amended Effective Date (a total term of five years from the Effective Date of the original Agreement)
- B. Project: Assist PDL in the prosecution and defense of the Queen et al. family of humanization patents in the U.S. and foreign countries; assist PDL in the prosecution and if necessary defense of the Light/Queen patent filings on use of anti-IL-2R antibodies for prevention of organ transplant rejection; assist in the drafting, prosecution and if necessary defense of such other PDL patent filings as requested by PDL's Patent group; and undertake such other projects on behalf of PDL as reasonably requested by PDL's CEO. Consulting will be for 15 days in a calendar quarter or up to 40 days per year, anything in excess of 15 days in a calendar quarter or 40 days in a year will be paid at rate of \$2,500 per day.
- C. Consultant's fee for the original two-year term was governed by the original Agreement. For the additional three-year term, compensation will be governed by this Agreement. Fixed Fee: \$100,000 per annum, paid quarterly. As additional compensation, certain previous PDL stock option grants to Consultant will continue to vest according to the following schedule:

<u>Option No.</u>	<u>Date of grant</u>	<u>Number of shares</u>	<u>Vesting schedule</u>
001715	April 20, 2000	100,000	1/192 per month
001830	April 26, 2001	100,000	1/192 per month
002648	April 24, 2002	20,000	1/96 per month

NOTE: This Engagement is governed by the terms of a Consulting Agreement in effect between PDL and Consultant. Any item in this Engagement, which is inconsistent with that Agreement, is invalid.

PROTEIN DESIGN LABS, INC.:

By: /s/ Mark McDade  
Print Name: Mark McDade  
Title: CEO

CONSULTANT:

By: /s/ Cary Queen  
Print Name: Cary Queen  
Title: \_\_\_\_\_

**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 PDL BioPharma, Inc.,
- (2) Registration Statement (Form S-3 No. 333-122760) of PDL BioPharma, Inc.,
- (3) Registration Statement (Form S-3 No. 333.123958) of PDL BioPharma, Inc.,
- (4) Registration Statement (Form S-3 No. 333-128644) of PDL BioPharma, Inc.,
- (5) Registration Statement (Form S-8 No. 333-125906) pertaining to the 2005 Equity Incentive Plan of PDL BioPharma, Inc.,
- (6) Registration Statement (Form S-8 No. 333-44762) pertaining to the 1993 Employee Stock Purchase Plan of PDL BioPharma, Inc.,
- (7) Registration Statement (Form S-8 No. 333-87957) pertaining to the 1999 Stock Option Plan and 1999 Nonstatutory Stock Option Plan of PDL BioPharma, Inc.,
- (8) Registration Statement (Form S-8 No. 33-65224) pertaining to the 1993 Employee Stock Purchase Plan of PDL BioPharma, Inc.,
- (9) Registration Statement (Form S-8 No. 33-50116) pertaining to the 2002 Outside Directors Stock Option Plan of PDL BioPharma, Inc.,
- (10) Registration Statement (Form S-8 No. 33-50114) pertaining to the 1991 Stock Option Plan of PDL BioPharma, Inc.,
- (11) Registration Statement (Form S-8 No. 33-96318) pertaining to the 1991 Stock Option Plan of PDL BioPharma, Inc.,
- (12) Registration Statement (Form S-8 No. 33-68314) pertaining to the 1999 Stock Option Plan and 1999 Nonstatutory Stock Option Plan of PDL BioPharma, Inc., and
- (13) Registration Statement (Form S-8 No. 333-104170) pertaining to the 1999 Nonstatutory Stock Option Plan and 2002 Outside Directors Stock Option Plan of PDL BioPharma, Inc.;

of our reports dated March 10, 2006, with respect to the consolidated financial statements and schedule of PDL BioPharma, Inc., PDL BioPharma, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of PDL BioPharma, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2005.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

## CERTIFICATIONS

I, Mark McDade, Chief Executive Officer (Principal Executive Officer) of PDL BioPharma, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of PDL BioPharma, 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 16, 2006

/s/ MARK MCDADE

Mark McDade

*Chief Executive Officer*

*(Principal Executive Officer)*

## CERTIFICATIONS

I, George T. Jue, Vice President, Finance and Corporate Controller (Principal Accounting Officer) of PDL BioPharma, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of PDL BioPharma, 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 16, 2006

/s/ GEORGE T. JUE

George T. Jue

**Vice President, Finance and Corporate Controller**  
**(Principal Accounting Officer)**

**CERTIFICATION**

Mark McDade, Chief Executive Officer, and George T. Jue, Vice President, Finance and Corporate Controller of PDL BioPharma, 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, 2005 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 16, 2006

By:

/s/ MARK MCDADE

Mark McDade

***Chief Executive Officer***

/s/ GEORGE T. JUE

George T. Jue

***Vice President, Finance and Corporate Controller  
(Principal Accounting Officer)***