

PDL BIOPHARMA, INC.
Form 10-K
March 01, 2007
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

**x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE
ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006**

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: 000-19756

PDL BioPharma, Inc.

(Exact name of registrant as specified in its charter)

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

34801 Campus Drive

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

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

Fremont, CA 94555

(Address of principal executive offices)

Registrant's telephone number, including area code

(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 \$0.01 per share

Preferred Stock Purchase Rights, no par value

(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 shares of common stock held by non-affiliates of the registrant, based upon the closing sale price of a share of common stock on June 30, 2006, as reported on the NASDAQ National Market System, was \$1,743,518,277.

As of February 22, 2007, the registrant had outstanding 115,265,960 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be delivered to stockholders with respect to the registrant's 2007 Annual Meeting of Stockholders to be filed by the registrant with the U.S. Securities and Exchange Commission (hereinafter referred to as the Proxy Statement) are incorporated by reference into Part III of this Annual Report on Form 10-K. The registrant intends to file its proxy statement within 120 days after its fiscal year end.

Table of Contents

PART I

Forward-looking Statements

This Annual Report contains 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 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).

We own or have rights to numerous trademarks, trade names, copyrights and other intellectual property used in our business, including PDL BioPharma, the PDL logo, RESTORE and HuZAFeach of which is considered a trademark, and *Cardene*[®], *Retavase*[®], *Busulfex*[®] and *Nuvion*[®]. All other company names, tradenames 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 currently market and sell products in the acute-care hospital setting in the United States and Canada. We also receive royalties and other revenues through licensing agreements with numerous biotechnology and pharmaceutical companies based on our proprietary antibody-based platform. These licensing agreements have contributed to the development by our licensees of nine marketed products and cover several antibodies in clinical development. We currently have several investigational compounds in clinical development for severe or life-threatening diseases, and we have entered or intend to enter into collaborations with other pharmaceutical or biotechnology companies for the joint development, manufacture and commercialization of certain of these compounds. Our research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases.

We continue to evolve 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. The key elements of our strategy include continuing to build our acute-care, hospital-focused commercial organization and developing novel, proprietary products by leveraging our antibody-based discovery and development platform, while pursuing corporate development activities that may enable expansion of our product portfolio prior to the launch of products from our current proprietary pipeline:

Acute-care focused commercial organization. Our hospital sales force specializes in the acute-care setting and currently markets our *Cardene IV*, *Retavase* and *IV Busulfex* products to nearly 1,800 hospitals in the United States. In the hospital setting, our sales force focuses its efforts on the cardiac, neurological and intensive care units as well as in emergency departments.

Table of Contents

Development of proprietary drugs. Our aim is to develop antibody- or other protein-based products through our own research and development efforts, as well as to selectively and opportunistically license proprietary therapeutic candidates from other companies. Our current stated aim is to submit to the FDA, on average, one investigational new antibody-based drug application (IND) per calendar year, and augment this pipeline generation through additional in-licensing at various stages of development. Our internal research and development efforts are focused on novel antibodies for the treatment of cancer and autoimmune diseases and life cycle management activities for our currently marketed products, including the development of new formulations, dosage forms and indications of use. Our goal is to market our hospital-focused products in North America. However, certain of our products in development address indications that require specific expertise or large development and marketing efforts, such as heart failure, multiple sclerosis (MS), respiratory diseases and some oncology indications, and our strategy for those products is to seek appropriate partners with global development, manufacturing and commercialization capabilities.

Major acquisitions that have supported our strategy include our April 2003 acquisition of Eos Biotechnology, Inc. (Eos) and our March 2005 acquisitions of ESP Pharma Holding Company, Inc. (ESP Pharma) and rights to the *Retavase* product. Eos was a development stage company engaged in drug discovery of therapeutic antibodies based on information from the human genome. The acquisition of Eos expanded our development pipeline of potential products in oncology and enhanced our overall antibody discovery and development capabilities. The acquisitions of ESP Pharma and the rights to the *Retavase* product facilitated our transformation from a purely development-focused biotechnology company to a full-fledged commercial biopharmaceutical enterprise.

We were organized as a Delaware corporation in 1986 under the name Protein Design Labs, Inc. In 2006, we changed our name to PDL BioPharma, Inc. to better reflect our status as a commercial biopharmaceutical enterprise.

OUR COMMERCIAL PRODUCTS

We market our *Cardene IV*, *Retavase* and *IV Busulfex* products through our hospital-focused sales force, which focuses on the emergency cardiac, neurological and intensive care units of hospitals. In addition, with our recent acquisition of various *Cardene* product-related rights from Roche, we began selling *Cardene SR* products in September 2006 to broaden our overall product offering in the treatment of emergency hypertension. Our commercial products are summarized below:

Cardene. We sell our *Cardene* product in two formulations, *Cardene IV* and *Cardene SR*. The *Cardene IV* product is the only branded, U.S.-approved pharmaceutical in its specific chemical category delivered intravenously that is indicated for short-term treatment of hypertension when oral therapy is not feasible or desirable. The market for antihypertensives has experienced moderate growth in recent years and we expect this market to continue its growth rate into the foreseeable future. We have been able to increase *Cardene IV* product's market share and expect to continue to increase our market share as we invest in promotional programs; however, we expect the pace of that growth ultimately to slow over time. We expect that growth in sales of *Cardene IV* product will be the most significant contributor to our product sales in the next several years. Our patent protection in the United States on our *Cardene IV* product expires in November 2009.

We began selling the *Cardene SR* product in September 2006 after our acquisition of various *Cardene* product-related rights from Roche in September 2006. The *Cardene SR* product is a patented, sustained-release formulation which is sold in capsule form for oral administration. Our *Cardene SR* product is indicated for the treatment of hypertension and may be used alone or in combination with other antihypertensive drugs. We do not expect sales of our *Cardene SR* product to significantly contribute to our total product sales or total revenues going forward, but our acquisition of various *Cardene* product-related rights solidified our *Cardene* brand franchise in the United States. Our patent protection in the United States on our *Cardene SR* product expires in March 2010.

We are working on lifecycle management initiatives, including a study in pediatric patients beginning in 2007, to extend the life of our *Cardene* brand franchise in the United States.

Table of Contents

Retavase. Our *Retavase* product is indicated for use in the management of heart attacks (acute myocardial infarction, or AMI) in adults for the improvement of the efficiency of heart muscle contraction following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. The thrombolytics market in which the *Retavase* product competes has been declining due to physicians' increased use of emergency surgical procedures to treat AMI, and we expect that this market will continue to decline in the foreseeable future. While we believe that opportunities may exist to expand our market share within the thrombolytics segment, the overall market dynamics for thrombolytics in the treatment of AMI will continue to have a significant impact on our total sales opportunity over the next several years. Our patent protection in the United States on our *Retavase* product expires in March 2014.

IV Busulfex. Our IV *Busulfex* product, an intravenous formulation of busulfan, is a chemotherapeutic agent indicated for use in the United States in combination with cyclophosphamide as a conditioning regimen prior to bone marrow transplantation for chronic myelogenous leukemia (CML). Our IV *Busulfex* product is our first global product and is sold outside the United States through our distributors, including Pierre Fabre Medicament S.A. in Europe and Kirin Brewery Company, Limited in several Asian countries. Although we do not market our IV *Busulfex* product for uses other than its FDA-approved indicated use, we believe that the IV *Busulfex* product is primarily administered by physicians in the United States for uses other than the FDA-approved use in regimens that include bone marrow transplantation. We expect that any near-term growth of this product will be generated primarily by international expansion by our distribution partners. Our patent protection in the United States on the IV *Busulfex* product expires in September 2013 while regulatory extensions in the United States for the IV *Busulfex* product will expire in March 2014. Patent protection for the IV *Busulfex* product in the European Union (EU), Japan and certain other foreign countries will expire in August 2014. We also have been granted marketing exclusivity in Japan that begins upon the expiration of our Japanese patent and ends on July 2016. We have filed for similar regulatory and marketing exclusivity in other jurisdictions.

See Product sales, net under Results of Operations in Part II, Item 7 of this Annual Report for additional information regarding our product sales in the last two years.

OUR PRODUCTS IN DEVELOPMENT

We have several investigational compounds in clinical development for severe or life-threatening diseases, some of which we are developing in collaboration with other pharmaceutical or biotechnology companies. These potential products include both antibodies and small molecule therapeutics in oncology, autoimmune disease and cardiovascular indications. The table below lists various investigational compounds for which we are pursuing clinical development activities either on our own or in collaboration. Not all clinical trials for each product candidate are listed below. The development and commercialization of our product candidates are subject to numerous risks and uncertainties, as noted in our Risk Factors of Part I, Item 1A of this Annual Report.

Product Candidate	Indication/Description	Program Status	Collaborator
<i>Nuvion</i> [®] (visilizumab)	IV steroid-refractory ulcerative colitis Crohn's disease	Phase 2 / 3 program ongoing Phase 2 program being evaluated	
Ularitide (synthetic peptide)	Acute decompensated heart failure	Phase 1 (US) anticipated to begin in 2007 Phase 3 (Europe) program pending partnership	
Daclizumab	Asthma Multiple sclerosis Transplant maintenance	Phase 2 program advancement pending partnership Phase 2 program ongoing in partnership Phase 2 program being evaluated	Biogen Idec
Volociximab (M200)	Solid tumors	Phase 2 program ongoing in partnership	Biogen Idec
HuLuc63 <i>Nuvion</i> (visilizumab)	Multiple myeloma	Phase 1 program ongoing	

Nuvion (visilizumab). Our *Nuvion* antibody is a humanized monoclonal antibody that binds to CD3, a protein found on the outer membrane of T cells. T cells are white blood cells that play a role in inflammatory and immune-mediated processes in the body. We hold all worldwide rights to the development, manufacturing and sales of the *Nuvion* antibody.

Table of Contents

The *Nuvion* antibody is currently being tested in a registrational program in patients with intravenous steroid-refractory ulcerative colitis (IVSR-UC). Our Phase 2/3 pivotal trial of the *Nuvion* antibody in patients with IVSR-UC, a study we refer to as RESTORE 1, continues to enroll patients. We plan to initiate a second pivotal Phase 3 study, called RESTORE 2, pending an interim analysis from the first 60 patients in the RESTORE 1 study by an independent Data Monitoring Committee (DMC) and subsequent support from the FDA to proceed with this second study. We continue to track towards a DMC review in the second quarter of 2007. The primary endpoint of both the RESTORE 1 and RESTORE 2 studies is patient response at day 45 using standard clinical assessments of disease symptoms. Each study is expected to enroll up to 150 patients.

As part of the RESTORE program, we have also initiated a suite of supportive trials for the *Nuvion* antibody in patients with IVSR-UC. These include an ongoing trial evaluating lower doses of the *Nuvion* antibody and a retreatment trial that may help determine if the *Nuvion* antibody can be used as a maintenance therapy. A related observational study is ongoing monitoring long-term follow up for patients treated with the *Nuvion* antibody. Finally, a study of the *Nuvion* antibody in pediatric patients with ulcerative colitis is also planned for 2007.

While our near-term focus continues to be in the area of severe ulcerative colitis, the *Nuvion* antibody has shown potential as a treatment for severe Crohn's disease and may also be useful as a treatment for certain other autoimmune diseases, such as multiple sclerosis.

Ularitide. Ularitide is a synthetic form of urodilatin, a naturally occurring human natriuretic peptide that is involved in regulating blood pressure and the excretion of water and sodium from the kidneys. Urodilatin is produced in the kidney and excreted into the urine, and thus exists in low levels naturally in the systemic blood circulation. When injected into the blood, ularitide appears to cause diuresis (urine output) and natriuresis (sodium excretion), as well as vasodilation. We hold worldwide rights under an exclusive license from CardioPep Pharma GmbH to develop, manufacture and sell ularitide.

In April 2006, we completed the Scientific Advice procedure with the EMEA for our Phase 3 trial of ularitide for the treatment of acute decompensated heart failure and began planning a two-study, 3,300-patient Phase 3 program. Given the scope of this program and the benefits of a potential development collaboration, we decided to secure a development partnership prior to moving forward with additional European clinical activities for ularitide, and such effort is ongoing. Our pursuit of a partnership prior to advancing the European-focused Phase 3 trials of ularitide will not affect our initiation of a U.S.-based dose-ranging Phase 1 study to define dose-limiting toxicity, which is planned for early 2007.

Daclizumab. Daclizumab is a humanized monoclonal antibody that binds to the alpha chain (CD25) of the interleukin-2 (IL-2) receptor on activated T cells, which are white blood cells that play a role in inflammatory and immune-mediated processes in the body. Daclizumab is the active component of the approved drug marketed worldwide by Roche as Zenapax, which is indicated for the prevention of acute organ transplant rejection following transplant surgery.

We and our partner, Biogen Idec, are currently testing daclizumab in a Phase 2 study in patients with multiple sclerosis. We anticipate results from the ongoing Phase 2 program in this indication during mid-2007. Since Roche's election to terminate its co-development of daclizumab in treating asthma and transplant maintenance with us, we are evaluating opportunities to establish a new collaboration for these indications. Refer to the Collaboration and Strategic Agreements section of this Part 1, Item 1 of this Annual Report for further details regarding our collaboration agreement with Roche.

Volociximab (M200). Volociximab is a chimeric monoclonal antibody that inhibits the functional activity of $\alpha 5\beta 1$ integrin, a protein found on activated endothelial cells. Blocking the activity of $\alpha 5\beta 1$ integrin has been found to prevent angiogenesis, which is the formation of new blood vessels that feed tumors and allow them to grow and metastasize.

We and our partner, Biogen Idec, are currently investigating volociximab in various Phase 2, open-label clinical trials in patients with advanced solid tumors. We expect to broaden the scope of this program during 2007 to include clinical trials in additional tumor types, including non-small cell lung cancer (NSCLC) and ovarian cancer. Additional trials in renal cell carcinoma (RCC), melanoma and pancreatic cancer may also be pursued pending results of the ongoing open-label studies. The design and size of these trials will vary by indication.

Table of Contents

HuLuc63. HuLuc63 is a humanized monoclonal antibody that binds to CS1, a cell surface glycoprotein that is highly expressed on myeloma cells but minimally expressed on normal cells. HuLuc63 may induce anti-tumor effects through antibody-dependent cellular cytotoxicity activity on myeloma cells. In the fourth quarter of 2006, we began a Phase 1 trial of HuLuc63 in patients with advanced multiple myeloma, and plan to present preliminary data from this trial by the end of 2007.

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.

OUR RESEARCH AND PRECLINICAL DEVELOPMENT

Our proprietary antibody humanization technology has positioned us as a leader in the development of therapeutic antibodies that overcome many of the problems associated with mouse antibodies. Although mouse monoclonal antibodies are relatively easy to generate, they can have significant drawbacks as therapeutics, including a short half life that requires frequent administration and the high likelihood that a mouse antibody will be 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.

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.

Building upon our antibody humanization platform, our research efforts are now focused on creating and developing humanized antibodies for the treatment of cancer and autoimmune diseases. 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 our antibody 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.

Based on our proprietary and focused antibody discovery capabilities, we are evaluating a number of additional therapeutic antibody candidates, at earlier stages of development, focused on the treatment of cancer and autoimmune diseases. This effort is consistent with our stated aim of entering a proprietary candidate into clinical studies each calendar year beginning in 2006, which we achieved with the initiation of the Phase 1 trial of HuLuc63 in patients with advanced multiple myeloma in the fourth quarter of 2006.

Table of Contents

We anticipate that the next antibody to advance from our preclinical research pipeline to the clinical development stage will be a humanized antibody for patients with solid tumor cancers. In addition, we have several humanized antibody candidates in earlier research stages, the most-advanced of which could enter clinical studies over the next several years if ongoing preclinical development is successful.

Research and development expenses were \$260.7 million in 2006, \$172.0 million in 2005, and \$122.6 million in 2004. We expect our research and development expenses to continue to increase as we advance our product candidates into later stages of development and add new product candidates, and such expenses may change unexpectedly due to changes in trial design, cancellation of projects, or initiation or in-licensing of new programs.

OUR MANUFACTURING

The manufacture of pharmaceutical products is an expensive, multi-step, complex process. Products must be manufactured in facilities approved by the FDA that are subject to periodic FDA inspection. Steps in the manufacturing process, including the manufacture of the active pharmaceutical ingredient, filling, labeling and packaging, may be managed by multiple third-parties and require extensive coordination.

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 intend to continue to manufacture potential antibodies 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 currently manufacture the *Nuvion* antibody and daclizumab for use as clinical trial material in our commercial manufacturing facility in Brooklyn Park, Minnesota. Physical construction of our approximately 22,000-liter capacity manufacturing facility was completed in December 2004, and the facility was validated in June 2006. In July 2006, we began manufacturing products for use in clinical trials at this facility.

We outsource the manufacturing of our non-antibody-based products, both commercial and development stage, to third-party contract manufacturers. Our commercial products, *Cardene IV*, *Retavase* and *IV Busulfex*, are manufactured in the continental United States, and our *Cardene SR* product is manufactured in Puerto Rico. 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.

Additional information regarding risks associated with manufacturing that affect our business is contained under the headings "The manufacturing of *Retavase* product is a complex process that requires the services of a number of third parties, and our failure to timely or efficiently manufacture *Retavase* product could cause our results of operations to suffer"; "Because we do not have the capability to manufacture our commercial products or our ularitide development product, we rely on third-party contract manufacturers to manufacture these products. If we are unable to continue those manufacturing arrangements successfully or at a reasonable cost, our operations and future results could suffer";

"Our own ability to manufacture our products on a commercial scale is uncertain, which may make it more difficult to sell our products" and "Our business may be harmed if we cannot obtain sufficient quantities of raw materials" in Item 1A below under the heading "Risk Factors."

COLLABORATION AND STRATEGIC AGREEMENTS

Biogen Idec Collaboration. In September 2005, we entered into a Collaboration Agreement with Biogen Idec MA Inc. (Biogen Idec) pursuant to which we and Biogen Idec agreed to jointly develop, manufacture and commercialize three

Table of Contents

antibodies. The Collaboration Agreement provides for shared development and commercialization of daclizumab in multiple sclerosis (MS) and indications other than transplant and respiratory diseases, and for shared development and commercialization of volociximab (M200) and *HuZAF* (fontolizumab) in all indications.

Biogen Idec paid us an upfront license fee of \$40.0 million in connection with the Collaboration Agreement. In addition, in connection with the execution of the Collaboration Agreement, Biogen Idec purchased approximately 4.1 million shares of our common stock, at \$24.637 per share, for approximately \$100.0 million in cash.

Under the Collaboration Agreement, we and Biogen Idec share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies share the development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. We are eligible to receive development and commercialization milestones based on the further successful development of these antibodies. 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.

In August 2006, we announced that we and Biogen Idec would discontinue development of *HuZAF* in rheumatoid arthritis and that we and Biogen Idec do not currently have any plans for development of *HuZAF* in other indications.

The Collaboration Agreement requires each party to undertake extensive efforts in support of the collaboration, and requires the performance of both parties to be successful. In general, the collaboration is 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 whole in certain events.

Roche Collaboration. Effective October 2003, we entered into an Amended and Restated Worldwide Agreement (the 2003 Worldwide Agreement) with Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd. (together, Roche) under which we paid \$80 million to Roche for the acquisition of exclusive rights to daclizumab in all indications other than transplant indications and an option to acquire Roche's rights to daclizumab in transplant indications.

In October 2005, we and Roche entered into the Second Amended and Restated Worldwide Agreement (the 2005 Worldwide Agreement), which amended and restated the 2003 Worldwide Agreement. Pursuant to the 2005 Worldwide Agreement, we acquired all of Roche's remaining rights to daclizumab subject to Roche's exclusive right to continue to commercialize daclizumab under the trademark *Zenapax*® for the prevention of acute organ rejection in patients undergoing kidney transplants. The 2005 Worldwide Agreement also provides that Roche will only be obligated to pay us royalties on sales of *Zenapax* above a threshold level which we do not expect to be reached based on our current expectations. As a result, we do not expect to receive royalties from Roche under the 2005 Worldwide Agreement.

In October 2005, we and Roche also entered into the Amended and Restated Co-Development and Commercialization Agreement (the Roche Co-Development Agreement), which provided that we and Roche would collaborate to jointly develop and commercialize daclizumab for the treatment of asthma and other respiratory diseases (the Asthma Collaboration) and for transplant indications, with an emphasis on transplant maintenance (the Transplant Collaboration). The Roche Co-Development Agreement broadened a co-development and commercialization agreement we entered into in September 2004 that covered only the Asthma Collaboration to also cover the Transplant Collaboration.

In August 2006, however, Roche decided to first discontinue its involvement in the co-development of daclizumab in treating asthma and then later, in November 2006, elected to discontinue its co-development of daclizumab in transplant maintenance and terminate the Roche Co-Development Agreement effective in May 2007. Roche's remaining rights to daclizumab subsequent to May 2007 will be limited to the commercialization of the *Zenapax* product, under the 2005 Worldwide Agreement.

Table of Contents

TECHNOLOGY OUT-LICENSE AGREEMENTS

Humanization Patent License Agreements

We have been issued patents in the United States and elsewhere, covering the humanization of antibodies, which are known generally as the Queen, *et. al.* patents, which expire in 2013 and 2014, and are described in more detailed below under the heading Our Patents and Other Proprietary Rights. We have entered into license agreements with numerous entities that are independently developing or have developed humanized antibodies pursuant to which we have licensed certain rights under our Queen patents to make and sell therapeutic antibodies targeting antigens specified in the license agreements. In general, we received an upfront licensing fee, and rights to receive annual maintenance fees and royalties on any product sales under these license agreements. Under some of these agreements, we also may receive milestone payments. In addition to granting licenses under our Queen patents, some of these agreements provide that we will perform for a fee certain services related to the humanization of specified antibodies for the licensee.

We have entered into agreements for the license of rights under our Queen patents with several drug development companies, including, among others, Genentech, Inc. (Genentech), MedImmune, Inc. (MedImmune), Wyeth and Elan Corporation, Plc (Elan), each of which pays us royalties under their respective license agreements. 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 2006: Genentech's *Avastin*[®]/*Herceptin*[®], *Xolair*[®], *Raptiva*[®] and *Lucentis* ; MedImmune's *Synagis*[®]; Wyeth's *Mylotarg*[®]; Elan's *Tysabri*[®] and Hoffmann-La Roche's *Zenapax*[®]. We are aware of more than 75 humanized antibodies in development worldwide by various pharmaceutical and biotechnology companies, and we have entered into patent license agreements that may cover many of these products.

Under most of these patent license agreements, we are entitled to receive a flat-rate royalty based upon our licensee's net sales of covered products. Our master patent license agreement with Genentech, however, provides for a tiered royalty structure under which the royalty rate Genentech must pay on royalty-bearing products sold in the United States or manufactured in the United States and sold anywhere (U.S.-based Sales) in a given calendar year decreases on incremental U.S.-based Sales above several net sales thresholds. As a result, Genentech's average annual royalty rate will decline as Genentech's U.S.-based Sales increase. Because we receive royalties in arrears, the average royalty rate for the payments we receive from Genentech in the second calendar quarter which would be for Genentech's sales from the first calendar quarter will be higher than the average royalty rate for following quarters and will be lowest for royalty payments we receive with respect to Genentech's fourth quarter sales in the first calendar quarter when more of Genentech's U.S.-based Sales bear royalties at lower royalty rates.

In 2006, we received \$183.6 million of royalty revenues under the license agreements with the entities identified above. Because of the fundamental and significant value of the Queen patents, we will continue to pursue discussions with entities involved in research and development of humanized antibodies and from time to time expect to enter into additional agreements under which we would license rights under our Queen patents to these entities.

Other Out-License Agreements

In addition to our Queen patents, we have developed other intellectual property and been issued patents covering a variety of other technology, including with respect to potential drug products. In addition to the collaboration agreements described above under the heading Collaboration and Strategic Agreements, we have entered into agreements pursuant to which we have licensed to other entities certain of our intellectual property rights, including patent rights. For example, in 2005, we outlicensed PR-1, a prostate cancer antibody, to Genentech and we outlicensed lintuzumab, an antibody targeting certain hematologic malignancies, formerly named Zamy1 or HuM195, to Seattle Genetics, a biotechnology company focused on the development of monoclonal antibody-based therapies for the treatment of cancer and immunologic diseases. Because some of these potential drug products to which we have rights are humanized antibodies, some of these license agreements include licenses under our Queen patents as well. From time to time we may pursue discussions with companies regarding the outlicense of our intellectual property rights and may enter into other agreements under which we will outlicense our rights to our intellectual property, including rights to drug products.

Table of Contents

MAJOR CUSTOMERS

We define our customers as purchasers of our commercial products, our collaboration partners and our licensees from whom we receive royalties and other milestone payments. Note 16, Revenues by Geographic Area and Significant Customers, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Annual Report lists our major customers who each provided over 10% of our total operating revenues in each of the last three years. Also discussed in the note are material net foreign revenues by country in 2006, 2005, and 2004.

OUR PATENTS AND OTHER PROPRIETARY RIGHTS

We expend a significant amount of our resources on research and development efforts to discover, develop and commercialize innovative therapies for severe or life-threatening illnesses. Obtaining, maintaining and protecting the intellectual property rights, including patent rights, developed through our research and development efforts is essential for our business to succeed. To that end, we actively seek to implement patent strategies to maximize the effectiveness of our intellectual property positions. We have been issued numerous U.S and foreign patents and have a variety of patent applications pending in the U.S. and various foreign countries covering, among other things, compositions of matter, drug formulations, methods of use and action, and manufacturing.

Our Queen patents, which expire in the United States in the 2013/2014 timeframe, are of significant value to us. We have licensed to other entities rights under our Queen patents pursuant to which we have received and expect to continue to receive royalty revenues (see Technology Out-License Agreements above). These patents cover, among other things, humanized antibodies, methods for humanizing antibodies, polynucleotide encoding in humanized antibodies and methods of producing humanized antibodies.

Two humanization patents based on the Queen technology were issued to us by the European Patent Office. However, 18 notices of opposition to our first European patent and eight notices of opposition to our second European patent were filed by major pharmaceutical and biotechnology companies, among others. Five opponents, including Genentech, have withdrawn from the opposition proceedings regarding our first European patent. Additional information regarding these proceedings and their status is set forth under the heading Legal Proceedings in Part I, Item 3 of this Annual Report.

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.

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.

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, commonly referred to as our freedom to operate, 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.

Table of Contents

The scope, enforceability and effective term of issued patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar 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. We cannot assure you that the patents we obtain or the unpatented proprietary technology we hold will afford us significant commercial protection. Additional information regarding risks associated with our patents and other proprietary rights that affect our business is contained under the headings **Patent and Proprietary Rights**. If we are unable to protect our patents and proprietary technology, we may not be able to compete successfully ; Our humanization patents are being opposed and a successful challenge or refusal to take a license could limit our future revenues ; and We may require additional patent licenses in order to manufacture or sell our potential products in Item 1A below under the heading **Risk Factors**.

GOVERNMENT REGULATION

The manufacturing, testing, labeling, approval, storage, advertising and marketing of our products are subject to rigorous regulation by numerous governmental authorities in the United States and other countries at the federal, state and local level, including the FDA. 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.

The process for obtaining FDA approval of drug candidate customarily begins with the filing with the FDA of an IND for the use of a drug candidate to treat a particular indication. If the IND is accepted by the FDA, we would then start human clinical trials to determine, among other things, the proper dose, safety and efficacy of the drug candidate in the stated indication. The clinical trial process is customarily divided into three phases Phase 1, Phase 2 and Phase 3. Each successive phase is generally larger and more time-consuming and expensive than the preceding phase. Throughout each phase we are subject to extensive regulation and oversight by the FDA. Even after a drug is approved and being marketed for commercial use, the FDA may require that we conduct additional trials, including Phase 4 trials, to further study safety or efficacy.

As part of the regulatory approval process, we must demonstrate to the FDA the ability to manufacture a pharmaceutical product before we receive marketing approval. The manufacturing and quality control procedures we must undertake must conform to rigorous standards 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 also subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, state, local and other authorities may also regulate pharmaceutical product manufacturing facilities. Before we are able to manufacture commercial products in our Brooklyn Park, Minnesota facility, we must meet 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, we and our distribution partners 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. We or our licensees or marketing partners may encounter difficulties or unanticipated costs or price controls 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, our promotional materials and activities must also comply with FDA regulations and other guidelines.

Table of Contents

Both before and after marketing 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 inspections 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 company'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.

Additional information regarding the regulatory matters that affect our business is contained under the heading "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 below under the heading "Risk Factors."

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 for our marketed products include Baxter International Inc., Bedford Laboratories, Hospira, Inc., Genentech and GlaxoSmithKline.

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. In addition, competitors may succeed in developing products and technologies that are more effective, safer 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.

Other competitive factors affecting our business generally include:

product efficacy and safety;

Table of Contents

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;

the capabilities of our collaborative partners; and

the ability to hire qualified personnel.

EMPLOYEES

As of January 31, 2007, we had approximately 1,100 full-time employees. Of the total, approximately 200 employees were engaged in research and process development, 210 in clinical and regulatory, 170 in manufacturing, 140 in quality assurance and 380 in sales, marketing, 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. We consider our relations with our employees to be good.

ENVIRONMENTAL COMPLIANCE

We seek to comply with environmental statutes and the regulations of federal, state and local governmental agencies. We have put into place processes and procedures and maintain records in order to monitor environmental compliance. We may invest additional resources, if required, to comply with applicable regulations, and the cost of such compliance may increase significantly.

AVAILABLE INFORMATION

For a report of our fiscal year 2006 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.

We file electronically with the Securities and Exchange Commission (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>.

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

We make available free of charge on or through our website at www.pdl.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements, as well as amendments to these reports and statements, as soon as practicable after we have electronically filed such material with, or furnished it to, the SEC. You may also obtain copies of these filings free of charge by contacting our Corporate and Investor Relations Department by calling (510) 574-1400.

Table of Contents

ITEM 1A. RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Annual Report, 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 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, 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 our revenues. As of December 31, 2006, we had an accumulated deficit of \$570.1 million. We expect our expenses to increase primarily because of the extensive resource commitments required to achieve regulatory approval of potential products and commercial success for our portfolio of existing products and any other products we add to our portfolio through our development or in-licensing activities. 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 successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market such products with desired margins, we may not sustain positive cash flow from operations as we have projected. We may also incur additional acquisition-related or impairment charges related to our acquisitions of ESP Pharma and the rights to the *Retavase* product, 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:

our earlier stage potential products move into later stage clinical development, which is generally a more expensive stage of development;

additional potential products are selected as clinical candidates for further development;

we pursue clinical development of our potential products in new indications;

we invest in life cycle management initiatives for our 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;

we invest in research or acquire additional technologies, product candidates or businesses; and

we invest in our new facilities which will require significant capital expenditures, resulting in higher depreciation expenses. In the absence of substantial revenues from additional sales of existing or newly approved or acquired 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.

Table of Contents**If we do not effectively manage the life cycle of our product portfolio, our results of operations will suffer.**

In the year ended December 31, 2006, our product sales accounted for 40% of our total revenues. We expect that revenues from our product portfolio will continue to represent a significant and possibly growing portion of our total revenue. The patents that we own or hold licenses to that cover our *Cardene*, *IV Busulfex* and *Retavase* products, our three marketed products, will expire between late 2009 and 2014. We are developing or may develop new dosage forms, formulations or manufacturing processes and we are identifying or may identify new indications for these products or otherwise develop new intellectual property with respect to these products. As a result of these efforts, we may secure additional or extended patent or marketing or other nonpatent statutory exclusivity rights. If obtained, these additional rights may extend the life cycle of these products and permit us to maintain or expand our position in the marketplace and sustain our revenue stream from the sale of these products. If we do not succeed in our efforts to effectively extend the life cycle of any of these products, we likely would be exposed to significantly more competition from generic versions of these products upon expiration of the patents that cover these products. Competition from generic forms of any of our products likely would cause significant declines in the amount of revenues and profit margins we recognize from the sale of that product.

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

Sales of our *Cardene IV* product have accounted for a significant portion of our total revenues and growth in our sales since we acquired rights to it through our acquisition of ESP Pharma in March 2005. For example, our *Cardene* product sales, net, accounted for 22% of total revenues in 2005 and 26% of total revenues in 2006. However, our *Cardene IV* product faces a competitive marketplace from branded and generic intravenous anti-hypertensive products marketed in the United States and it may be harder to continue to penetrate this market and continue to grow *Cardene IV* product sales especially at the recent rate. While we expect to increase committed sales and marketing resources in an effort to ensure the continued growth of our *Cardene IV* product sales, there can be no assurance that we can continue a significant growth rate. 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 the *Cardene IV* product to continue its success, we will have to maintain and expand its position in the marketplace against these competitors' drugs.

Our *Retavase* product is sold in a market that has recently declined and if our continued sales and promotional efforts do not increase or at least maintain our market share, our results of operations will suffer.

We expect our *Retavase* product to continue to account for a significant portion of our total revenues and product sales, net. However, *Retavase* product is sold into a thrombolytic market that has recently declined due to the more widespread use of stents and gpIIb/IIIa inhibitor products. Moreover, our *Retavase* product competes for use in the management of acute myocardial infarction with the TNKase and *Activase*[®] products from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we possess. While we continue to invest in promotional efforts for our *Retavase* product, there can be no assurance that we can increase the market share of our *Retavase* product, or that even if we are able to increase our market share, that the thrombolytic market will not decline significantly regardless of our efforts.

The manufacturing of our *Retavase* product is a complex process that requires the services of a number of third parties, and our failure to timely or efficiently manufacture our *Retavase* product could cause our results of operations to suffer.

The *Retavase* product is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth RTP Inc. (Diosynth) and Roche. The manufacturing of this product for use as a therapeutic in compliance with regulatory requirements is complex, time-consuming and expensive and historically subject to relatively frequent batch failures because of the complexity of the manufacturing process. For example in 2006, one of our contract manufacturers experienced higher than expected batch failure rates. As a result, we and that contract manufacturer agreed to temporarily cease *Retavase* product manufacturing and run three test batches to extensively sample and analyze the process prior to making potential improvements. Although we believe we will be able to improve the manufacturing process to reduce batch failure rates, there can be no assurance that we will not experience subsequent manufacturing issues or batch failures that could result in the reduction or interruption of commercial sales and could impair our competitive position. In addition, we expect that our future cost of goods sold for our *Retavase* product will increase under our amended supply agreement with our contract manufacturer. This new supply agreement requires higher per gram fee payments as well as charges for additional testing during the manufacturing process.

Table of Contents

Because we do not have the capability to manufacture our commercial products or our ularitide development product, we rely on third-party contract manufacturers to manufacture these products. If we are unable to continue those manufacturing arrangements successfully or at a reasonable cost, our operations and future results could suffer.

We do not have the capability to manufacture any of our marketed products or our ularitide development product. We have entered into manufacturing agreements with various third parties to manufacture and supply these products under our label. Each of our products is manufactured by a single manufacturer. If there are supply problems with any third-party manufacturer, there may not be sufficient supplies of the product which that manufacturer produces for us to meet commercial or clinical trial demand, in which case our operations and results could suffer.

For example, earlier in 2006, we encountered manufacturing challenges for our *Retavase* product and temporarily ceased manufacturing of the *Retavase* product to run test batches to analyze and improve the manufacturing process. In connection with these efforts, we also negotiated an amended supply agreement with our contract manufacturer pursuant to which our expected manufacturing costs will increase. These cost increases prompted us to conduct an asset impairment analysis and, in the fourth quarter of 2006, we recognized a \$72.1 million asset impairment charge to our *Retavase* product rights intangible assets.

Our products must be manufactured in facilities approved by the FDA and the process for qualifying and obtaining approval for a manufacturing facility is a time-consuming process. If our relationship with any of our manufacturers were to terminate unexpectedly or on short notice, our ability to meet commercial or clinical trial demand for the product manufactured by that single manufacturer could be adversely affected while we qualify a new manufacturer for that product and our operations and future results could suffer.

We also engage third parties for product filling, labeling and packaging. If any filling, labeling or packaging errors occur and are not discovered until after the products are sold, we would need to recall those products, which could be very costly and could damage our credibility and adversely affect our future sales.

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

Our product revenues are substantially dependent on a limited number of wholesalers and distribution partners, and such product revenues may fluctuate from quarter to quarter based on the buying and return patterns of these wholesalers and distribution partners and our ability to estimate reserves for potential product returns.

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, 2006, revenues from the sales of our products to our three largest U.S. wholesalers totaled approximately 90% of our gross 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, 2006, these three U.S. wholesalers represented approximately 81% of our outstanding accounts receivable from product sales. We have received a significant number of returns of *Cardene IV*, *Retavase* and *IV Busulfex* products and off-patent products that were sold prior to our acquisitions of rights to these products in March 2005. The level of returns of these products sold prior to March 2005 exceeded our expectations at the time we acquired the rights to these products. We believe these unexpected returns resulted from overstocking of inventory by wholesalers in anticipation of future price increases that did not occur, and therefore affected the rate of returns. We continue to monitor current levels of inventory at the wholesalers consistent with our forecasts of end user demand and we continue to refine our trade practices and more effectively enforce trade policies including declining or holding orders to align selling patterns with our estimate of the end user demand for our products. We believe these efforts have led to inventory levels at wholesalers below prior levels, and this should reduce the level of returns. Nevertheless, 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 our product return policy, we do not believe that we will experience the same level of returns for products we sold subsequent to March 2005, the date we acquired ESP Pharma and rights to the *Retavase* product. In accordance with our product returns reserve policy, we review the estimated rate for product sales returns on a quarterly basis. We review historical product returns, channel inventory levels and activities and other factors pursuant to this review. This review may result in an estimate that is higher or lower than our prior estimates for product sales returns to reflect the projected future level of returns. For example, in the second quarter of fiscal 2006 we increased our

Table of Contents

estimate of the rate of product returns and the effect of this change was to reduce product sales, net, in that quarter by approximately \$5.6 million. The effect of any change in estimate would affect product sales, net, during the quarter in which we revise our estimate. If returns exceed our expectations as they have in the past, 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, 2006, we had approximately \$674.4 million in total liabilities outstanding, including \$250.0 million in principal that remains outstanding under our 2.00% Convertible Senior Notes due February 15, 2012 (the 2005 Notes) and \$250.0 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2023 (the 2003 Notes). The 2003 and 2005 Notes do not restrict our future incurrence of indebtedness and we may incur additional indebtedness in the future. Our level of indebtedness will significantly affect our future operations because:

we will have additional cash requirements in order to support the payment of interest on our outstanding indebtedness;

increases in our outstanding indebtedness and leverage will increase our vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and

the levels of our outstanding debt could limit our ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes .

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 we cannot control. Our ability to generate sufficient cash flow from operations in the future to service our debt may require us to, among other things:

seek additional financing in the debt or equity markets;

refinance or restructure all or a portion of our indebtedness, including the 2005 Notes or the 2003 Notes;

sell selected assets;

reduce or delay planned capital expenditures; or

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.

Difficulties in managing our sales, marketing and distribution groups could adversely affect our product revenues and financial results.

Prior to our acquisitions of ESP Pharma and rights to the *Retavase* product in March 2005, we did not sell, market or distribute any products. Although we have integrated our pre-merger operations with the operations of ESP Pharma and we have retained and increased the size of the hospital-focused sales and sales-related infrastructure, we have encountered and may encounter further challenges in the continued and efficient management of such capabilities which could adversely affect our financial results.

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

We sell our products to wholesale distributors who in turn sell our products to hospitals and clinics, our end customers. We cannot assure you that our end customers will continue their current patterns of purchasing and using our products. Any delay or deferral in purchasing decisions or any decision to return our products by our wholesalers or end customers due to our marketing and sales efforts, competition or other factors could have a material adverse effect on our product revenues and financial results. We continue to refine our trade practices and more effectively enforce trade policies with our wholesalers to be more consistent with what we believe to be industry standards and the natural demand for our products by end customers. Our recent efforts in this regard have resulted in our declining or holding orders to more closely align selling patterns with our estimate of the end user demand for our products. We expect to continue to make refining adjustments to our trade practices to more effectively manage our channel inventory levels to meet end customer demand.

Table of Contents

We are a large, geographically diverse organization, and if our management does not manage our organization efficiently, our operating results will suffer.

We face challenges inherent in efficiently managing a large number of employees over large geographic distances and across multiple functional disciplines, including the need to implement appropriate systems, policies, benefits and compliance programs. The inability to manage successfully our large, geographically diverse organization and the inability to retain or replace key employees could have a material adverse effect on the operating results of our company and, as a result, on the market price of our common stock.

If our collaborations are not successful, we may not 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 rely on our partners to manufacture such products and essential components for those products, design and conduct clinical trials, compile and analyze the data received from these trials, obtain regulatory approvals and, if approved, market these licensed products. As a result, we may have limited 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.

Our collaboration arrangement with Biogen Idec is particularly important to us. Effective in August 2005, we entered into a long-term agreement with Biogen Idec under which Biogen Idec became our partner on three of our antibody clinical programs, daclizumab in certain indications including MS and volociximab (M200) and the *HuZAF* antibody in all indications. We and Biogen Idec were conducting a proof of concept Phase 2 trial of the *HuZAF* antibody in severe rheumatoid arthritis, however, based on our preliminary evaluation of data from this open label study, we and Biogen Idec jointly agreed to discontinue development of the *HuZAF* antibody in severe rheumatoid arthritis. We and Biogen Idec do not currently have any plans for development of the *HuZAF* antibody in other indications.

This collaboration agreement provides significant combined resources for the development, manufacture and potential commercialization of products. PDL and Biogen Idec each assume certain responsibilities and share expenses. Because of the broad scope of the collaborations, we are particularly dependent upon the performance by Biogen Idec of their obligations under the agreement. The failure of Biogen Idec to perform their obligations, our failure to perform our obligations, our failure to effectively manage the relationship, or a material contractual dispute between us and Biogen Idec would have a material adverse effect on our prospects or financial results. Moreover, our financial results depend in substantial part upon our efforts and related expenses for these programs. Our revenues and expenses recognized under the collaboration will vary depending on the work performed by us and Biogen Idec in any particular reporting period.

The arrangement with Roche pursuant to which we were co-developing daclizumab for asthma and transplant maintenance was also particularly important to us. In 2006, however, Roche decided to first discontinue its involvement in the co-development of daclizumab in treating asthma and then later to discontinue its co-development of daclizumab in transplant maintenance and terminate the Roche Co-Development Agreement effective in May 2007.

We rely on other collaborators, 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 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 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.

Table of Contents

Our partners can terminate our collaborative agreements 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. For example, in August 2006, following a portfolio review at Roche, Roche elected to discontinue its involvement in the development of daclizumab in treating asthma and other respiratory diseases in accordance with the terms of our collaboration agreement with Roche, and in November 2006, Roche elected to terminate the entire collaboration agreement effective May 2007. 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 rules adopted under 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 complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal control over financial reporting successfully in 2004, 2005 and 2006.

The Section 404 compliance process has resulted, and will continue to result, in increased expenses and the devotion of significant management resources and we expect that the expenses for this process will continue to increase modestly. 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 and in September of that quarter, 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 and completed a more timely review during our financial statement close process as well to ensure compliance with our existing internal control over financial reporting.

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 continue to market and sell our products;

Table of Contents

the response of wholesalers to 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 occurrence of key events under collaborative arrangements, including milestones, development decisions or program or collaboration terminations;

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;

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; and

the structure of out-licensing, collaboration and royalty arrangements.

We receive a significant portion of our royalty revenues from 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 to contribute to fluctuation in our revenues from quarter to quarter.

License, collaboration and other revenues 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 revenues 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. The recognition of license, collaboration and other revenues that we otherwise would defer and recognize over a period of time under applicable accounting principles may be accelerated in certain circumstances. For example, if a licensee of ours terminates a development program for which we received an upfront non-refundable fee that required our ongoing performance, the recognition of the revenues would be accelerated and recognized in the period in which the termination occurred. In such a case, it may cause our revenues during that period to be higher than it otherwise would have been had the circumstances not occurred. For example, during the third quarter of 2006 we recognized \$18.8 million of deferred revenue, or 17% of the total revenues for that quarter, related to Roche's election in August 2006 to discontinue its co-development of daclizumab in treating asthma and other respiratory diseases. In addition, revenues historically recognized under our prior agreements may not be an indicator of revenues 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 payments owed by us and to us under collaborative agreements for reimbursement of expenses and which are

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

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. Moreover, the underlying terms of in-licensing and royalty arrangements, especially those with tiered payment structures, will impact the timing of costs and expenses recognized during any particular quarter. In addition, the recognition of clinical trial and other expenses that we otherwise would recognize over a period of time under applicable accounting principles may be accelerated in certain circumstances. In such a case, it may cause our expenses during that period to be higher than they otherwise would have been had the circumstances not occurred. For example, if we terminate a clinical trial for which we paid non-refundable upfront fees to a clinical research organization and in which we did not accrue all of the patient costs, the recognition of the expense associated with those fees that we were recognizing as we accrued patient costs would be accelerated and recognized in the period in which the termination occurred.

Table of Contents

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 began recognizing expense for stock-based awards exchanged for employee services in the first quarter of 2006 under SFAS 123(R) and, as a result, our operating expenses are significantly higher than prior to the adoption of SFAS 123(R).

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

Our Queen patents are of significant value to us. In 2006, we received royalty revenues under license agreements covering our Queen patents which represented approximately 44% of our total revenues in 2006. We expect that in 2007, we will continue to experience aggregate royalty revenue growth based on the assumed continued growth in aggregate product sales underlying our royalty revenues and that these royalty revenues will continue to represent a significant portion of our total revenues.

Two of our Queen patents were issued to us by the European Patent Office. Eighteen notices of opposition to our first European patent and eight notices of opposition to our second European patent were filed by major pharmaceutical and biotechnology companies, among others, and we are currently in two separate opposition proceedings with respect to these two patents. Although five opponents, including Genentech, have withdrawn from the opposition proceedings with respect to the opposition to our first European patent, 13 opponents to this patent remain. A description of these two proceedings is included under the heading *Legal Proceedings* in Part I, Item 3 of this Annual Report. If our patents are successfully opposed in either of these two proceedings or third parties decline to take licenses to our Queen patents, our future revenues would be adversely affected. For example, if the opponents in the proceeding regarding our first European patent 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.

In addition, until the opposition proceedings are resolved, we may be limited in our ability to collect royalties or to negotiate future license agreements based on our Queen patents. An adverse decision by the Opposition Division could encourage challenges to our related Queen patents in other jurisdictions, including the United States. Such a 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 proceedings to enforce our rights under our Queen patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. patents.

Although we intend to vigorously defend the European patents in these two proceedings, we may not prevail in either of these opposition proceedings or any litigation contesting the validity of these patents. For example, our Japanese humanization patent, which was issued in September 1998, was opposed and eventually revoked by the Japanese Patent Office in March 2001. Although we appealed the Japanese Patent Office's revocation of this patent, the Tokyo High Court upheld the revocation of the patent and, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court's decision. The decision by the Japanese Supreme Court concluded the proceedings in the matter and the Japanese Patent Office's decision to revoke our patent is final and nonappealable.

If the outcome of either 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.

Table of Contents

Our ability to maintain and increase our revenues from licensing our Queen patents 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 succeeded 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 succeed 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 was covered under our humanization patents. Although we subsequently 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.

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 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

Table of Contents

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 progress 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 higher number of potential targets than we expect to be able to progress through clinical development. 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

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.

Table of Contents

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 or efficacy data to obtain necessary regulatory approvals. For example, in August 2006, we announced that the Phase 3 study of terlipressin, a drug to which we had commercialization rights at the time, did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo. 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 reaching 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, European Medicines Agency (EMA), 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

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

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.

Table of Contents

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 the *Nuvion* antibody for the treatment of intravenous steroid-refractory ulcerative colitis, 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 the *Nuvion* antibody will receive regulatory approval.

We may be unable to enroll a sufficient number of 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;

Table of Contents

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 the *Nuvion* antibody are dependent on our ability to timely enroll a worldwide clinical program.

Our royalty revenues from technologies we license to others depend on, among other things, 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, in part, 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 a licensee will be affected by competitive products, including potential competing therapies, that may be marketed by the licensee or others. In addition, even if a licensee receives regulatory approval to sell a drug on which we would receive royalties, the marketing of such drug could be suspended or terminated either voluntarily by the licensee or by order of a regulatory agency or other governmental body as a result of safety or other events. For example, in February 2005, Biogen Idec and Elan announced that they had voluntarily suspended the marketing and commercial distribution of the *Tysabri* antibody, a drug approved to treat MS and which is licensed under our humanization patents, because Biogen Idec and Elan had received reports of cases of progressive multifocal leukoencephalopathy (PML), a rare and frequently fatal, demyelinating disease of the central nervous system, in certain patients treated with *Tysabri* antibody. In July 2006, Biogen Idec and Elan reintroduced the *Tysabri* antibody, however, the *Tysabri* antibody's label now includes prominent warnings regarding the *Tysabri* antibody's risks and Biogen Idec and Elan implemented a risk management plan to inform physicians and patients of the benefits and risks of *Tysabri* antibody treatment and to minimize the risk of PML potentially associated with *Tysabri* antibody monotherapy.

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 continue to seek to hire and retain key personnel; however, we face significant competition for experienced personnel. We believe that the move of our corporate headquarters from Fremont, California, to Redwood City, California, in the second half of 2007, may before and for a period after the move cause employee turnover to increase and make retaining key employees more difficult because our new headquarters is 12 miles away from our current headquarters and on the other side of the San Francisco Bay, which will increase the commute time of the many employees that reside in and around Fremont, California, and the greater East Bay Area of the San Francisco Bay Area.

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.

Table of Contents

We intend to continue to manufacture potential products for use in preclinical and clinical trials using our manufacturing facility in Brooklyn Park, Minnesota in accordance with standard procedures that comply with appropriate regulatory standards. The manufacture of sufficient quantities of antibodies that comply with these standards is an expensive, time-consuming and complex process and subject to a number of risks that could result in delays 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 ourselves at an acceptable cost, we will need to improve and significantly expand our manufacturing capabilities. Our current plans are to use our new manufacturing plant in order to manufacture initial commercial supplies of the *Nuvion* product and daclizumab. Our ability to file for, and to obtain, regulatory approvals for such products, as well as the timing of such filings, will depend on our ability to successfully operate our manufacturing plant. We may encounter problems with the following:

production yields;

quality control and assurance;

availability of qualified personnel;

availability of raw materials;

adequate training of new and existing personnel;

on-going compliance with our standard operating procedures;

on-going compliance with FDA regulations;

production costs; and

development of advanced manufacturing techniques and process controls.

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

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 of a drug is considered to be a change in the manufacturing process for that drug, therefore, moving production to our Brooklyn Park, Minnesota manufacturing facility from our Plymouth, Minnesota facility or from third parties will entail manufacturing changes

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

that would require FDA approval. 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 volociximab antibody, ICOS Corporation (ICOS), a wholly owned subsidiary of Eli Lilly and Company, has manufactured all of the drug material contemplated for use in our current Phase 2 clinical studies. Biogen Idec and we will need to demonstrate that the volociximab 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.

Table of Contents

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.

Competition and rapid technological change may adversely affect our revenues.

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 development products 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.

Table of Contents

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.

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 and the Department of Health and Human Services, among others, 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. The FDA prohibits the marketing of any pharmaceutical or biologic products for off-label uses. If our advertising or promotional activities fail to comply with applicable regulations or guidelines, including with respect to off-label use, we may be subject to warnings, fines, sanctions or other enforcement action.

Further, regulatory approvals may be withdrawn if we do not comply with regulatory standards or if problems with our marketed products occur. 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.

Table of Contents

If our product candidates 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;

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 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 product candidates, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our 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 product candidates 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. For example, one of our contract manufacturers recently had production issues and incurred additional production costs. As a result, we agreed to share the related costs even though we are only responsible for purchasing the inventory from successfully manufactured lots.

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.

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

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.

Table of Contents

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.

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, 2006 to February 22, 2007, our common stock closed as high as \$32.80 per share and as low as \$16.51 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:

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 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;

litigation or the threat of litigation;

public concern as to the safety of drugs developed by us;

Table of Contents

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, the compensation expense reported under SFAS 123(R) has had, and will continue to 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 has resulted in additional expenses, and the expenses have been, and may in the future be unpredictable, and adversely affect our results. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new Securities and Exchange Commission regulations or guidance and Nasdaq Global Select 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 Global Select 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

Table of Contents

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 as a result of amortization or impairment of assets resulting from our acquisitions may adversely affect the market value of our common stock.

In accordance with U.S. generally accepted accounting principles, we accounted for the acquisition of ESP Pharma, the acquisition of the rights to the *Retavase* product and the 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 acquired intangible assets becomes impaired in the future, as experienced with the review for impairment of the off-patent products in the second half of 2005, we may be required to incur material charges relating to the impairment of such assets, and possibly goodwill as well. 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. For example, during the fourth quarter of 2006, we recognized a \$72.1 million impairment charge related to our *Retavase* intangible assets as discussed in Note 10 of the Notes to Consolidated Financial Statements.

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 acquisitions of ESP Pharma and certain rights to the *Retavase* product required net cash payments of approximately \$432.5 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 our *Cardene* products are commercially successful;

the extent to which we can maintain our *Retavase* product sales relative to 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* antibody, ularitide and volociximab;

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;

Table of Contents

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 may face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of our products. 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.

Our ability to generate future revenues 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.

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;

the federal Foreign Corrupt Practices Act, which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity; and

state law equivalents to the Anti-Kickback Law and False Claims Act, which may not be limited to government reimbursed items.

Table of Contents

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 which 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.

Table of Contents**ITEM 2. PROPERTIES**

The following table identifies the location and general character of each of our principal facilities as of December 31, 2006:

Location	Principal Uses	Approximate Floor Area (Sq. Ft.)	Owned/Lease Expiration date
Fremont, California	Laboratory and General Office Space	92,000	Owned
Fremont, California	Laboratory and General Office Space	160,000	Dates up to March 2008
Plymouth, Minnesota	Laboratory and General Office Space	75,000	February 2009
Brooklyn Park, Minnesota	Manufacturing, Laboratory and General Office Space	214,000	Owned
Edison, New Jersey	General Office Space	21,000	January 2008
Paris, France	General Office Space	4,300	August 2013
Redwood City, California	Laboratory and General Office Space	450,000	December 2021

Our current corporate headquarters is located in Fremont, California. In July 2006, we entered into lease agreements to lease two buildings in Redwood City, California, to serve as our future corporate headquarters. We plan to move into these buildings in the second half of 2007 after we complete the improvements we are currently making to this space. Once we move our headquarters, we plan to sell the property we own in Fremont and we do not plan to renew or extend the leases for the property we currently lease in Fremont.

We have options to extend the terms of our Redwood City leases for up to ten years to December 2031. We also have a right of first refusal to lease space in two other buildings on the corporate office campus in which our two leased buildings in Redwood City are located.

Although we believe that the properties we currently occupy are adequate and suitable for our current and foreseeable needs, we may lease or acquire additional laboratory and general office space in the future as required.

We own substantially all of the equipment used in our facilities. (See Note 9 to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report for additional information.)

ITEM 3. LEGAL PROCEEDINGS

Two humanization patents based on the Queen technology were issued to us by the European Patent Office. Eighteen notices of opposition to our first European patent and eight notices of opposition to our second European patent were filed by major pharmaceutical and biotechnology companies, among others, and we are currently in two separate opposition proceedings with respect to these two patents. Five opponents, including Genentech, have withdrawn from the opposition proceedings with respect to the opposition to our first European patent leaving 13 remaining opponents. A description of these two proceedings is set forth below.

Opposition to First European Patent

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 August 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to occur in April 2007. 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

Table of Contents

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, which is also being opposed, 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, if the Opposition Division rules against us, that decision could encourage challenges of our related patents in other jurisdictions, including the United States. Such a decision may also 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.

Opposition to Second European Patent

At an oral hearing in February 2005, the Opposition Division of the European Patent Office also 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. The Technical Board of Appeal has not scheduled a date for the appeal hearing.

We intend to vigorously defend our two European Queen patents in these two proceedings. We may not prevail in either of the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of either 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.

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

None.

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

Our common stock trades on the Nasdaq Global Select Market under the symbol PDLI. Prices indicated below 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.

	High	Low
2006		
First Quarter	\$ 33.30	\$ 27.15
Second Quarter	32.97	16.79
Third Quarter	19.95	16.39
Fourth Quarter	23.29	18.70
2005		
First Quarter	\$ 21.36	\$ 13.79
Second Quarter	20.56	14.84
Third Quarter	30.79	20.12
Fourth Quarter	30.50	24.76

As of February 22, 2007, we had approximately 252 common stockholders of record. Most of our outstanding shares of common stock are held of record by one stockholder, Cede & Co., a nominee for Depository Trust Company. Many brokers, banks and other institutions that hold shares as nominees for beneficial owners deposit these shares in participant accounts at the Depository Trust Company. The actual number of beneficial owners of our stock is likely significantly greater than the number of stockholders of record, however, we are unable to reasonably estimate the total number of beneficial holders.

Table of Contents**COMPARISON OF STOCKHOLDER RETURNS**

The line graph below compares the cumulative total stockholder return on our common stock between December 31, 2001 and December 31, 2006 with the cumulative total return of (i) the Nasdaq-Biotechnology Index and (ii) the Nasdaq Composite Index over the same period. This graph assumes that \$100.00 was invested on January 1, 2002, in our common stock at the closing sale price for our common stock on December 31, 2001 and at the closing sales price for each index on that date and that all dividends were reinvested. No cash dividends have been declared on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns and are not intended to be a forecast.

	12/31/01	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06
PDL BioPharma, Inc.	100.00	25.91	54.57	62.99	86.65	61.40
Nasdaq Biotechnology Index	100.00	54.67	79.68	84.56	86.96	87.85
Nasdaq Composite Index	100.00	68.47	102.72	111.54	113.07	123.84

The information under this heading Comparison of Stockholder Returns shall not be deemed to be soliciting material or to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate it by reference in such filing.

Table of Contents**EQUITY COMPENSATION PLAN INFORMATION**

The following tables sets forth information regarding all of our existing equity compensation plans under which we are authorized to issue shares of our common stock as of December 31, 2006.

Plan category	Number of securities to be	Weighted-average exercise	Number of securities
	issued upon exercise of		remaining available for future
	outstanding options, warrants	price of outstanding options,	issuance under equity
	and rights	warrants and rights	compensation plans (excludes
	(a)	(b)	securities reflect in column (a))
Equity compensation plans approved by security holders	7,990,704	\$ 18.05	3,122,852 ⁽¹⁾
Equity compensation plans not approved by security holders ⁽²⁾	6,459,037	\$ 19.70	1,090,398
Total	14,449,741	\$ 18.79	4,213,250

(1) Includes 328,506 shares of common stock available for future issuance under our 1993 Employee Stock Purchase Plan.

(2) See Note 2, Stock-Based Compensation, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Annual Report for a description of our 1999 Nonstatutory Stock Option Plan.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA****CONSOLIDATED STATEMENTS OF OPERATIONS DATA:**

(In thousands, except per share data)	Years Ended December 31,				
	2006	2005	2004	2003	2002
Revenues:					
Product sales	\$ 165,701	\$ 122,106	\$	\$	\$
Royalties	184,277	130,068	83,807	52,704	40,421
License, collaboration and other	64,792	28,395	12,217	13,982	5,952
Total revenues	414,770	280,569	96,024	66,686	46,373
Costs and expenses:					
Cost of product sales	86,292	60,257			
Research and development	260,660	172,039	122,563	82,732	57,978
Selling, general and administrative	120,856	82,386	31,806	27,613	18,373
Acquired in-process research and development ⁽¹⁾		79,417		85,993	
Other acquisition-related charges ⁽²⁾	6,199	20,349			
Asset impairment charges ⁽³⁾	74,650	31,269			
Total costs and expenses	548,657	445,717	154,369	196,338	76,351
Operating loss	(133,887)	(165,148)	(58,345)	(129,652)	(29,978)
Interest and other income, net	17,704	9,616	10,212	9,831	25,978
Interest expense	(13,070)	(10,177)	(5,028)	(9,770)	(9,146)
Impairment loss on investment				(150)	(1,366)
Loss before income taxes	(129,253)	(165,709)	(53,161)	(129,741)	(14,512)
Income tax expense	767	868	80	73	42
Net loss	\$ (130,020)	\$ (166,577)	\$ (53,241)	\$ (129,814)	\$ (14,554)
Net loss per basic and diluted share	\$ (1.14)	\$ (1.60)	\$ (0.56)	\$ (1.40)	\$ (0.16)
Shares used in computation of net loss per basic and diluted share	113,571	104,326	94,982	92,478	88,865

CONSOLIDATED BALANCE SHEET DATA:

(In thousands)	2006	2005	2004	2003	2002
Cash, cash equivalents, marketable securities and restricted investments	\$ 426,285	\$ 333,922	\$ 397,080	\$ 504,993	\$ 606,410
Working capital	274,037	307,302	356,660	467,248	599,215
Total assets	1,141,893	1,163,154	713,732	742,030	717,818
Long-term obligations, less current portion	537,527	507,294	257,768	258,627	158,426
Accumulated deficit	(570,129)	(440,109)	(273,532)	(220,291)	(90,477)
Total stockholders' equity	467,541	526,065	412,510	448,331	544,766

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, 2002 through 2006.

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

- (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 and 5 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 and sales returns of *Retavase* product from sales made prior to our acquisition of the rights to the *Retavase* product in March 2005. See Notes 1, 5 and 6 to the Consolidated Financial Statements.
- (3) Represents the impairment of certain intangible assets, including product rights and a reversion right. For a description of these charges, see Note 10 to the Consolidated Financial Statements.

Table of Contents**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.

OVERVIEW

We are a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life-threatening illnesses. We currently market and sell products in the acute-care hospital setting in the United States and Canada. We also receive royalties and other revenues through licensing agreements with numerous biotechnology and pharmaceutical companies based on our proprietary antibody humanization technology platform. These licensing agreements have contributed to the development by our licensees of nine marketed products. We currently have several investigational compounds in clinical development for severe or life-threatening diseases, and we have entered into collaborations with other pharmaceutical or biotechnology companies for the joint development, manufacture and commercialization of certain of these compounds. Our research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases.

We continue to evolve from a company dependent on licensing activities, development arrangements, humanization services and royalties as the primary sources of revenues to a commercial enterprise that ultimately derives the majority of its revenues from sales of proprietary products. The key elements of our strategy include continuing to build our acute-care, hospital-focused commercial organization and developing novel, proprietary products by leveraging our antibody humanization platform and pursuing corporate development activities:

Acute-care focused commercial organization. Our hospital sales force specializes in the acute-care setting and currently markets our *Cardene IV*, *Retavase* and *IV Busulfex* products to nearly 1,800 hospitals in the United States. In the hospital setting, our sales force focuses its efforts in the cardiac, neurological and intensive care units as well as in emergency departments.

Development of proprietary drugs. Our aim is to develop antibody- or other protein-based products through our own research and development efforts, as well as to selectively and opportunistically license proprietary therapeutic candidates from other companies. Our current stated aim is to submit to the FDA, on average, one new IND per calendar year, and augment this pipeline generation through additional in-licensing at various stages of development. Our internal research and development efforts are focused primarily on novel antibodies for the treatment of cancer and autoimmune diseases. Our goal is to market our hospital-focused products in North America. However, certain of our products in development address indications that require specific expertise or large development and marketing efforts, such as heart failure, multiple sclerosis (MS), respiratory diseases and some oncology indications, and our strategy for those products is to seek appropriate partners with global development, manufacturing and commercialization capabilities.

Table of Contents

We were organized as a Delaware corporation in 1986 under the name Protein Design Labs, Inc. In 2006, we changed our name to PDL BioPharma, Inc. to better reflect our status as a commercial biopharmaceutical enterprise.

SUMMARY OF 2006 FINANCIAL RESULTS

During 2006, we experienced significant growth from both commercial products and licensing royalties, while investing in the development of new products both alone and through development collaborations. We completed our first full year as a commercial biopharmaceutical company following our acquisitions of ESP Pharma and the rights to the *Retavase* product in March 2005, which, along with the growth in our royalty revenues, enabled us to generate positive net cash flow from operations in 2006 for the second straight year.

Our total revenues for 2006 were \$414.8 million, a 48% increase from \$280.6 million in 2005. This revenue growth was driven by increases in royalties from our licensees, sales of our marketed products, and license, collaboration and other revenues. Of the total revenues we generated in 2006, approximately 44% was from royalty payments we received, 40% was from the sale of our marketed products and 16% was from license, collaboration and other revenues, compared to 46%, 44%, and 10%, respectively, in 2005. During 2006, royalty revenues from our antibody humanization technology licenses grew 43% from the previous year, which reflects the growing importance of antibody therapeutics in the treatment of diverse diseases, such as cancer, viral infections, asthma and eye disorders. The increase in net product sales was primarily attributable to the growth of the *Cardene IV* product, our most significant marketed product in terms of overall contribution to our net product sales and rate of growth. Also, because we first acquired commercial products in late March 2005, the comparable 2005 period included net product sales for only approximately nine months, as compared to 12 months of sales for the 2006 period. The increase in license, collaboration and other revenues was principally attributable to the recognition of \$20.5 million of previously deferred revenue during the third and fourth quarters of 2006 due to Roche's election to discontinue its co-development of daclizumab for asthma and transplant maintenance indications in the second half of 2006, and the recognition of a \$5.0 million milestone payment related to our co-development collaboration with Roche for daclizumab in treating asthma in the fourth quarter of 2006.

Our total costs and expenses in 2006 increased \$102.9 million compared to 2005 as we continued to expand our research, development, manufacturing, sales and marketing capabilities. In addition, our sales and marketing costs increased during the year as 2006 represented our first full year of commercial operations. In 2006, total costs and expenses included asset impairment charges of \$74.7 million primarily related to our *Retavase* intangible assets, and in 2005, total costs and expenses included acquired in-process research and development and asset impairment charges of \$79.4 million and \$31.3 million, respectively.

Our net loss for 2006 was \$130.0 million, compared to \$166.6 million in 2005. Net cash provided by operating activities in 2006 was \$78.8 million compared to \$31.6 million in 2005. At December 31, 2006, we had cash, cash equivalents, marketable securities and restricted cash and investments of \$426.3 million, compared to \$333.9 million at December 31, 2005. As of December 31, 2006, we had \$674.4 million in total liabilities outstanding, which included \$500.0 million in convertible notes, \$250.0 million of which are callable in each of 2008 and 2010 and due in 2023 and 2012, respectively.

We expect that in the foreseeable future, our revenue growth will be generated primarily by product sales, principally *Cardene* product sales, and royalties. We expect our total costs and expenses to continue to grow as we continue to identify, develop and manufacture our potential products, to invest in research, to expand our development, marketing and manufacturing capabilities and to sell our products. Our expectations regarding the growth of licensing and collaboration revenues as well as our research and development expenses could be impacted significantly depending on the timing and structure of any collaboration or partnering transaction we may enter into in the future and on decisions by us and our partners regarding development programs in existing or future collaborations.

MAJOR DEVELOPMENTS IN 2006

In addition to the growth from our commercial products and licensing royalties, the events noted below affected our financial results and operations during 2006 or otherwise affected our business prospects:

In July 2006, we entered into agreements to lease two buildings with a total of approximately 450,000 square feet of space located in Redwood City, California, to serve as our future corporate headquarters.

Table of Contents

Also in July 2006, we began manufacturing products for use in clinical trials in our manufacturing facility in Brooklyn Park, Minnesota. The facility also has the ability and capacity to manufacture products on a commercial-scale.

In early August 2006, we announced that the Phase 3 study of terlipressin did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo. In December 2006, following a meeting among representatives of FDA, Orphan Therapeutics, LLC (Orphan) and the Company regarding the outcome of the Phase 3 trial of terlipressin, we and Orphan mutually agreed to terminate the agreement under which we held exclusive marketing, sales and distribution rights to terlipressin, and the rights we previously held under this collaboration agreement reverted back to Orphan effective as of December 16, 2006.

In late August 2006 as a result of a portfolio review, Roche elected to discontinue the co-development and commercialization of daclizumab in asthma and, in November 2006, after another portfolio review, Roche elected to discontinue the co-development and commercialization of daclizumab in organ transplant patients on longer-term maintenance therapy (transplant maintenance). We are seeking a partnership for the development of daclizumab in the asthma indication and are in the process of considering appropriate options for the daclizumab transplant maintenance program.

In September 2006, we acquired various *Cardene* product-related rights from Roche to solidify our *Cardene* brand franchise in the United States.

Despite the discontinuation of the development of terlipressin and the termination of our collaboration with Roche, our pipeline continues to evolve and focus on our core antibody programs, which include the *Nuvion* antibody, daclizumab, volociximab and our newest humanized antibody to enter the clinic, HuLuc63. We continue to develop the *Nuvion* antibody and HuLuc63 on our own, but maintain a collaboration agreement with Biogen Idec for the joint development, manufacture and commercialization of volociximab and daclizumab in multiple sclerosis (MS).

We also continue to seek a partner for the continued development of ularitide, our natriuretic peptide product. Given the large and complex Phase 3 trials needed to bring ularitide successfully to market in the EU, we decided to seek a large, global partner with expertise in the cardiovascular arena for this program. Based on partnering discussions, potential partners would want to have active involvement in the registration program for ularitide. As such, we decided to delay these Phase 3 trials of ularitide until such time that we have a partner for ularitide. In parallel, we continue to move forward with a Phase 1 trial of ularitide in the United States. Our delay of the European-focused Phase 3 trials of ularitide will not affect the timing of a U.S.-based dose-ranging Phase 1 study to define dose-limiting toxicity, and we plan to commence that trial in early 2007.

ECONOMIC AND INDUSTRY-WIDE FACTORS

Various economic and industry-wide factors are relevant to us and could affect our business, including the factors set forth below.

Our business will depend in significant part on our ability to develop and commercialize innovative new drugs. Drug development, however, is highly uncertain and very expensive, typically requiring tens to hundreds of millions invested in research, development and manufacturing elements. Identifying drug candidates to study in clinical trials requires significant investment and may take several years. In addition, the clinical trial process for drug candidates is usually lengthy, expensive and subject to high rates of failure throughout the development process. As a result, a majority of the clinical trial programs for drug candidates are terminated prior to applying for regulatory approval. Even if a drug receives FDA or other regulatory approval, such approval could be conditioned on the need to conduct additional trials, or we could be required to or voluntarily decide to suspend marketing of a drug as a result of safety or other events.

Table of Contents

Our industry is subject to extensive government regulation, and we must make significant expenditures to comply with these regulations. For example, 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 our products. The development and marketing of our products outside of the United States is subject to similar extensive regulation by foreign governments, which regulations are not harmonized with the regulations of the United States.

The manufacture of drugs and antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. 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 or retain regulatory approval for our products. 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, and we are currently reliant on third-party manufacturers for all of our formulated and fully-packaged final products.

Our business success is dependent in significant part on our success in establishing intellectual property rights, either internally or through in-license of third-party intellectual property rights, and protecting our intellectual property rights. If we are unable to protect our intellectual property, we may not be able to compete successfully and our sales and royalty revenues and operating results would be adversely affected. Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages or may be reduced in scope. Proceedings to our protect intellectual property rights are expensive, can, and have, continued over many years and could result in a significant reduction in the scope or invalidation of our patents, which could adversely affect our results of operations.

To be successful, we must attract and retain qualified clinical, manufacturing, commercial, scientific and management personnel. We face significant competition for experienced personnel and continue to focus on hiring and retaining key personnel.

See also Item 1A Risk Factors of this Annual Report for additional information on these economic and industry-wide and other factors and the impact they could have on our business and results of 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, chargebacks, rebates, and wholesaler 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.

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.

Table of Contents

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 under Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, 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 under Staff Accounting Bulletin No. 104, Revenue Recognition.

We recognize revenues 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 revenues recognized on the contract. For example, we did not establish fair value for either the delivered or the undelivered elements of the Roche Co-Development Agreement or the Collaboration Agreement with Biogen Idec (collectively, the Agreements). Accordingly, we are recognizing the upfront license fees, milestone payments and the reimbursement of research and development expenses for each of the Agreements as a single unit of accounting over their respective terms as services are provided. If we had determined that fair value existed for the undelivered elements under either or both of the Agreements, we would have recognized the upfront license fees when they became due to us.

In addition, we occasionally enter into non-monetary transactions in connection with our patent licensing arrangements. 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 available to us. 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 reductions to product sales for estimated returns of products sold by us for chargebacks, wholesaler rebates, government rebate programs, such as Medicaid reimbursements, and for customer incentives, such as cash discounts for prompt payment. Estimates for chargebacks, 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 wholesaler rebates are based on a certain percentage of sales per wholesaler contract terms. Estimates for product returns are based on an on-going analysis of industry and our products' historical return patterns, monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, reviewing channel inventory data available to us and reviewing third-party data purchased in order to monitor the sell-through of our products. Further, we monitor the activities and clinical trials of our key competitors to assess the potential impact on our future sales and return expectations.

If conditions or other circumstances change for any of the markets in which we compete, we may take actions to revise our product return estimates or we may offer additional customer incentives. These revisions could result in an incremental reduction of revenues at the time the return estimate is changed or new incentives are offered. For example, in June 2006, based on product returns experienced in the quarter, additional visibility into channel inventory levels and activity and enhancements made to our estimation process, we changed our estimates for product sales returns to better reflect the projected future level of returns. The effect of this change in estimate was to reduce product sales, net, in June 2006 by approximately \$5.6 million, which increased net loss per basic and diluted share by approximately \$0.05 for the year ended December 31, 2006. Accounts receivable allowances for chargebacks, wholesaler rebates and product returns, as well as rebate accruals, require substantial judgment. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

Table of Contents

We also maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We base this allowance on our analysis of several factors, including 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

We base our cost accruals for clinical trials on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations (CROs). In the normal course of business, we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements vary from contract to contract, are subject to negotiation 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 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, we recognize direct expenses related to each patient enrolled in a clinical trial 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 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 and recognize expenses in 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 we actually may incur.

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

Once the values for intangible assets are established, we must test intangible assets with definite useful lives for impairment in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144). 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, during the fourth quarter of 2006, in connection with the negotiation of an amended supply agreement for the manufacture of *Retavase* product in December 2006, we determined that indicators existed that suggested our *Retavase* product rights intangible assets could be impaired. As such, we tested these intangible assets for recoverability under SFAS 144 and determined that the carrying value of our *Retavase* product rights was impaired. As a result, we recognized an impairment charge of \$72.1 million. To calculate the discounted future cash flows, we used a discount rate of 15% in our impairment analysis; had we used a discount rate that differed by 5% either higher or lower than 15%, the charge would have been higher by \$2.3 million or lower by \$3.2 million, respectively.

Table of Contents**Employee Stock-Based Compensation Adoption of SFAS 123 (R)**

On January 1, 2006, we began accounting for employee stock-based compensation in accordance with SFAS 123(R). Under the provisions of SFAS 123(R), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change.

Further, SFAS 123(R) requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. Accordingly, in 2006 we recognized employee stock-based compensation as part of our operating expenses and allocated \$13.5 million to research and development expenses and \$9.8 million to selling, general and administrative expenses, and we capitalized \$75,000 of employee stock-based compensation costs in inventory as a cost of production. All of the products sold during 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs and, therefore, during 2006 we did not record any employee stock-based compensation expense as a component of cost of sales. The allocation of employee stock-based compensation costs to each operating expense line and to inventory are estimated based on specific employee headcount information at each grant date and revised, if necessary, in future periods if actual employee headcount information differs materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category and capitalize in inventory in future periods may differ significantly from what we have recorded in the current period. As of December 31, 2006, total compensation cost related to unvested stock options not yet recognized was \$41.1 million, which is expected to be allocated to expense and production costs over a weighted-average period of 2.8 years.

At this time, we do not include SFAS 123(R) employee stock-based compensation as a shared expense in our collaborations. Therefore, stock-based compensation expense has not affected license, collaboration and other revenues.

RESULTS OF OPERATIONS**Years ended December 31, 2006, 2005 and 2004**

(In thousands)	Years Ended December 31,			Annual Percent Change	
	2006	2005	2004	2006 / 2005	2005 / 2004
Revenues					
Product sales, net	\$ 165,701	\$ 122,106*	\$	36%	**
Royalties	184,277	130,068	83,807	42%	55%
License, collaboration and other	64,792	28,395	12,217	128%	132%
Total Revenues	\$ 414,770	\$ 280,569	\$ 96,024	48%	192%

* Represents net product sales generated during the nine-month period since our acquisitions of ESP Pharma and rights to the *Retavase* product on March 23, 2005.

** Not presented as we did not sell products prior to 2005.

Table of Contents**Product sales, net**

(In thousands)	Years Ended December 31,		Annual Percent Change
	2006	2005*	2006 /2005
<i>Cardene</i>	\$ 109,689	\$ 62,143	77%
Retavase	30,833	32,715	-6%
IV <i>Busulfex</i>	24,062	17,417	38%
Total marketed products	164,584	112,275	47%
Off-patent brands	1,117	9,831	-89%
Total revenues from product sales, net	\$ 165,701	\$ 122,106	36%

Net product sales of *Cardene*, *Busulfex* and *Retavase* products, our currently marketed products, increased \$52.3 million, or 47%, for the year ended December 31, 2006 compared to 2005. This \$52.3 million increase was primarily attributable to increases in sales of our *Cardene IV* product and, to a lesser degree, our IV *Busulfex* product, which were partially offset by a decline in *Retavase* product sales volumes as well as a \$5.6 million charge related to a change in estimate for our product returns reserve that occurred in the second quarter of 2006. The increase in product sales volumes of our *Cardene IV* and IV *Busulfex* products was due primarily to the fact that we had nearly three additional months of sales in 2006 as compared to the comparable period in 2005, because we first acquired commercial products in late March 2005. Therefore, net product sales in 2005 included sales for only approximately nine months as compared to 12 months of sales for the 2006 period. The increase was also attributable to increases in *Cardene IV* product sales volumes in the second, third and fourth quarters of 2006 compared to the same periods in 2005. We expect net sales of our currently marketed products, as a group, will continue to increase, principally driven by expected *Cardene* product sales growth.

The increase in net product sales for the year ended December 31, 2005 from the comparable period in 2004 is due to the acquisition of marketed products in connection with the acquisitions in March 2005 of ESP Pharma and the rights to the *Retavase* product, both of which closed on March 23, 2005.

Cardene

Net product sales of our *Cardene* product increased by \$47.5 million, or 77%, in 2006 from 2005. In addition to the fact that the 2006 period included 12 months of sales, while the 2005 period included only approximately nine months, we believe this increase was primarily due to an increase in our market share, which increased the sales volume of our *Cardene IV* product, and, to a lesser extent, higher average per unit sales prices due to the increase in the price of our *Cardene IV* product in January 2006. Additionally, we recognized *Cardene SR* net product sales of \$1.0 million since our acquisition of the product in September 2006. We expect our market share of our *Cardene IV* product to continue to increase and that growth in sales of our *Cardene IV* product will be the primary driver of our anticipated product sales growth in the foreseeable future.

The increase in net product sales of our *Cardene* product in 2005 from 2004 is due to the acquisition of this marketed product in connection with the acquisition of ESP Pharma, which closed on March 23, 2005.

Retavase

Net product sales of our *Retavase* product decreased by \$1.9 million, or 6%, from 2005 to 2006, notwithstanding the fact that the 2006 period included 12 months of sales and the 2005 period included only nine months of sales. This decrease was primarily due to a reduction in sales volume as a result of the decline of the thrombolytics market because of physicians' increased use of emergency surgical procedures to treat AMI. We expect that this market will continue to decline in the foreseeable future. Despite the continuing decline of the thrombolytics market in which the *Retavase* product competes, we believe that opportunities exist for us to expand our market share through focused sales and promotional efforts. This increase in market share may, or may not, result in an increased volume of sales. We did not institute a price increase for our *Retavase* product in 2006, and the competitiveness of the market for thrombolytics may limit our ability to obtain price increases in the future.

Table of Contents

The increase in net product sales of the *Retavase* product in 2005 from 2004 is due to the acquisition of our rights to *Retavase*, which closed on March 23, 2005.

IV Busulfex

Net product sales of our IV *Busulfex* product increased by \$6.6 million, or 38%, in 2006 from 2005. As discussed above, this increase was primarily due to the fact that the 2006 period included 12 months of sales while the 2005 period included only approximately nine months and, to a lesser extent, a price increase for our IV *Busulfex* product that was effective in January 2006. We expect IV *Busulfex* net product sales to increase in the future as we expand our international sales through our distribution partners.

The increase in net product sales of our IV *Busulfex* product in 2005 from 2004 is due to the acquisition of this marketed product in connection with the acquisition of ESP Pharma, which closed on March 23, 2005.

Off-Patent Products

Sales of our off-patent products in 2006 consisted of net product sales of *Sectral*, *Ismo* and *Tenex* products as compared to net product sales of *Declomycin*, *Sectral*, *Ismo* and *Tenex* products in 2005. We divested all of our off-patent products in the first quarter of 2006.

Royalties

Nearly all of the royalty revenues we receive are received under agreements we have entered into for the license of rights under our Queen patents. In 2006, our royalty revenues were principally from revenue on the sale of the following products: Genentech's *Avastin*, *Herceptin*, *Xolair*, *Raptiva* and *Lucentis* antibodies; MedImmune's *Synagis* antibody; Wyeth's *Mylotarg* antibody and Elan's *Tysabri* product. Genentech launched the *Lucentis* antibody in the second quarter of 2006 and we began receiving royalties in the third quarter of 2006. The *Tysabri* antibody was re-introduced to the market in the third quarter of 2006 and we began receiving royalties again in the fourth quarter of 2006.

Under most of the agreements for the license of rights under our Queen patents, we receive a flat-rate royalty based upon our licensee's net sales of covered products. Royalty payments are generally due one quarter in arrears; that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. Our master patent license agreement with Genentech, however, provides for a tiered royalty structure under which the royalty rate Genentech must pay on royalty-bearing products sold in the United States or manufactured in the United States and sold anywhere (U.S.-based Sales) in a given calendar year decreases on incremental U.S.-based Sales above several net sales thresholds. As a result, Genentech's average annual royalty rate will decline as Genentech's U.S.-based Sales increase. Because we receive royalties in arrears, the average royalty rate for the payments we receive from Genentech in the second calendar quarter which would be for Genentech's sales from the first calendar quarter will be higher than the average royalty rate for following quarters and will be lowest in the first calendar quarter when more of Genentech's U.S.-based Sales bear royalties at lower royalty rates.

Royalties from licensed product sales exceeding more than 10% of our total royalty revenues are set forth below (by licensee and product, as a percentage of total royalty revenue):

Licensee	Product Name	Years Ended December 31,		
		2006	2005	2004
Genentech	<i>Avastin</i>	29%	24%	13%
	<i>Herceptin</i>	42%	34%	38%
MedImmune	<i>Synagis</i>	18%	25%	34%

Royalty revenues increased by \$54.2 million, or 42%, in 2006 from 2005. This increase was primarily due to higher reported product sales of the *Avastin* and *Herceptin* antibodies, which are marketed by Genentech, and was offset partially by the elimination of royalties from product sales of the *Zenapax* antibody, which is marketed by Roche, beginning in the second quarter of 2006. In 2005, the increase was primarily due to a 53% increase in combined *Herceptin* and *Avastin* antibody sales reported by Genentech and *Synagis* antibody sales reported by MedImmune.

Table of Contents

We expect that in 2007, we will continue to experience aggregate royalty revenue growth based on the assumed continued growth in aggregate product sales underlying our royalty revenues. Genentech launched the *Lucentis* antibody in June 2006 and the *Tysabri* antibody was reintroduced to the market in July 2006, but it is too early to determine the significance of the impact on our future royalty revenues. Further, we expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of *Synagis* antibody, which results in higher royalty revenues reported to us in the first and second quarters of the year as compared to the third and fourth quarters. With respect to *Zenapax* antibody, as per the terms of our Second Amended and Restated Worldwide Agreement with Roche, Roche will pay us royalties at a reduced rate only once *Zenapax* product sales have reached a certain threshold, and we do not expect to receive royalty revenues from Roche's sales of *Zenapax* antibody going forward.

License, Collaboration and Other Revenues

(In thousands)	Years Ended December 31,			Annual Percent Change	
	2006	2005	2004	2006 / 2005	2005 / 2004
License, Collaboration and Other Revenues					
License and milestone from collaborations	\$ 29,764	\$ 9,395	\$ 611	217%	1438%
R&D services from collaborations	29,093	10,607	3,134	174%	238%
Other	5,935	8,393	8,472	-29%	-1%
Total License, collaboration and other revenues	\$ 64,792	\$ 28,395	\$ 12,217	128%	132%

Total license, collaboration and other revenues recognized in 2006, 2005 and 2004 consisted of upfront licensing and patent rights fees, milestone payments related to licensed technology, license maintenance fees and revenues recognized under our collaboration agreements.

Total license, collaboration and other revenues increased \$36.4 million in 2006 from 2005 primarily due to the recognition of \$23.8 million as a result of the discontinuation of our co-development collaboration with Roche for daclizumab in treating asthma (the Asthma Collaboration) and an increase in revenue recognized from our collaborations with Biogen Idec and Roche, which we entered into in August 2005 and October 2005, respectively. (Refer to the Collaboration and Strategic Agreements section of Part 1, Item 1 of this Annual Report for further details regarding our collaborations with Biogen Idec and Roche).

In August 2006, Roche elected to discontinue its involvement in the Asthma Collaboration. On that date, as we had no further obligations to Roche under this arrangement, we recognized approximately \$18.8 million in deferred license, collaboration and other revenues related to previously unearned amounts that we had received from Roche specifically related to the Asthma Collaboration. Of the \$18.8 million, \$15.2 million represented the previously unrecognized portion of the \$17.5 million upfront license fee that we received from Roche at the onset of the Asthma Collaboration, and \$3.6 million represented research and development expense reimbursements that we received from Roche during the term of the Asthma Collaboration, but that we had not yet recognized because the associated research and development services had not yet been completed. In November 2006, we earned and received from Roche a final \$5.0 million milestone payment under the Asthma Collaboration, which we recognized as license, collaboration and other revenues in the fourth quarter of 2006. Had the Asthma Collaboration not been discontinued, the \$18.8 million of deferred revenues and the \$5.0 million milestone payment would have been deferred to and recognized in future periods.

In November 2006, Roche notified us that it had elected to terminate the Roche Co-Development Agreement under which we were also co-developing daclizumab for transplant indications, with an emphasis on transplant maintenance (the Transplant Collaboration). As a result of the termination of the Asthma Collaboration and the termination of the Roche Co-Development Agreement, we will not receive any further milestone payments related to the Asthma Collaboration or the Transplant Collaboration, however, we will continue to recognize unearned amounts under the Transplant Collaboration through the date of the termination of the Roche Co-Development Agreement in May 2007. During the fourth quarter of 2006, we recognized approximately \$1.7 million in previously deferred revenues that otherwise would have been deferred to future periods had the termination not occurred.

Table of Contents

Total license, collaboration and other revenues increased in 2005 from 2004 primarily due to the revenues 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 expect quarterly fluctuations in total license, collaboration and other revenues depending on the level of services that we perform under our collaboration contracts during any particular period, the number of new contract arrangements we enter into and milestones achieved by us or by our licensees. A portion of the total license, collaboration and other revenues we expect to recognize in 2007 and future years will be based upon recognition over time of upfront license fees which were paid to us in 2005 and milestones that have been paid to us since or may be paid in the future. In addition, we continue to evaluate potential opportunities to partner certain programs or capabilities of our drug development, manufacturing and commercialization with other pharmaceutical or biotechnology companies and if we enter into other collaboration agreements in the future, our license, collaboration and other revenues would likely increase.

Costs and Expenses

(In thousands)	Years Ended December 31			Annual Percent Change	
	2006	2005	2004	2006 / 2005	2005 / 2004
Costs and Expenses					
Cost of product sales	\$ 86,292	\$ 60,257	\$	43%	*
Research and development	260,660	172,039	122,563	52%	40%
Selling, general and administrative	120,856	82,386	31,806	47%	159%
Acquired in-process research and development		79,417		-100%	*
Other acquisition-related charges	6,199	20,349		-70%	*
Asset impairment charges	74,650	31,269		139%	*
Total costs and expenses	\$ 548,657	\$ 445,717	\$ 154,369	23%	189%

* Not presented as calculation is not meaningful.

Cost of Product Sales

Cost of product sales (COS) relates to our marketed products and consists primarily of cost of goods sold, royalty expenses and amortization of product rights related to the products acquired from ESP Pharma, the rights to the *Retavase* product, which we acquired from Centocor and re-launched in April 2005, and, beginning September 2006, the *Cardene* product-related rights that we acquired from Roche. The following table summarizes COS by component, as a percentage of products sales:

	Years Ended December 31,		
	2006	2005	2004
Cost of goods sold	13%	11%	*
Royalty expense	13%	9%	*
Amortization of intangibles	26%	29%	*
Cost of product sales	52%	49%	*

* Not presented as we did not sell products prior to 2005.

COS increased from \$60.3 million to \$86.3 million from 2005 to 2006, or approximately \$26.0 million. As a percentage of product sales, COS was 52% in 2006, compared to 49% in 2005. Amortization of product rights was \$43.1 million, or 26% of COS, in 2006, compared to \$35.4 million, or 29% of COS, in 2005.

In 2006, the increase in COS as a percentage of product sales was primarily due to a higher effective royalty rate related to sales of our *Cardene* IV product in 2006 as compared to the 2005 period and, to a lesser extent, *Retavase* product-related manufacturing and inventory costs as

discussed below. This increase was partially offset by a more profitable product mix, particularly with respect to higher sales of our *Cardene IV* product, and lower manufacturing and inventory-related costs for our IV *Busulfex* and *Cardene* products when compared to the 2005 period. The decline in the amortization of intangibles as a percentage of product sales is due to the straight-line amortization of our product rights compared to an increase in product sales from the 2005 period.

Table of Contents

During the first six months of 2006, our contract manufacturer for our *Retavase* product experienced excess costs related to manufacturing difficulties as a result of higher than expected batch failure rates. In connection with our efforts to resolve these difficulties and improve the manufacturing process, during the second quarter of 2006, we and the contract manufacturer agreed to temporarily cease *Retavase* product manufacturing and run three batches under change order to extensively sample and analyze the process prior to making potential improvements. We also agreed to reimburse the contract manufacturer for certain costs incurred by them and additional costs that they were likely to incur in connection with the halt in manufacturing and related activities. In connection with this agreement, we recognized \$2.5 million in COS in the second quarter of 2006 to reflect our actual and accrued payments to this contract manufacturer.

In addition, during our year-end close process we were notified of a *Retavase* product lot stability testing failure. Accordingly, during the fourth quarter of 2006, we recognized a \$3.0 million charge in COS related to this lot, which has a high probability of being unsalable. We continue to work with our contract manufacturer to improve the *Retavase* product manufacturing process.

For *Cardene IV*, *IV Busulfex* and *Retavase* product sales, we are obligated to make royalty payments, generally based on a percentage of net product sales. In the case of *Cardene IV* product sales, the percentage of net product sales that we are obligated to pay within any calendar year declines as sales increase. As a result, we generally expect our COS as a percentage of product sales to decrease quarter-over-quarter in each calendar year, and then increase again at the beginning of the subsequent calendar year. Excluding the impact of these royalty payments, we expect continued quarter-to-quarter variability based on product mix changes and production results, acknowledging that there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing or inventory related issues. For our *Retavase* product, in connection with an amended supply agreement signed with our contract manufacturer during January 2007, we expect our future cost of goods sold as a percentage of product sales to increase.

Research and Development Expenses

Research and development expenses consist primarily of costs of personnel to support our research and development activities, milestone payments and technology licensing fees, costs of preclinical studies, costs of conducting our clinical trials, such as CRO costs and clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility and overhead, principally information technology, costs. Beginning with the first quarter of 2006, research and development costs also include stock-based compensation expense accounted for under SFAS 123(R) as a component of personnel-related costs. Total stock-based compensation expense recognized as research and development expenses, including amounts recognized under SFAS 123(R), was \$13.6 million in 2006. Our research and development costs have increased in each of the last two years as we have continued to invest to advance our product candidates into later stages of development and add new product candidates and to hire the necessary personnel to support these efforts.

The \$88.6 million increase in research and development expenses in 2006 compared to 2005 was primarily due to increases in personnel-related costs of \$34.7 million, facility-related costs of \$14.9 million, costs of \$11.5 million related to consulting services and research grants, external clinical development expenses for our major research and development projects of \$9.8 million, research and development licensing costs of \$5.9 million, \$5.6 million incurred in connection with our acquisition in September 2006 of certain *Cardene* product-related rights from Roche and information technology-related costs of \$3.8 million. These increases were partially offset by a decrease in production materials costs of \$4.3 million.

The \$49.5 million increase in research and development costs in 2005 compared to 2004 was primarily due to increases in personnel-related 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 and production material costs of \$4.4 million. These increases were partially offset by decreases in contract manufacturing services of \$6.8 million.

We expect our research and development expenses to continue to increase as we advance our product candidates into later stages of development and add new product candidates, and such expenses may change unexpectedly due to changes in trial design, cancellation of projects, or initiation or in-licensing of new programs.

The table below summarizes the stage of development for each of our products in clinical development, including the research and development expenses recognized in connection with each product.

Table of Contents

Product Candidate	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Years Ended December 31,		
					2006	2005	2004
					(In thousands)		
Daclizumab ⁽¹⁾	Healthy Volunteer SC	Phase 1	Roche	Completed	\$ 52,939	\$ 37,908	\$ 30,444
	Asthma	Phase 2a		Completed			
	Multiple Sclerosis	Phase 2	Biogen Idec	2007			
Nuvion (visilizumab)	IV steroid-refractory ulcerative colitis	Phase 2/3		2007	55,914	28,209	21,407
	Crohn's Disease	Phase 2		2007			
Volociximab (M200)	Solid tumors	Phase 2	Biogen Idec	2008	23,338	27,588	20,574
Ularitide ⁽²⁾	Acute Decompensated Heart Failure	Phase 2		Completed	20,887	11,170	N/A
HuZAF (fontolizumab) ⁽³⁾				Program			
	Rheumatoid Arthritis	Phase 2	Biogen Idec	Ceased	2,821	4,055	7,266
Other ⁽⁴⁾	Multiple programs	See note below		N/A	104,761	63,109	42,872
Total Research and Development Expenses					\$ 260,660	\$ 172,039	\$ 122,563

- (1) The Roche Amended and Restated Co-Development and Commercialization Agreement provided that Roche would jointly develop and commercialize daclizumab for the treatment of asthma and transplant indications; however, in August 2006, Roche decided to first discontinue its involvement in the development of daclizumab in treating asthma and then later, in November 2006, elected to discontinue its co-development of daclizumab in transplant indications and terminate the Roche Co-Development Agreement effective in May 2007.
- (2) We acquired worldwide development and commercialization rights to this product pursuant to our acquisition of ESP Pharma in the first quarter of 2005. We have been planning to initiate a two-study, 3,300-patient Phase 3 trial in Europe; however, we have decided to delay the start of these trials pending a partnership for the ularitide program to better ensure the successful development of ularitide. This delay does not affect our planning and initiation of a Phase 1 trial in the United States.
- (3) In July 2006, we and Biogen Idec jointly agreed to terminate further development of the HuZAF antibody in rheumatoid arthritis because the HuZAF antibody did not show positive results from the related Phase 2 trial that we conducted together with Biogen Idec. We and Biogen Idec do not currently have any plans for development of the HuZAF antibody in other indications. This Phase 2 trial is currently being completed.
- (4) No other clinical product included in other constitutes more than 5% of the total research and development expenses for the periods presented. Also includes research and pre-clinical related expenses and 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 10 years, or longer, 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses generally consist of costs of personnel, professional services, consulting and other expenses related to our selling and administrative functions and an allocation of facility and overhead, principally information technology, costs. Of total selling, general and administrative expenses for the year ended December 31, 2006, 57%, or \$68.8 million, related to sales and marketing expenses, compared to 59%, or \$48.3 million, for 2005. Beginning with the first quarter of 2006, selling, general and administrative costs also include stock-based compensation expense accounted for under SFAS

Table of Contents

123(R) as a component of personnel-related costs. Total stock-based compensation expense recognized as selling, general and administrative expenses, including amounts recognized under SFAS 123(R), was \$10.0 million for the year ended December 31, 2006.

Selling, general and administrative expenses for the year ended December 31, 2006 increased \$38.5 million, or 47%, from 2005. This increase was primarily due to increases in personnel-related expenses of \$27.5 million, costs of \$10.5 million related to consulting services, a \$4.1 million payment to Wyeth in the first quarter of 2006 in consideration of Wyeth's consent to our transfer of rights to the off-patent products and facility-related expenses of \$3.0 million. These increases were partially offset by decreases in information technology-related costs of \$4.4 million. The majority of the increase in personnel-related expenses was attributable to the fact that the 2006 period included 12 months of operations during which we operated with the sales force and other personnel we added in connection with our acquisitions of ESP Pharma and the rights to the *Retavase* product in late March 2005, and the 2005 period included only approximately nine months of operations with these added personnel.

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 and other personnel in connection with our acquisitions of ESP Pharma and the rights to the *Retavase* product in late March 2005, outside services expenses of approximately \$25.9 million for advertising, market research and promotion materials and facility-related expenses of \$2.9 million, which were partially offset by lower information technology-related costs of \$8.0 million.

We expect that selling, general and administrative expenses will continue to increase in the near future as we operate our expanded sales force and support staff and initiate or continue promotional programs for our products.

Acquired In-Process Research and Development

In connection with our acquisitions of ESP Pharma in March 2005 and Eos Biotechnology, Inc. (Eos) in April 2003, we recognized charges for acquired in-process research and development of \$79.4 million in March 2005 and \$37.8 million in April 2003 due to incomplete research and development programs related to terlipressin and ularitide from ESP Pharma as well as volociximab (M200) and F200 from Eos that had not yet reached technological feasibility and had no alternative future use as of the respective acquisition dates.

In addition, during the fourth quarter of 2003, we recognized 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 acquired exclusive worldwide rights to market, develop, manufacture and sell daclizumab (*Zenapax*) in all disease indications other than transplantation. The \$48.2 million charge 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.

A summary and the status of these programs at December 31, 2006, and of the value assigned and recognized as expense as of the acquisition date follows:

Program/Product Candidate	Description/Indication	Acquired from	Status of Program	Value Assigned on Acquisition Date (In thousands)
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for hepatorenal syndrome	ESP Pharma	As of December 2006, we relinquished our rights to this product candidate by terminating the agreement under which we held exclusive marketing, sales and distribution rights.	\$ 23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	ESP Pharma	Phase 1 (US) anticipated to begin in 2007	55,652
			Total from ESP Pharma	\$ 79,417
		Eos	Phase 2 clinical trials ongoing	24,067

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

Volociximab (M200, Anti- α 5 β 1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including melanoma, pancreatic, and renal cell cancers			
Ocular Neovascularization (F200, Anti- α 5 β 1 Integrin Antibody)	Fab fragment of Anti- α 5 β 1 Integrin Antibody for ocular indications, including age-related macular degeneration	Eos	No further development expected	13,767
			Total from Eos	\$ 37,834
Asthma and Ulcerative Colitis (daclizumab)		Roche	Phase 2 program advancement pending partnership for asthma and no further development expected for ulcerative colitis	\$ 48,200
			Total from Roche	\$ 48,200

Table of Contents

Assumptions Underlying In-Process Research and Development Charges

We determined the values of the acquired in-process research and development from the ESP Pharma acquisition, the Eos acquisition and the Roche arrangement by estimating the related future probability-adjusted net cash flows, which we then discounted to present values using a discount 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. We based the projected cash flows from such projects 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 and 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 as of the respective dates of acquisition 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.

Table of Contents**Other Acquisition-related Charges**

Other acquisition-related charges represent costs incurred that relate to ESP Pharma operations prior to our acquisition of ESP Pharma and sales returns of *Retavase* product from sales made prior to our acquisition of the rights to the *Retavase* product in March 2005. These costs primarily relate to product sales returns, but also include charges for uncollectible accounts receivable and other miscellaneous liabilities related to pre-acquisition ESP Pharma operations. As the product sales returns directly relate to operations prior to our acquisitions of ESP Pharma and the rights to the *Retavase* product, we recognize them as operating expenses rather than as a reduction to product sales. We recognize other acquisition-related charges under the specific identification method. We recognized a total of \$6.2 million in other acquisition-related charges in 2006 compared to \$20.3 million in 2005 and zero in 2004.

Initially in 2005, we recognized sales returns of *Retavase* product from sales made prior to our acquisition of the rights to the *Retavase* product as contra-revenues. During 2006, we reclassified such amounts to be consistent with the accounting treatment for other similar charges incurred subsequent to our acquisition of ESP Pharma in March 2005 that were associated with pre-acquisition operations. The impact of the reclassification increased product sales, net, and other acquisition-related charges by approximately \$0.9 million for the year ended December 31, 2005.

Asset Impairment Charges

Total asset impairment charges for the year ended December 31, 2006 were \$74.7 million, compared to \$31.3 million in 2005 and zero in 2004. In connection with the negotiation of a supply agreement for the manufacture of *Retavase* product in December 2006, which was signed in January 2007, we determined that indicators existed that suggested our *Retavase* product rights intangible assets could be impaired. As such, we tested these intangible assets for recoverability under SFAS 144, and the total of the estimated future cash flows directly related to the sale of our *Retavase* product was less than the carrying value of the asset as of December 31, 2006. Therefore, we determined that the carrying value of our *Retavase* product rights was impaired, and we used a present value technique to calculate the fair market value of the asset. As a result, we recognized an impairment charge totaling approximately \$72.1 million, which represented the difference between the carrying value of the asset and the present value of estimated future cash flows as of December 31, 2006. After recognizing the impairment charge, the book value of this intangible asset as of December 31, 2006 was approximately \$12.9 million.

In September 2006, we recognized a \$1.5 million impairment charge for our product rights related to the distribution of the *Retavase* product in certain territories. This amount represented the difference between the carrying value of the asset and the present value of estimated future cash flows as of September 30, 2006 under SFAS 144. After recognizing the impairment charge, the book value of this intangible asset as of September 30, 2006 was approximately \$0.2 million and remained unchanged at December 31, 2006.

In June 2006, we concluded that the carrying amount of certain of our licensed research technology was impaired because we abandoned the related technology associated with certain research projects we originally acquired in the third quarter of 2004. Accordingly, we recorded an impairment charge of \$0.9 million, representing the unamortized balance prior to the impairment assessment, during the three months ended June 30, 2006.

In September 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 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 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 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 SFAS 144. In addition, we reserved \$1.1 million of this off-patent product inventory on hand as of December 31, 2005 based on its expected realizable amount.

Table of Contents

Pursuant to the terms of the 2005 Worldwide Agreement with Roche and the Roche Co-Development Agreement, each of which we entered into in October 2005, we agreed not to exercise the reversion right we had held under the 2003 Worldwide Agreement with Roche to promote and sell the *Zenapax* antibody for prevention of acute kidney transplant rejection, and we are no longer required to make a payment for such right that would otherwise would have been due in 2006 under this agreement. 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 2003 Worldwide Agreement with Roche in October 2003.

Interest and Other Income, net and Interest Expense

(In thousands)	Years Ended December 31,			Annual Percent Change	
	2006	2005	2004	2006 / 2005	2005 / 2004
Interest and Other Income, net and Interest Expense					
Interest and other income, net	\$ 17,704	\$ 9,616	\$ 10,212	84%	-6%
Interest expense	(13,070)	(10,177)	(5,028)	28%	102%
Total interest and other income, net and interest expense	\$ 4,634	\$ (561)	\$ 5,184	-926%	-111%

Interest and other income, net, in 2006 increased from 2005 primarily due to the increased interest earned on our cash, cash equivalents, marketable securities and restricted cash and investments balances as a result of higher interest rates and higher invested balances. Interest and other income, net, in 2006, 2005 and 2004 included interest income of \$17.5 million, \$9.7 million and \$9.7 million, respectively.

Interest expense in both 2006 and 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 2006 increased from 2005 as a result of both the 2005 Notes and the 2003 Notes being outstanding during the entire year of 2006, compared to the 2005 Notes being outstanding only for 10 out of 12 months of 2005 as the 2005 Notes were issued in mid-February 2005. In addition, interest expense increased in 2006 as compared to 2005 due to the absence of capitalized interest expense in the third quarter of 2006, since we completed the construction of the Minnesota facility in the second quarter of 2006 and began construction at our future headquarters in Redwood City, California, during the fourth quarter of 2006. We expect to complete this project in the second half of 2007. Interest expense for 2005 increased from 2004 as a result of both the 2005 Notes and 2003 Notes being outstanding during 2005, compared to only the 2003 Notes being outstanding in 2004.

Going forward, we expect interest expense to increase by approximately \$1.7 million per year related to our long-term financing liability for our Lab Building in Redwood City once we occupy the facility, which we expect to occur in the second half of 2007. We didn't purchase the building, but as a result of the terms of the lease agreement, we were required to record the fair value of the building and a corresponding long-term financing liability on our Consolidated Balance Sheet. See the Liquidity and Capital Resources section of this Annual Report for further details of this lease and the related accounting treatment.

Income Taxes

We recorded a tax expense of approximately \$0.8 million, \$0.9 million and \$0.1 million for the years ended December 31, 2006, 2005 and 2004, respectively. Income tax expense in 2006 was primarily related to federal alternative minimum taxes and foreign taxes on income earned by our foreign operations and accrued interest expense on contingent liabilities of ESP Pharma, reduced by a state tax benefit due to a change in the deferred tax position and the lapsing of certain contingent tax liabilities of ESP Pharma for the tax year ended December 31, 2002.

Income tax expense in 2005 primarily related to state income taxes on income earned by ESP Pharma and foreign taxes on income earned by our foreign operations. Income tax expense in 2004 primarily related to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee.

Table of Contents**LIQUIDITY AND CAPITAL RESOURCES**

To date, we have financed our operations primarily through public and private placements of equity and debt securities, royalty revenues, license revenues, collaboration and other revenues under agreements with third parties, interest income on invested capital and, more recently, product sales. At December 31, 2006, we had cash, cash equivalents, marketable securities and restricted cash and investments in the aggregate of \$426.3 million, compared to \$333.9 million at December 31, 2005.

Net cash provided by our operating activities in 2006 was \$78.8 million compared with net cash provided by our operating activities of \$31.6 million and net cash used in operating activities of \$27.2 million in 2005 and 2004, respectively. The \$78.8 million net cash provided by operating activities in 2006 was primarily attributable to our increased product sales and revenues from royalties, which were offset partially by the increases in spending for advancing our clinical programs, expanded sales and marketing activities and increased headcount. In 2005, the \$31.6 million net cash provided by operating activities was primarily attributable to our product sales and increased revenues from royalties, which were 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, the cash used in operating activities related primarily to the funding of greater operating expenses partially offset by an increase in deferred revenue resulting from a co-development and commercialization agreement we entered into with Roche in September 2004.

Net cash used in investing activities in 2006 was \$116.0 million, compared to \$320.8 million and \$240.2 million in 2005 and 2004, respectively. The \$116.0 million net cash used in investing activities in 2006 was primarily attributable to net purchases of approximately \$75.4 million due to the timing differences of purchases and maturities of our available-for-sale marketable securities, \$36.5 million in capital expenditures, of which \$2.8 million relates to the development and construction of our new headquarters, and \$15.0 million related to the first of two milestone payments payable to Centocor under the *Retavase* product purchase agreement (see Note 6 to the Consolidated Financial Statements for further information). These net purchases were partially offset by the repayment to us by Exelixis of a \$30.0 million note receivable and the establishment of letters of credit related to the lease of and construction at our new corporate headquarters totaling \$18.3 million. The \$320.8 million net cash used in investing activities in 2005 was primarily attributable to \$432.6 million in cash payments (net of cash acquired) related to the acquisitions of ESP Pharma and the rights to the *Retavase* product 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 were primarily the result of the timing of purchases of marketable securities, as well as an increase in capital expenditures, primarily related to the development, construction and validation activities for our manufacturing facility in Brooklyn Park, Minnesota.

Net cash provided by financing activities in 2006 was \$32.9 million, compared to \$381.2 million and \$17.0 million in 2005 and 2004, respectively. The \$32.9 million net cash provided by financing activities in 2006 was primarily due to the issuance of our common stock primarily in connection with option exercises. The \$381.2 million net cash provided by financing activities in 2005 was primarily due to the issuance of the 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. Net cash provided by financing activities in 2004 primarily related to the proceeds from the exercise of stock options.

We estimate that our existing capital resources will be sufficient to fund our operations through the foreseeable future. Our future capital requirements will depend on numerous factors, including, among others, continued growth in sales of our marketed products; royalties from sales of products by third-party licensees; 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 Redwood City, California facility; significant resources we will need to expend to update or modify our manufacturing facilities as new products are introduced or manufacturing processes are revised; significant resources we will need to expend in the long term to refurbish or replace our manufacturing facilities due to obsolescence; 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 us of existing relationships with partners, distributors, third party vendors, manufacturers, and customers of acquired companies; and the costs

Table of Contents

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 2006, we entered into agreements to lease two buildings in Redwood City, California, to serve as our corporate headquarters. The largest of the two buildings, the Administration Building, will primarily serve as general office space, while the other will serve as our principal laboratory space (the Lab Building). We took possession of the buildings during the fourth quarter of 2006. We are currently constructing leasehold improvements for both buildings, and we expect to move into the facilities during the second half of 2007.

Another tenant previously occupied the Administration Building, and therefore, our leasehold improvements to this building primarily consist of simply renovating the interior office space to meet our personnel needs. However, more significant leasehold improvements are planned for the Laboratory Building, which has never been occupied or improved for occupancy. While this building had electricity, plumbing, elevators and stairs as of the date of the lease, it lacked a heating and air conditioning system, interior walls and various other improvements that would be necessary for occupancy. We expect to incur approximately \$70 million to \$80 million in leasehold improvements in the Lab Building, and in the case that we fail to complete such improvements, our landlord has the right to draw upon the \$15 million letter of credit we established in connection with the lease agreement (see letter of credit discussion below). Therefore, we have financial risk related to the completed construction of the facility.

Due to our involvement in and assumed risk during the construction period, as well as the nature of the leasehold improvements for the Lab Building, we are required under Emerging Issues Task Force No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, to reflect the lease of the Lab Building in our financial statements as if we purchased the building. Therefore, we recorded the fair market value of the building and a corresponding long-term financing liability, which approximated \$24.7 million, at the time when we took possession of the building. Moreover, we are required to recognize interest expense on our financing liability, which is based on our secured borrowing rate at the time we entered into the lease in July 2006. During the construction period, we will be capitalizing such interest as the building has not yet been placed in service and is classified as construction-in-process on our balance sheet. In addition, since we are not the legal owner of the land, we must assume that we are leasing the land and recognize this amount as ground lease rentals (rental expense) under Financial Accounting Standards Board Staff Position SFAS No. 13-1, *Accounting for Rental Costs Incurred During a Construction Period*. During 2006, we capitalized approximately \$0.4 million in interest expense and we recognized approximately \$0.3 million in rental expense related to the Lab Building. At December 31, 2006, our financing liability related to the Lab Building was approximately \$25.4 million.

Since we are financing a substantive amount of the leasehold improvements, the lease of the Lab Building does not qualify for sale-leaseback accounting under SFAS No. 98, *Accounting For Leases*, and therefore, we are required to keep the fair value of the building in our balance sheet throughout the lease term. As a result, after the construction is complete and the Lab Building is placed into service, we will depreciate the value of the building using the straight-line method over the term of our lease, and we will allocate our lease payments to rental expense for the land, interest expense, and the reduction of the financing liability. Our underlying lease term is approximately 15 years, or through December 31, 2021. We do not expect to have a material gain or loss on the financing obligation at the end of our lease commitment in 2021.

In November 2006, we established an irrevocable letter of credit in the amount of \$15.0 million with a financial institution in connection with the building leases in Redwood City, California. This letter of credit expires in November 2007, but will be automatically extended to November 2008 if this letter of credit is not returned by the holder before November 2007.

In February 2005, we issued the 2005 Notes, which are convertible into our common stock at a conversion price of \$23.69 per share, subject to adjustment in certain events. Interest on the 2005 Notes is payable semiannually in arrears on February 15 and August 15 of each year. The 2005 Notes are unsecured and subordinated to all our existing and future indebtedness and may be redeemed at our option, in whole or in part, beginning on February 19, 2010 at par value. We used the proceeds from the 2005 Notes to help fund the acquisitions of ESP Pharma and the rights to the *Retavase* product.

Table of Contents

In July 2003, we issued the 2003 Notes, which 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 SEC 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 certain interest payments on the 2003 Notes. These pledged securities, and the earnings thereon, were sufficient to pay the first six scheduled interest payments due on the 2003 Notes. The amount was paid off in 2006 and there is no further obligation to provide security for payments under the 2003 Notes.

In May 2001, we signed a collaboration agreement with Exelixis, Inc., which 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 shares of common stock of Exelixis. In May 2006, Exelixis paid to us the outstanding balance of principle and interest on this note.

In September 1999, Fremont Holding L.L.C., our wholly owned subsidiary, obtained a \$10.2 million term loan to purchase two of our Fremont, California facilities. The outstanding balance on this term loan as of December 31, 2006 was \$6.8 million. The loan bears interest at the rate of 7.64% per year and is amortized over 15 years with principal and interest payable monthly. The loan is secured by the two Fremont, California facilities we own and is subject to the terms and covenants of the loan agreement.

Our material contractual obligations under lease, debt, construction, contract manufacturing and other agreements for the next five years and thereafter as of December 31, 2006 are as follows:

(In thousands)	Payments Due by Period				Total
	Less Than 1 Year	1-3 Years	4-5 Years	More than 5 Years	
Contractual Obligations ⁽¹⁾					
Operating leases	\$ 7,125	\$ 7,834	\$ 6,879	\$ 66,412	\$ 88,250
Long-term liabilities (including interest payments) ⁽²⁾	7,979	12,827	9,798	46,706	77,310
Convertible notes (including interest payments)	11,875	23,750	266,873	252,500	554,998
Construction contracts ⁽³⁾	4,776				4,776
Contract manufacturing	31,938	9,651			41,589
Total contractual obligations	\$ 63,693	\$ 54,062	\$ 283,550	\$ 365,618	\$ 766,923

(1) This table does not include (a) any milestone payments from us to third parties which may become payable under research collaborations or license agreements as the timing and likelihood of such payments are not known, or (b) any royalty payments from us to third parties as the amounts of such payments and / or likelihood of such payments are not known in any period presented above. This table also excludes a \$15 million letter of credit related to our Redwood City facilities, from which our landlord can draw if we do not fulfill our obligations with respect to the construction of our leasehold improvements as discussed in Note 13 of the Consolidated Financial Statements.

(2) Includes lease payments related to our Lab Building in Redwood City, California as discussed in Note 13 of the Consolidated Financial Statements, mortgage payments for the buildings we own in Fremont, California, the milestone payments related to our purchase from Roche of *Cardene* product-related rights as discussed in Note 10 of the Consolidated Financial Statements, and post-retirement benefit obligations.

(3) Relates to the construction of our leasehold improvements at our Redwood City facilities as discussed in Note 13 of the Consolidated Financial Statements.

Table of Contents**Off-Balance Sheet Arrangements**

None.

Recent Accounting Pronouncements

In July 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, which is effective for fiscal years beginning after December 15, 2006. The interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition. We will adopt the interpretation on January 1, 2007 and we do not believe the interpretation will have a material impact on our financial position and results of operations.

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.

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, 2006 levels, the fair value of the portfolio would decline by approximately \$2.0 million. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes ending fair values include principal plus accrued interest.

As of December 31, 2006, the aggregate fair values of our long-term debt and convertible subordinated notes were approximately \$7.1 million and \$547.5 million, respectively, based on available pricing information. The long-term debt bears interest at a fixed rate of 7.64%, the 2003 Notes bear interest at a fixed rate of 2.75% and the 2005 Notes 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.

(In thousands)	2007	2008	2009	2010	2011	Thereafter	Total	Fair Value
Long-term debt, including current portion								
Fixed Rate	\$ 635	\$ 685	\$ 741	\$ 800	\$ 865	\$ 3,067	\$ 6,793	\$ 7,116 ⁽¹⁾
Avg. Interest Rate	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	7.64%	
Convertible subordinated notes								
Fixed Rate	\$	\$	\$	\$	\$	\$ 499,998	\$ 499,998	\$ 547,500 ⁽²⁾
Avg. Interest Rate	2.38%	2.38%	2.38%	2.38%	2.38%	2.38%	2.38%	

(1) 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.

(2) 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.

Table of Contents

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.

Table of Contents**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA****Consolidated Balance Sheets**

(In thousands, except per share data)	December 31,	
	2006	2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 179,009	\$ 183,377
Marketable securities, including zero and \$6.8 million of restricted investments at December 31, 2006 and 2005, respectively	154,115	101,617
Accounts receivable, net of allowances of \$13.7 million and \$12.9 million at December 31, 2006 and 2005, respectively	18,780	19,116
Inventories	19,663	17,728
Prepaid and other current assets	7,929	27,516
Short-term note receivable		30,000
Total current assets	379,496	379,354
Long-term marketable securities	74,892	48,928
Restricted cash	18,269	
Land, property and equipment, net	296,529	266,053
Goodwill	69,954	57,783
Other intangible assets, net	285,713	397,266
Other assets	17,040	13,770
Total assets	\$ 1,141,893	\$ 1,163,154
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 13,478	\$ 2,728
Accrued compensation	21,123	16,331
Royalties payable	4,780	3,295
Other accrued liabilities	52,000	37,732
Deferred revenue	13,443	11,290
Current portion of other long-term liabilities	635	676
Total current liabilities	105,459	72,052
Convertible notes payable	499,998	499,998
Long-term deferred revenue	31,366	57,743
Other long-term liabilities	37,529	7,296
Total liabilities	674,352	637,089
Commitments and contingencies (Note 13)		
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; 115,006 and 112,062 shares issued and outstanding at December 31, 2006 and 2005, respectively	1,150	1,121
Additional paid-in capital	1,037,846	969,118
Deferred stock-based compensation		(1,998)
Accumulated deficit	(570,129)	(440,109)
Accumulated other comprehensive loss	(1,326)	(2,067)
Total stockholders' equity	467,541	526,065

Total liabilities and stockholders' equity	\$ 1,141,893	\$ 1,163,154
--	---------------------	--------------

See accompanying notes.

Table of Contents**Consolidated Statements of Operations**

(In thousands, except per share data)	Years Ended December 31,		
	2006	2005	2004
Revenues:			
Product sales, net	\$ 165,701	\$ 122,106	\$
Royalties	184,277	130,068	83,807
License, collaboration and other	64,792	28,395	12,217
Total revenues	414,770	280,569	96,024
Costs and expenses:			
Cost of product sales	86,292	60,257	
Research and development	260,660	172,039	122,563
Selling, general and administrative	120,856	82,386	31,806
Acquired in-process research and development		79,417	
Other acquisition-related charges	6,199	20,349	
Asset impairment charges	74,650	31,269	
Total costs and expenses	548,657	445,717	154,369
Operating loss	(133,887)	(165,148)	(58,345)
Interest and other income, net	17,704	9,616	10,212
Interest expense	(13,070)	(10,177)	(5,028)
Loss before income taxes	(129,253)	(165,709)	(53,161)
Income tax expense	767	868	80
Net loss	\$ (130,020)	\$ (166,577)	\$ (53,241)
Net loss per basic and diluted share	\$ (1.14)	\$ (1.60)	\$ (0.56)
Shares used in computation of net loss per basic and diluted share	113,571	104,326	94,982

See accompanying notes.

Table of Contents**Consolidated Statements of Cash Flows**

(In thousands)	Years Ended December 31,		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	\$ (130,020)	\$ (166,577)	(53,241)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Acquired in-process research and development		79,417	
Asset impairment charges	74,650	31,269	
Depreciation	30,816	15,126	11,361
Amortization of convertible notes offering costs	2,345	2,214	1,205
Amortization of intangible assets	44,854	37,557	2,502
Stock-based compensation expense	23,573	970	1,214
Loss on investment in marketable securities		302	
Loss on disposal of equipment	74	7	741
Tax benefit from employee stock option exercises	879		
Other non-cash research and development expenses		1,500	3,000
Non-cash license revenue			(4,000)
Changes in assets and liabilities:			
Accounts receivable, net	336	(21,626)	
Interest receivable	(1,416)	323	340
Inventories	(2,035)	923	
Other current assets	19,587	(6,618)	939
Other assets	(5,616)	(124)	405
Accounts payable	10,750	(4,029)	1,277
Accrued liabilities	30,215	10,772	(9,627)
Other long-term liabilities	4,002		
Deferred revenue	(24,224)	50,144	16,728
Total adjustments	208,790	198,127	26,085
Net cash provided by (used in) operating activities	78,770	31,550	(27,156)
Cash flows from investing activities:			
Purchases of marketable securities	(384,206)	(600)	(291,271)
Maturities of marketable securities	301,930	147,660	139,290
Maturities of restricted securities	6,829	6,876	7,487
Collection of note receivable	30,000		
Adjustment to goodwill related to ESP Pharma acquisition		(873)	
Cash paid for ESP Pharma acquisition, net of cash acquired		(322,558)	
Cash paid for the acquisition of the <i>Retavase</i> product		(110,000)	
Purchase of intangible assets	(18,777)		
Sale of intangible assets	2,750		
Purchase of property and equipment	(36,518)	(41,268)	(95,683)
Proceeds from sale of property and equipment	269		
Transfer to restricted cash	(18,269)		
Net cash used in investing activities	(115,992)	(320,763)	(240,177)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	33,529	139,868	18,313
Proceeds from issuance of convertible notes		242,048	
Payments on other long-term debt	(675)	(721)	(1,353)

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

Net cash provided by financing activities	32,854	381,195	16,960
Net increase (decrease) in cash and cash equivalents	(4,368)	91,982	(250,373)
Cash and cash equivalents at beginning of the year	183,377	91,395	341,768
Cash and cash equivalents at end of the year	\$ 179,009	\$ 183,377	\$ 91,395

Supplemental Disclosure of Cash Flow Information:

Cash paid during the year for interest	\$ 12,431	\$ 9,994	\$ 8,220
Cash paid during the year for income taxes	914	365	
Non-cash investing and financing activities:			
Capitalization of facilities under financing lease transaction, including accrued interest, and corresponding long-term financing liability	25,117		
Goodwill adjustments related to ESP Pharma acquisition	12,170		

Cash Flow for Acquisitions of ESP Pharma and Rights to Retavase:

Cash and cash equivalents	\$	\$ 2,442	\$
Inventories		19,712	
Other current assets		1,904	
Property and equipment		2,208	
Intangible assets		432,700	
Accounts payable		(1,836)	
Accrued compensation		(1,803)	
Other liabilities		(20,767)	
Acquisition and transaction costs incurred		(5,388)	
Common stock issued		(104,851)	

See accompanying notes.

Table of Contents**Consolidated Statements of Stockholders Equity**

	Common Stock		Additional
			Paid-In
(In thousands, except shares of common stock data)	Shares	Amount	Capital
Balance at December 31, 2003	93,885,904	\$ 939	\$ 666,793
Issuance of common stock under employee benefit plans	1,971,233	20	18,293
Stock-based compensation expense for consultants			1,214
Issuance of common stock upon conversion of convertible notes	99		2
Balance at December 31, 2004	95,857,236	959	686,302
Issuance of common stock under employee benefit plans, net	3,554,878	35	42,091
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
Stock-based compensation expense for consultants			710
Issuance of common stock in connection with release of escrow shares from ESP Pharma acquisition	1,260,842	13	35,278
Balance at December 31, 2005	112,062,073	1,121	969,118
Issuance of common stock under employee benefit plans, net	2,542,779	25	33,504
Issuance of common stock in connection with release of escrow shares from ESP Pharma acquisition	401,408	4	12,696
Elimination of deferred stock compensation upon adoption of SFAS 123(R)			(1,998)
Stock-based compensation expense for employees			23,383
Stock-based compensation expense for consultants			264
Tax benefit from employee stock option exercises			879
Balance at December 31, 2006	115,006,260	\$ 1,150	\$ 1,037,846

	Deferred Stock-based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stock- Holders Equity
Balance at December 31, 2003	\$	\$ (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)
Balance at December 31, 2004		(273,532)	(1,219)	412,510
Issuance of common stock under employee benefit plans, net	(2,258)			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
Stock-based compensation expense for employees	260			260

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

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)
Balance at December 31, 2005	(1,998)	(440,109)	(2,067)	526,065
Issuance of common stock under employee benefit plans, net				33,529
Elimination of deferred stock compensation upon adoption of SFAS 123(R)	1,998			
Stock-based compensation expense for employees				23,383
Stock-based compensation expense for consultants				264
Issuance of common stock in connection with release of escrow shares from ESP Pharma acquisition				12,700
Tax benefit from employee stock option exercises				879
Comprehensive loss:				
Net loss	(130,020)			(130,020)
Change in unrealized gains and losses on investments in available-for-sale securities			1,599	1,599
Adjustment to initially apply SFAS 158, net of tax			(858)	(858)
Total comprehensive loss				(129,279)
Balance at December 31, 2006	\$	\$ (570,129)	\$ (1,326)	\$ 467,541

See accompanying notes.

Table of Contents

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2006

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 currently market and sell products in the acute-care hospital setting in the United States and Canada. We also receive royalties and other revenues through licensing agreements with numerous biotechnology and pharmaceutical companies based on our proprietary antibody humanization technology platform. These licensing agreements have contributed to the development by our licensees of nine marketed products. We currently have several investigational compounds in clinical development for severe or life-threatening diseases, and we have entered into collaborations with other pharmaceutical or biotechnology companies for the joint development, manufacture and commercialization of certain of these compounds. Our research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases. We were organized as a Delaware corporation in 1986 under the name Protein Design Labs, Inc. In 2006, we changed our name to PDL BioPharma, Inc. to better reflect our status as a commercial biopharmaceutical enterprise.

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. In addition, we reclassified certain prior year charges from contra-revenues to other acquisition-related charges for *Retavase* product returns that related to products sold by Centocor, Inc. prior to our acquisition of the rights to the product in March 2005. In 2006, we reclassified such amounts to be consistent with the accounting treatment for other similar charges incurred subsequent to our acquisition of ESP Pharma in March 2005 that were associated with pre-acquisition operations. The impact of the reclassification increased product sales, net, and other acquisition-related charges by approximately \$0.9 million for the year ended December 31, 2005.

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.

Cash Equivalents, Restricted Cash, 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, marketable securities and restricted cash and investments 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.

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 net realizable value, reserves are recorded for the difference between the cost and the net realizable 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 acquisitions of ESP Pharma and the rights to the *Retavase* product in 2005 (see Notes 5 and 6), we acquired and recorded inventories at their fair market values, which approximated the original cost of the inventory purchased from third-party manufacturers.

Table of Contents

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.

If we determine that separate elements exist in a revenue arrangement under Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, when payment is reasonably assured and 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 rebate in exchange for product distribution and inventory management services. Such rebates are recorded as a reduction to product sales in the consolidated statements of operations in accordance with EITF 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 accounting treatment for financial reporting purposes, are as follows:

Product Sales

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. Product sales are recorded net of estimated allowances, discounts, sales returns, chargebacks and rebates.

Royalties

Under most of our patent license agreements, we receive royalty payments based upon our licensees' net sales of covered 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 recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we recognize royalty revenues in the quarter reported to us by our licensees (i.e., generally royalty revenues are recognized one quarter following the quarter in which sales by our licensees occurred).

License, Collaboration and Other Revenues

We include revenues recognized from upfront licensing and license maintenance fees, milestone payments and reimbursement of development expenses in License, collaboration and other revenues in our Consolidated Statements of Operations.

Upfront License and License Maintenance Fees

We generally recognize revenues 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. If the agreements require continuing involvement in the form of development, manufacturing or other commercialization efforts by us, we recognize revenues 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.

Table of Contents

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 revenues 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 with respect to that milestone 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:

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

Amounts received from our collaborators are 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. In those cases, we recognize these upfront fees, milestones and reimbursements of development costs as the services are performed.

Table of Contents**Accounts Receivable, Sales Allowances and Rebate Accruals**

Accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, chargebacks, wholesaler rebates and sales returns. Estimates for chargebacks and cash discounts are based on contractual terms, historical utilization rates and expectations regarding future utilization rates for these programs. Estimates for wholesaler rebates are based on a certain percentage of sales per wholesaler contract terms. Estimates for product returns are based on an on-going analysis of industry and historical return patterns, monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, reviewing channel inventory data available to us and reviewing third-party data purchased in order to monitor the sell-through of our products. Further, we monitor the activities and clinical trials of our key competitors to assess the potential impact on our future sales and return expectations. We base our allowance for doubtful accounts on our analysis of several factors, including 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.

Accrued rebates include amounts due under Medicaid and other commercial contractual rebates. Rebates are recorded in the same period that the related revenues are recognized resulting in a reduction of product sales revenues and the establishment of a liability included in other accrued liabilities. Accrued rebates are recorded based on contractual terms, historical utilization rates and expectations regarding future utilization rates for these programs. Medicaid rebate accruals are evaluated based on historical rebate payments by product as a percentage of historical sales, product pricing and current contracts. Our product returns allowance is calculated based on a percentage of total sales. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made.

Since our acquisitions of ESP Pharma and rights to the *Retavase* product, 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 continue to market and promote these products for ourselves. In June 2006, based on product returns experienced in the quarter, additional visibility into channel inventory levels and activity and enhancements made to our estimation process, we changed our estimates for product sales returns to better reflect the projected future level of returns. The effect of this change in estimate was to reduce product sales, net, in June 2006 by approximately \$5.6 million, which increased net loss per basic and diluted share by approximately \$0.05 for the year ended December 31, 2006. We continually monitor our allowances and make adjustments when we believe actual experience may differ from our estimates.

Advertising and Promotional Expenses

We engage in promotional activities, which typically take the form of industry publications, journal ads, exhibits, speaker programs, and other forms of media. In accordance with Statement of Position (SoP) 93-7, Reporting on Advertising Costs, advertising and promotion expenditures are expensed as incurred. These expenses for the years ended December 31, 2006, 2005 and 2004 were \$19.5 million, \$9.3 million and zero, respectively.

Shipping and Handling

We record costs related to shipping and handling of revenues in cost of product sales for all periods presented.

Clinical Trial Expenses

We base our cost accruals for clinical trials on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations (CROs). In the normal course of business, we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements vary from contract to contract, are subject to negotiation 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 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, we recognize direct expenses related to each patient enrolled in a clinical trial 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 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

Table of Contents

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 we actually may incur.

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. In 2006, other comprehensive loss also included the liability that has not yet been recognized as net periodic benefit cost for our postretirement benefit plan due to our adoption of Statement of Financial Accounting Standards (SFAS) No. 158, Employers Accounting for Defined Benefit Pension and Other Postretirement Plans an amendment of FASB Statements No. 87, 88, 106, and 132(R) (SFAS 158) during the fourth quarter of 2006. Our comprehensive loss for the years ended December 31, 2006, 2005 and 2004 is reflected in the Consolidated Statements of Stockholders Equity.

Segment and Concentrations Disclosure

In accordance with SFAS No. 131, Disclosure About Segments of an Enterprise and Related Information, we are required to report operating segments and make related disclosures about our products, services, geographic areas and major customers. Our chief operating decision-maker is comprised of our executive management. Our chief operating decision-maker reviews our operating results and operating plans and makes 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.

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. For the years ended December 31, 2006, 2005 and 2004, we capitalized software development costs of approximately \$6.3 million, \$3.7 million and \$1.3 million, respectively. 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

Table of Contents**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 headquarters in Redwood City, California 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 \$14.8 million, \$14.1 million and \$8.8 million during the years ended December 31, 2006, 2005 and 2004, we capitalized interest of \$1.7 million, \$3.9 million and \$3.8 million, respectively. In addition, we capitalized \$0.4 million in interest related to payments for our Lab Building in Redwood City, California (see Note 13 for further details).

Goodwill, Other Intangible Assets and Other Long-Lived Assets

In March 2005, we recorded goodwill in connection with our acquisition of ESP Pharma (see Note 5). In accordance with SFAS No. 142, Goodwill and Other Intangible Assets, (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 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, four to 12 and five years, respectively. Amortization of intangible assets is included primarily in research and development expenses and cost of product sales in the Consolidated Statement of Operations.

In accordance with SFAS 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 2006, 2005 and 2004, we recorded asset impairment charges of \$74.7 million, \$31.3 million and zero, respectively.

Postretirement Benefits

We sponsor a postretirement health care plan to offer medical benefits to certain of our former officers and their dependents. As of December 31, 2006, we adopted SFAS 158.

Recent Accounting Pronouncement

In July 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, which is effective for fiscal years beginning after December 15, 2006. The interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition. We will adopt the interpretation on January 1, 2007 and we do not believe the interpretation will have a material impact on our financial position and results of operations.

2. STOCK-BASED COMPENSATION

Effective January 1, 2006, we adopted SFAS No. 123, Share-Based Payment (Revised 2004) (SFAS 123(R)), which supersedes our previous accounting under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and related interpretations. SFAS 123(R) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based awards including stock options and stock issued to our employees and directors under our stock plans. It requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our Condensed Consolidated Statements of Operations.

Table of Contents

In November 2005, the FASB issued FASB Staff Position No. 123R-3, Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards. We have adopted the simplified method to calculate the beginning balance of the additional paid-in-capital (APIC) pool of the excess tax benefit and to determine the subsequent effect on the APIC pool and Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that were outstanding upon our adoption of FAS 123(R).

We account for stock options granted to persons other than employees or directors 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 such persons 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 during the service period over which the non-employee provides services to us. The stock-based compensation expense related to non-employees for the years ended December 31, 2006, 2005 and 2004 was \$0.3 million, \$0.3 million and \$1.2 million, respectively.

Stock-Based Incentive Plans

We have four active stock-based incentive plans under which we may grant stock-based awards to our employees, officers, directors and consultants. The total number of shares of common stock authorized for issuance, shares of common stock issued upon exercise of options or as restricted stock that have vested and are no longer subject to forfeiture, subject to outstanding awards and available for grant under each of these plans as of December 31, 2006 is set forth in the table below:

Title of Plan	Total Shares of			Total Shares of
	Total Shares of Common Stock Authorized	Common Stock Issued	Total Shares of Common Stock Subject to Outstanding Awards	Common Stock Available for Grant
1999 Stock Option Plan	9,568,694	2,361,838	5,168,947	2,037,909
1999 Nonstatutory Stock Option Plan	11,000,000	3,450,565	6,459,037	1,090,398
2002 Outside Directors Stock Option Plan	480,000	40,000	233,500	206,500
2005 Equity Incentive Plan	2,300,000	25,800	1,724,263 ⁽¹⁾	549,937
1991 Nonstatutory Stock Option Plan ⁽²⁾	14,131,306	13,267,312	863,994 ⁽³⁾	

⁽¹⁾ Includes 136,900 restricted shares of our common stock that had not vested and were subject to forfeiture as of December 31, 2006.

⁽²⁾ This plan expired in 2001 and we no longer may grant awards under this plan.

⁽³⁾ These shares of common stock are subject to options that were granted before the 1991 Nonstatutory Stock Option Plan expired. All of the shares subject to these options are vested. Shares subject to options that are cancelled or expire without being exercised will automatically be added to the number of shares of common stock authorized for issuance under our 1999 Stock Option Plan.

Under our 2005 Equity Incentive Plan, we are authorized to issue a variety of incentive awards, including stock options, stock appreciation rights, restricted stock unit awards, performance share and performance unit awards, deferred compensation awards and other stock-based or cash-based awards. Under our 1999 Stock Option Plan, 1999 Nonstatutory Stock Option Plan and 2002 Outside Directors Stock Option Plan, we are only authorized to issue stock options.

Our 2002 Outside Directors Stock Option Plan provides for the automatic grant of stock options to outside directors upon appointment and annually after our annual meeting of stockholders. Stock options granted under our 2002 Outside Directors Stock Option Plan generally vest monthly over one year after the date of grant.

Stock options granted to employees under our plans in connection with the start of employment customarily vest over four years with 25% of the shares subject to such an option vesting on the first anniversary of the grant date and the remainder of the stock option vesting monthly after the first anniversary at a rate of one thirty-sixth of the remaining nonvested shares subject to the stock option. Stock options granted to employees as additional incentive and for performance reasons after the start of employment customarily vest monthly after the grant date or such other vesting start date set by the company on the grant date at a rate of one forty-eighth of the shares subject to the option. Each outstanding stock option granted prior to mid-July 2005 has a term of 10 years. Stock options granted after mid-July 2005 have a term of seven years.

Table of Contents*Employee Stock Purchase Plan*

In addition to the stock-based incentive plans described above, we adopted the 1993 Employee Stock Purchase Plan (ESPP), which is intended to qualify as an employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended. Full-time employees who own less than 5% of our outstanding shares of common stock are eligible to contribute a percentage of their base salary, subject to certain limitations, over the course of six-month offering periods for the purchase of shares of common stock. The purchase price for shares of common stock purchased under our ESPP equals 85% of the fair market value of a share of common stock at the beginning or end of the relevant six-month offering period, whichever is lower. Of the 2,400,000 shares authorized for issuance under our ESPP, as of December 31, 2006, 2,071,494 have been issued and 328,506 remain available for future issuance. The stock-based compensation expense in connection with our ESPP for the year ended December 31, 2006 was \$1.6 million.

Common Stock Reserved for Future Issuance

Shares of our common stock reserved for future issuance at December 31, 2006 were as follows:

(In thousands)	
All stock option and equity incentive plans	18,334
Employee stock purchase plan	329
Convertible debt	22,970
Total	41,633

Prior to the Adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), we accounted for stock-based awards under the intrinsic value method, which followed the recognition and measurement principles of APB 25 and related interpretations. Accordingly, we did not recognize compensation expense in our Condensed Consolidated Statements of Operations with respect to options awarded to our employees and directors with exercise prices greater than or equal to the fair value of the underlying common stock on the date of grant. However, we did recognize compensation expense in our Condensed Consolidated Statements of Operations with respect to the modification of certain employee stock option awards and the issuance of restricted stock to certain employees.

The table below illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation, (SFAS 123) as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosures, to our stock-based compensation plans prior to the adoption of SFAS 123(R). For purposes of this pro forma disclosure, the value of the options was estimated using the Black-Scholes option-pricing model. Disclosures for the year ended December 31, 2006 are not presented in the table below because stock-based compensation to employees and directors were accounted for under SFAS 123(R) effective January 1, 2006 and recognized in our Consolidated Statements of Operations.

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

Table of Contents*Adoption of SFAS 123(R)*

We calculated stock-based compensation expense recognized in 2006 under SFAS 123(R) based on the number of awards ultimately expected to vest, net of estimated forfeitures. SFAS 123(R) requires us to estimate forfeiture rates at the time of grant and revise such rates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We adopted SFAS 123(R) using the modified prospective application transition method, which requires that we recognize compensation expense in our consolidated financial statements for all awards granted to employees and directors after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method does not require restatement of prior periods to reflect the impact of SFAS 123(R). Upon adopting SFAS 123(R), we changed from the multiple-option approach to the single-option approach to value stock-based awards with a measurement date on or subsequent to January 1, 2006. In addition, we are amortizing the fair value of these awards using the straight-line attribution method. We believe that the single-option approach with straight-line attribution better reflects the level of service to be provided over the vesting period of our awards. We continue to expense the nonvested awards granted prior to January 1, 2006 under the multiple-option approach with graded-vesting attribution. In addition, in connection with the adoption of SFAS 123(R), we eliminated the remaining balance of the deferred stock-based compensation against APIC.

During the year ended December 31, 2006, we capitalized stock-based compensation costs of approximately \$75,000 under SFAS 123(R) in inventory. Since substantially all of the products sold in 2006 were manufactured prior to January 1, 2006, when we did not capitalize stock-based compensation expense in inventory, we did not recognize any stock-based compensation expense as a component of cost of product sales in 2006. However, we will recognize the related expenses in cost of product sales in the period the related inventories are sold.

Stock-based compensation expense recognized under SFAS 123(R) for employees and directors was as follows:

(In thousands, except per share amounts)	Year Ended December 31, 2006
Research and development	\$ 13,509
Selling, general and administrative	9,801
Total stock-based compensation expense	23,310
Tax benefit related to stock-based compensation expense	
Net effect on net loss	\$ 23,310
Effect on net loss per basic and diluted share	\$ (0.21)

Valuation Assumptions

The stock-based compensation expense recognized under SFAS 123(R) for the year ended December 31, 2006 and presented in the pro forma disclosure required under SFAS 123 for the years ended December 31, 2005 and 2004 was determined using the Black-Scholes option valuation model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted-average assumptions used were as follows:

	Year Ended December 31,		
	2006	2005	2004
Stock Option Plans			
Expected life, in years	4.0	3.1	2.4
Risk-free interest rate	5.0%	3.7%	2.6%
Volatility	47%	63%	64%
Dividend yield			

Year Ended December 31,

	2006	2005	2004
Employee Stock Purchase Plan			
Expected life, in years	0.5	0.5	0.5
Risk-free interest rate	4.8%	3.4%	1.6%
Volatility	43%	42%	62%
Dividend yield			

Table of Contents

Our expected term represents the period that we expect our stock-based awards to be outstanding, which we determined based on historical experience of similar awards, the contractual terms of the stock-based awards, vesting schedules and expectations of future optionee behavior as influenced by changes to the terms of stock-based awards. We base expected volatility on both the historical volatility of our common stock and implied volatility derived from the market prices of traded options of our common stock. We base the risk-free interest rate on the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term of our options at the time of grant. We have not issued any dividends and do not anticipate paying any cash dividends in the foreseeable future. We therefore have assumed a dividend yield of zero for purposes of these fair value estimations.

Stock Option Activity

A summary of our stock option activity for the years ended December 31, 2006, 2005 and 2004 is presented below.

	2006		2005		2004	
	Weighted-		Weighted-		Weighted-	
	Average		Average		Average	
	Exercise		Exercise		Exercise	
(In thousands, except per share data)	Shares	Price	Shares	Price	Shares	Price
Outstanding at beginning of year	14,342	\$ 17.89	15,215	\$ 16.36	14,537	\$ 15.69
Granted	3,737	19.75	3,882	20.17	3,367	17.59
Exercised	(2,206)	13.23	(3,260)	11.22	(1,807)	8.69
Forfeited	(1,560)	20.73	(1,495)	22.96	(882)	25.73
Outstanding at end of year	14,313	18.79	14,342	17.89	15,215	16.36
Exercisable at end of year	8,301	18.20	8,041		9,377	
Weighted-average grant-date fair value of options granted during the year		\$ 8.28		\$ 8.98		\$ 6.93

Range of Exercise Prices	Outstanding			Exercisable		
	Number	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number	Weighted-Average Exercise Price	Aggregate Intrinsic Value
	Outstanding	(years)	Exercise Price	Exercisable	Exercise Price	Aggregate Intrinsic Value
(In thousands, except per share data and remaining contractual life data)						
\$4.25 - \$8.30	1,599	4.98	\$ 7.15	1,516	\$ 7.11	
\$8.39 - \$15.25	2,393	6.08	13.15	1,842	12.75	
\$15.35 - \$16.82	666	8.01	16.45	284	16.41	
\$16.86 - \$17.13	1,871	6.66	17.12	223	17.08	
\$17.19 - \$18.90	1,617	6.70	18.19	859	18.42	
\$18.91 - \$21.01	2,005	5.87	20.20	1,171	20.59	
\$21.02 - \$24.21	1,440	5.66	21.86	574	21.95	
\$24.27 - \$27.87	1,459	4.90	27.17	1,211	27.25	
\$27.90 - \$52.44	1,238	5.23	32.82	596	35.83	
\$56.84	25	3.80	56.84	25	56.84	
Totals	14,313	5.92	\$ 18.79	8,301	\$ 18.20	\$ 41,957

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

Aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the closing prices of our common stock of \$20.14 on December 29, 2006, which would have been received by the option holders had all option holders exercised their options as of that date. Total unrecognized compensation cost related to nonvested stock options outstanding as of December 31, 2006 was \$41.1 million, excluding forfeitures, which we expect to recognize over a weighted-average period of 2.8 years.

Table of Contents

Additional information regarding our options exercised is set forth below:

(In thousands)	Year Ended December 31, 2006
Cash received	\$ 29,182
Aggregate intrinsic value	\$ 28,469

Restricted Stock

A summary of our restricted stock activity for the year ended December 31, 2006 is presented below:

(In thousands, except per share data)	Number of shares	Weighted average grant-date fair value per share
Nonvested at December 31, 2005	103,200	\$ 21.88
Awards granted	59,500	\$ 19.09
Awards vested	(25,800)	\$ (21.88)
Nonvested at December 31, 2006	136,900	\$ 20.67

Stock-based compensation expense related to our restricted stock for the year ended December 31, 2006 was \$0.7 million. Total unrecognized compensation cost related to nonvested restricted stock outstanding as of December 31, 2006 was \$2.4 million, which we expect to recognize over a weighted-average period of 2.9 years. A total of 25,800 shares of restricted stock vested during the year ended December 31, 2006.

3. COLLABORATIVE AND LICENSING ARRANGEMENTS

Biogen Idec MA Inc. In September 2005, we entered into a collaboration agreement with Biogen Idec MA Inc. (Biogen Idec) for the joint development, manufacture and commercialization of three antibodies. 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 volociximab (M200) and *HuZAF* (fontolizumab) in all indications.

We received an upfront license fee payment of \$40.0 million, and, pursuant to a related stock purchase agreement, Biogen Idec purchased approximately 4.1 million shares of our common stock at \$24.637 per share, which represented the then fair market value of the stock, for approximately \$100.0 million in cash. These shares were 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 was restricted from acquiring, or soliciting other parties to acquire, our voting securities.

We and Biogen Idec share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies share the development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. We are eligible to receive development and commercialization milestones based on the further successful development of the antibodies covered by the collaboration agreement. 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.

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 are recognizing this amount over development periods of the three antibodies, ranging from five to nine years. During the years ended December 31, 2006 and 2005, we recognized revenues of

approximately \$27.2 million and \$11.4 million, respectively, under the Biogen Idec arrangement.

Table of Contents

Roche. Effective October 2003, we entered into an Amended and Restated Worldwide Agreement (the 2003 Worldwide Agreement) with Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd. (together, Roche) under which we paid \$80 million to Roche for the acquisition of exclusive rights to daclizumab in all indications other than transplant indications and an option to acquire Roche's rights to daclizumab in transplant indications (the reversion option). Of the \$80 million that we paid to Roche, 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 at that time, specifically to treat asthma and ulcerative colitis. We capitalized the remaining amount of \$31.8 million, \$16.0 million of which related to the daclizumab core technology, and \$15.8 million of which related to the reversion option. We are amortizing the value of the core technology over the term of the patents underlying the acquired technology, and in the fourth quarter of 2005, we wrote off the entire remaining value of the reversion option in connection with our entrance into the Second Amended and Restated Worldwide Agreement with Roche in October 2005 because we agreed to not exercise the reversion option (see below).

In September 2004, we entered into a Co-Development and Commercialization Agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and other respiratory diseases (the Asthma Collaboration).

In October 2005, we and Roche entered into the Second Amended and Restated Worldwide Agreement (the 2005 Worldwide Agreement), which amended and restated the 2003 Worldwide Agreement. Pursuant to the 2005 Worldwide Agreement, we acquired all of Roche's remaining rights to daclizumab subject to Roche's exclusive right to continue to commercialize daclizumab under the trademark *Zenapax*® for the prevention of acute organ rejection in patients undergoing kidney transplants. In consideration, we agreed that we would not exercise the reversion option under the 2003 Worldwide Agreement to promote *Zenapax* for the prevention of acute kidney transplant rejection. As a result, during the fourth quarter of 2005, we recorded an asset impairment charge of \$15.8 million to write off the carrying value of the reversion option asset. The 2005 Worldwide Agreement also provided that Roche will only be obligated to pay us royalties on sales of *Zenapax* antibody above a threshold level, which we do not expect to be reached based on our current expectations. As a result, we do not expect to receive royalties from Roche under the 2005 Worldwide Agreement.

Also in October 2005, we and Roche also entered into the Amended and Restated Co-Development and Commercialization Agreement (the Roche Co-Development Agreement), which broadened the scope of the Asthma Collaboration to include the joint development and commercialization of daclizumab for transplant indications, with an emphasis on transplant maintenance.

In August 2006, Roche elected to discontinue its involvement in the Asthma Collaboration under the Roche Co-Development Agreement. On that date, as we had no further obligations to Roche under this arrangement, we recognized approximately \$18.8 million in deferred license, collaboration and other revenues related to unearned amounts that we had received from Roche specifically related to the Asthma Collaboration. In November 2006, we earned and received from Roche a final \$5.0 million milestone payment under the Asthma Collaboration, which we recognized as license, collaboration and other revenues in the fourth quarter of 2006. Had the Asthma Collaboration not been discontinued, the \$18.8 million of deferred revenues and the \$5 million milestone payment would have otherwise been deferred to and recognized in future periods.

In November 2006, Roche also notified us that it had elected to terminate the Roche Co-Development Agreement under which we were also co-developing daclizumab for transplant indications, with an emphasis on transplant maintenance (the Transplant Collaboration). As a result of the termination of the Asthma Collaboration and the termination of the Roche Co-Development Agreement, we will not receive any further milestone payments related to the Asthma Collaboration or the Transplant Collaboration, however, we will continue to recognize unearned amounts under the Transplant Collaboration through the date of the termination of the Roche Co-Development Agreement in May 2007. During the fourth quarter of 2006, we recognized approximately \$1.7 million in previously deferred revenues that would have otherwise been deferred to future periods had the termination not occurred.

During 2006, 2005 and 2004, we recognized \$31.7 million, \$8.6 million and \$3.7 million, respectively, under these arrangements with Roche.

Genentech, Inc. In September 1998, we entered into an agreement with Genentech, Inc. (Genentech) covering patent rights under our humanization patents and under Genentech's patents relating to antibody engineering. 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 September 2003, Genentech and we mutually agreed to extend the master agreement for an additional 5-year term ending December 2008. Under this agreement, we currently receive royalties from the sale of *Herceptin*, *Avastin*, *Xolair*, *Raptiva* and *Lucentis* antibodies.

Table of Contents**4. 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 exercise of stock options, the issuance of restricted stock and the assumed purchase of common shares under ESPP using the treasury stock method, as well as the assumed release of shares in escrow from the ESP Pharma acquisition and the conversion of convertible notes using the if-converted 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 have been anti-dilutive.

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)	Years Ended December 31,		
	2006	2005	2004
Stock options	14,283	15,376	14,841
Common stock in escrow	953	1,608	
Restricted stock	120	49	
ESPP	69	42	41
Convertible notes	22,970	21,640	12,415
Total	38,395	38,715	27,297

5. ESP PHARMA ACQUISITION AND SUBSEQUENT DIVESTITURE OF OFF-PATENT PRODUCTS

In March 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 was accounted for as a business combination in accordance with SFAS No. 141, Business Combinations (SFAS 141). In addition to the issuance of 7,330,182 shares of PDL common stock and cash payment of \$325.0 million to ESP Pharma stockholders, we deposited 2,523,588 shares of common stock 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 an Escrow Agreement entered into in connection with the Amended and Restated Agreement and Plan of Merger. The value associated with these shares will be accounted for in the future as contingent consideration. We also incurred direct transaction costs of \$5.4 million.

During the second quarter of 2006, we reached a settlement with the IRS regarding certain pre-acquisition tax issues of ESP Pharma for the tax year ended December 31, 2003 and during the third quarter of 2006, certain contingent tax liabilities lapsed for the tax year ended December 31, 2002. Accordingly, we reduced certain recorded tax liabilities and the associated amounts allocated to goodwill by \$0.2 million in the second quarter ended June 30, 2006 and by \$0.4 million in the third quarter ended September 30, 2006.

Pursuant to the terms of the Escrow Agreement governing the escrow account, 1,260,842, 350,735 and 50,673 shares of common stock held in escrow were released from escrow to the ESP Pharma stockholders in September 2005, March 2006 and April 2006, respectively. In connection with these releases, we increased goodwill by \$35.3 million, \$11.2 million and \$1.5 million, representing the fair value of the shares released on the release dates. In addition, a total of 952 shares were removed from the escrow account and cancelled in 2005 due to ESP Pharma's breaches of certain representations and warranties under the Amended and Restated Agreement and Plan of Merger.

Table of Contents

In July 2006, we filed a demand for arbitration with Judicial Arbitration and Mediation Services to resolve the disputed claims against the remaining 860,386 shares of common stock in escrow. In September 2006, the ESP Pharma stockholders responded to our demand for arbitration denying all of our claims. An arbitrator has been chosen in this matter and the initial arbitration session is scheduled to occur on June 18, 2007.

In January 2007, we released our claim with respect to 18,842 shares held in escrow, because certain liabilities underlying the original claims had lapsed, and these shares were released to the ESP Pharma stockholders. We believe all current claims against the remaining 841,544 shares are valid and we will vigorously assert our claims against these shares in the arbitration proceeding; however, we cannot be certain of the outcome at this time.

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	\$ (14,640)

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	\$ 435,239

The \$339.2 million value assigned to the intangible assets related to product rights for the six products *Cardene IV*, *IV Busulfex*, *Declomycin*, *Sectral*, *Tenex* and *Ismo* products rights to which we acquired. During 2005, we concluded that the carrying amount of the product rights for the off-patent products, consisting of *Declomycin*, *Sectral*, *Tenex* and *Ismo*, was impaired as the estimated fair value of these product rights was less than the net carrying value. Accordingly, we recorded an impairment charge in 2005 to reduce the carrying value of these product rights to the fair value. During 2005, we also classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights in accordance with SFAS 144. In addition, we wrote down inventory by \$1.1 million related to the off-patent 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. 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.

Table of Contents

We entered into an agreement regarding the sale of rights to the *Declomycin* product with Glades Pharmaceuticals, LLC (Glades) in December 2005. The transfer of rights to the *Declomycin* product to Glades for total cash proceeds of \$8.3 million was completed in February 2006. We sold the rights to the *Sectral*, *Tenex* and *Ismo* products to Dr. Reddy's Laboratories Limited for total cash proceeds of \$2.7 million in March 2006. During the first quarter of 2006, we paid \$4.1 million to Wyeth and obtained the consent from Wyeth necessary to transfer all rights to the *Declomycin* product to Glades and all rights to our other three off-patent products to Dr. Reddy's Laboratories. The total expense recognized related to these two transactions aggregated to \$4.1 million and was recorded in selling, general and administrative expense in our Condensed Consolidated Statements of Operations during the first quarter of 2006.

As we did not identify any pre-acquisition contingencies on the acquisition date, under SFAS 141, charges incurred subsequent to our acquisition of ESP Pharma that are associated with pre-acquisition operations are included in Other acquisition-related charges in the Condensed Consolidated Statements of Operations. As such charges directly relate to ESP Pharma operations prior to our acquisition of the business, we recognize them as operating expenses rather than as a reduction to current period product sales.

As part of the allocation of the purchase price for ESP Pharma, we allocated \$79.4 million to acquired in-process research and development related to ESP Pharma's clinical stage 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:

Program	Description	Value (In thousands)
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for type 1 hepatorenal syndrome (HRS)	\$ 23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of acute decompensated heart failure	55,652
		\$ 79,417

Prior to December 2006, we were party to a collaboration agreement with Orphan Therapeutics, LLC (Orphan Therapeutics), the holder of the Investigational New Drug application for terlipressin, pursuant to which we held exclusive marketing, sales and distribution rights to terlipressin. In August 2006, we announced that the Phase 3 trial of terlipressin in patients with type 1 HRS did not meet its primary endpoint. Following a meeting among representatives of FDA, Orphan Therapeutics and us regarding the outcome of the Phase 3 trial of terlipressin, we and Orphan mutually agreed to terminate the agreement under which we held exclusive marketing, sales and distribution rights to terlipressin effective December 16, 2006 and the rights we previously held under this collaboration agreement reverted back to Orphan at that time.

We completed the Scientific Advice procedure with the European Medicines Agency (EMA) to define the Phase 3 trial requirements for ularitide and have been planning to initiate a two-study, 3,300-patient Phase 3 trial in Europe. As we have been planning for the initiation of these trials, we also have been conducting discussions with potential partners for the ularitide program. Based on our partnering discussions, we believe potential partners want to have active involvement in the registration process. As a result, we decided to delay the start of the planned European trials until we have partnered the ularitide program to better ensure the successful development of ularitide. Separately, we plan to start a U.S.-based Phase 1 dose-ranging study to define dose-limiting toxicity that the FDA asked us to conduct.

Table of Contents**6. RETAVASE® PRODUCT ACQUISITION**

On March 23, 2005, immediately after our acquisition of ESP Pharma, we completed the acquisition of rights to manufacture, develop, market and distribute *Retavase* product 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* product 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 *Retavase* product assets on March 23, 2005:

	(In thousands)
Tangible assets	\$ 16,500
Intangible assets	93,500
Transaction costs	500
Total purchase price	\$ 110,500

Under the March 2005 agreement with Centocor for the purchase of the rights to the *Retavase* product, in addition to the \$110.0 million paid upon the execution of the agreement, we agreed to pay up to \$45.0 million in milestone payments to Centocor upon the occurrence of certain future events. Of the \$45.0 million in potential milestone payments, a total of \$30.0 million will be recorded as additional purchase price if and when payable to Centocor. The remaining \$15.0 million in milestone payments will be recognized as research and development expense, if and when due and payable to Centocor. During September 2006, Centocor met the first milestone under the terms of the agreement, which triggered a \$15.0 million payment due to them. Accordingly, in September 2006, we recorded additional intangible assets of \$15.0 million as *Retavase* product rights.

During the third quarter of 2006, we recognized a \$1.5 million impairment charge for our product rights related to the distribution of *Retavase* product in certain territories. This amount represented the difference between the carrying value of the asset and the present value of estimated future cash flows as of September 30, 2006 under SFAS 144. After recognizing the impairment charge, the book value of this intangible asset as of September 30, 2006 was approximately \$0.2 million and remained unchanged at December 31, 2006.

During the fourth quarter of 2006, we recognized additional impairment charge of \$72.1 million to reduce the carrying value of our *Retavase* product rights to \$12.9 million, representing the present value of its estimated future cash flows as of December 31, 2006.

The remaining carrying value of these intangible assets of \$13.1 million as of December 31, 2006 is being amortized over periods between two to six and a half years, or a weighted-average period of 6.2 years, the estimated useful lives of these assets as of December 31, 2006.

7. 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 loss in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and discounts to maturity. Such amortization is included in interest income. The cost of securities sold is based on the specific identification method, when applicable.

To date, we have not experienced credit losses on investments in these instruments. During 2006, we recorded \$18.3 million as non-current restricted cash related to the lease of our future headquarters in Redwood City, California. Of this amount, \$15.0 million supports a letter of credit from which our landlord can draw if we do not fulfill our obligations with respect to the construction of our leasehold improvements, and the remaining \$3.3 million supports letters of credit serving as a security deposit. We did not have any restricted cash as of December 31, 2005.

The following is a summary of our marketable debt securities. Estimated fair value is based upon quoted market prices for these or similar instruments.

Table of Contents

(In thousands)	Marketable Debt Securities			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
December 31, 2006				
Securities of U.S. Government agencies maturing:				
within 1 year	\$ 144,671	\$	\$ (363)	\$ 144,308
between 1-3 years	74,997	39	(144)	74,892
U.S. corporate debt securities maturing:				
within 1 year	9,807			9,807
between 1-3 years				
Total marketable debt securities	\$ 229,475	\$ 39	\$ (507)	\$ 229,007
December 31, 2005				
Securities of the U.S. Government maturing:				
within 1 year	\$ 6,827	\$	\$	\$ 6,827
between 1-3 years				
Securities of U.S. Government agencies maturing:				
within 1 year	95,785		(995)	94,790
between 1-3 years	49,999		(1,071)	48,928
Total marketable debt securities	\$ 152,611	\$	\$ (2,066)	\$ 150,545

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, 2006 and 2005:

(in thousands)	Marketable Debt Securities			
	December 31, 2006		December 31, 2005	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Less than 12 months	\$ 49,853	\$ (144)	\$ 49,430	\$ (568)
Greater than 12 months	39,638	(363)	93,500	(1,498)
Total	\$ 89,491	\$ (507)	\$ 142,930	\$ (2,066)

During 2006 and 2004, we did not recognize any gain or loss on sales of available-for-sale securities. During 2005, we realized \$0.3 million in losses on sales 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, 2006, as the unrealized losses primarily relate to the fluctuation of interest rates, and we have the ability and intent to hold such securities to maturity. At December 31, 2005, we held \$6.8 million of U.S. government securities classified as held-to-maturity under SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, in addition to our available-for-sale portfolio (see below for further details of such securities). At December 31, 2006, we did not have any securities classified as held-to-maturity.

In July 2003, we issued 2.75% Convertible Subordinated Notes due August 16, 2023 with a principal amount of \$250.0 million (see Note 15 for further details). In connection with the issuance of these convertible notes, we pledged a portfolio of U.S. government securities as security, which, including the interest earned thereon, were sufficient to pay the first six scheduled interest payments for the notes. The pledged amount, which was zero at December 31, 2006 and \$6.8 million at December 31, 2005, consisted of securities of the U.S. government. As of December 31, 2005, the pledged amount was reflected on the Consolidated Balance Sheet within marketable securities. The basis for the carrying value of these restricted investments was the amortized cost of the investments, which approximated the fair value at December 31, 2005.

Table of Contents**8. INVENTORY**

Inventories consisted of the following:

(In thousands)	December 31,	
	2006	2005
Raw materials	\$ 9,689	\$ 6,249
Work-in-process	5,286	9,332
Finished goods	4,688	2,147
Total	\$ 19,663	\$ 17,728

9. LAND, PROPERTY AND EQUIPMENT

Land, property, and equipment consisted of the following:

(In thousands)	December 31,	
	2006	2005
Land	\$ 14,717	\$ 12,229
Buildings and improvements	178,624	43,069
Leasehold improvements	22,856	22,008
Laboratory and manufacturing equipment	79,552	31,310
Construction-in-process	42,642	180,381
Computer and office equipment	39,144	28,629
Furniture and fixtures	4,611	4,053
Gross land, property and equipment	382,146	321,679
Less accumulated depreciation and amortization	(85,617)	(55,626)
Net land, property and equipment	\$ 296,529	\$ 266,053

The construction-in-process account as of December 31, 2006 includes \$25.4 million, which represents the fair value of our Lab Building in our new facilities in Redwood City, California and related capitalized interest, as discussed in Note 13.

Table of Contents**10. INTANGIBLE ASSETS**

Intangible assets consisted of the following:

(In thousands)	December 31, 2006			December 31, 2005		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Product rights	\$ 328,876	\$ (53,865)	\$ 275,011	\$ 416,500	\$ (32,632)	\$ 383,868
Assembled workforce	1,410	(1,410)		1,410	(1,410)	
Core technology	16,053	(5,351)	10,702	16,053	(3,705)	12,348
Licensed research technology				1,500	(450)	1,050
Net intangible assets	\$ 346,339	\$ (60,626)	\$ 285,713	\$ 435,463	\$ (38,197)	\$ 397,266

Amortization expense for our intangible assets included in research and development expenses during the years ended December 31, 2006, 2005 and 2004 was approximately \$1.8 million, \$2.1 million and \$2.5 million, respectively. Amortization expense for our intangible assets included in cost of product sales during the years ended December 31, 2006 and 2005 was approximately \$43.1 million and \$35.4 million, respectively.

In September 2006, we acquired from Roche all *Cardene* product-related rights owned by them, including rights to the *Cardene* trademark, rights to the *Cardene* Immediate Release product (*Cardene* IR) and the *Cardene* Sustained Release product (*Cardene* SR), and inventories for both *Cardene* SR and *Cardene* IR products. In connection with this transaction, we now own rights to all formulations of the *Cardene* product. In consideration for these rights, we agreed to pay Roche \$13.9 million, \$3.7 million of which was due upon signing of the agreement, \$6.7 million of which is due during the first half of 2007 upon the delivery of additional *Cardene* SR product inventory from Roche, and \$3.5 million of which is due upon FDA approval of the technology transfer of the manufacturing process for nicardipine, the active pharmaceutical ingredient in the manufacture of all *Cardene* products, which we expect to occur in 2008. Under the terms of the arrangement, we are now obligated to pay royalties to Roche only on sales of intravenous *Cardene* products that fall under the existing relevant *Cardene* product-related U.S. patents through patent expiration, which is currently November 2009, but do not owe additional royalties on sales of the oral products.

In connection with the transaction, during the third quarter of 2006, we recorded \$10.7 million of the purchase price, which was allocated to each element of the arrangement based on each element's relative fair value, as follows:

	(In thousands)
Inventories	\$ 1,273
Intangible assets	3,776
Research and development expense	5,621
	\$ 10,670

We determined the fair value of the acquired assets consistent with SFAS 142. The fair value of the inventories and intangible assets acquired included both *Cardene* IR and *Cardene* SR products. Since we are not going to sell the *Cardene* IR product going forward, we wrote off the fair value attributable to *Cardene* IR product inventories and immediately recorded \$0.2 million as asset impairment charges during the third quarter of 2006. We expect to amortize the \$3.8 million we allocated to intangible assets relating to the *Cardene* SR product over a period of three years, which approximates the remaining patent life. We also recognized \$5.6 million of the purchase price as research and development expenses, representing the net present value of the estimated royalty amounts we potentially saved related to preliminary research pertaining to potential products that are outside the scope of the existing *Cardene* product-related U.S. patents. These research efforts were incomplete and had not yet reached technological feasibility as of the date of the transaction with Roche.

Table of Contents

In addition to the \$10.7 million purchase price recorded in the third quarter of 2006, we expect to record the fair value of additional *Cardene* SR product inventory, totaling approximately \$3.2 million, once such inventory is delivered to us from Roche, which is expected in the first half of 2007.

Also, in September 2006, we recorded \$15.0 million as additional *Retavase* product rights. See Note 6 for further details.

During December 2006, in connection with the negotiation of a new supply agreement for the manufacture of *Retavase* product, we determined that indicators existed that suggested our *Retavase* product rights intangible assets could be impaired. As such, we tested these intangible assets for recoverability under SFAS 144 and the total of the estimated future cash flows directly related to our sale of *Retavase* product was less than the carrying value of the asset as of December 31, 2006. Therefore, we determined that the carrying value of our *Retavase* product rights was impaired, and we used a present value technique to calculate the fair market value of the asset using a discount rate of 15%. As a result, we recognized an impairment charge totaling approximately \$72.1 million, which represented the difference between the carrying value of the asset and the present value of estimated future cash flows as of December 31, 2006.

In September 2006, we recognized a \$1.5 million impairment charge for our product rights related to the distribution of *Retavase* product in certain territories. This amount represented the difference between the carrying value of the asset and the present value of estimated future cash flows as of September 30, 2006 under SFAS 144. After recognizing the impairment charge, the book value of this intangible asset as of September 30, 2006 was approximately \$0.2 million and remained relative unchanged at December 31, 2006.

In June 2006, we concluded that the carrying amount of the licensed research technology acquired from Morphotek Inc. in 2004 was impaired because we abandoned the related technology associated with our research projects. Accordingly, we recorded an impairment charge of \$0.9 million, representing the unamortized balance prior to the impairment assessment, during the second quarter of 2006.

During the third quarter of 2005, we determined that the carrying value of the off-patent products, which were acquired through our acquisition of ESP Pharma in March 2005, was impaired. Accordingly, we wrote down the related product rights to fair value and ceased the amortization of the related product rights since these assets were then being held for sale (see Note 5 for further details).

For our product rights and core technology intangible assets, the expected future annual amortization expense is as follows:

	Product	Core
	Rights	Technology
(In thousands)		
For the year ending December 31,		
2007	\$ 33,486	\$ 1,647
2008	33,486	1,647
2009	33,282	1,647
2010	32,217	1,647
2011	32,217	1,647
Thereafter	110,323	2,467
Total amortization expense	\$ 275,011	\$ 10,702

Table of Contents**11. ACCRUED LIABILITIES**

Other accrued liabilities consisted of the following:

(In thousands)	December 31,	
	2006	2005
Consulting and services	\$ 12,105	\$ 9,757
Off-patent branded product sale deposit and accruals		9,175
Accrued clinical and pre-clinical trial costs	14,302	6,287
Accrued interest	4,453	4,454
Construction-in-process	3,294	1,694
Milestone payment related to the purchase of <i>Cardene</i> product-related rights from Roche	3,500	
Deferred tax liability	6,075	
Other	8,271	6,365
Total	\$ 52,000	\$ 37,732

The milestone payment related to the purchase of *Cardene* product-related rights is a milestone payment due during the first half of 2007 upon the delivery of additional *Cardene* SR product inventory from Roche, as discussed in Note 10.

The off-patent product sale deposit and accruals balance as of December 31, 2005 related to the sale of the off-patent products. Of the \$9.2 million accrued, \$8.3 million represents net cash received in December 2005 for the sale of rights to the *Declomycin* product to 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 occurred in February 2006.

12. POSTRETIREMENT BENEFIT PLAN

In June 2003, we established a postretirement health care plan (the Plan), which covers medical, dental and vision coverage for certain of our former officers and their dependents. Coverage for eligible retirees is noncontributory, but retirees are required to contribute 25% of dependent premium cost. In addition, coverage under the Plan ceases when participants become eligible for Medicare benefits.

In December 2006, we adopted SFAS 158 which required us to recognize the funded status of the Plan in our Consolidated Balance Sheets, which was a liability of \$1.7 million as of December 31, 2006. Prior to the adoption of SFAS 158, the amount recognized in our Consolidated Balance Sheets represented our Plan's accrued benefit cost. For the year ended December 31, 2005, that amount was approximately \$0.6 million.

The following table illustrates the incremental effect of applying SFAS 158 on individual line items in our Consolidated Balance Sheets as of December 31, 2006:

(In thousands)	Before		After
	Application of		Application of
	Statement 158	Adjustments	Statement 158
Other long-term liabilities	\$ 36,671	\$ 858	\$ 37,529
Total liabilities	673,494	858	674,352
Accumulated other comprehensive loss	(468)	(858)	(1,326)
Total stockholders' equity	468,399	(858)	467,541

Table of Contents

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

(In thousands)	December 31,	
	2006	2005
Accumulated postretirement benefit obligation at beginning of year	\$ 1,794	\$ 1,296
Service cost	148	109
Interest cost	97	72
Actuarial loss (gain)	(263)	356
Plan participants' contributions	11	6
Benefits paid	(81)	(45)
Accumulated postretirement benefit obligation at end of year	\$ 1,706	\$ 1,794

We calculated the accumulated postretirement benefit obligation using an assumed discount rate of 5.75 % and 5.50% for the years ended December 31, 2006 and 2005, respectively. In 2006 and 2005, we assumed the rate of increase in per capita costs of covered health care benefits to be 8% for 2006 and 9% for 2005, decreasing gradually to 5.5% for both assumptions by the year 2010.

As of December 31, 2006, the amounts recognized in our Consolidated Balance Sheets are as follows:

(In thousands)	
Other accrued liabilities	\$ 81
Other long-term liabilities	1,625
Net liability recognized	\$ 1,706

Net periodic benefit cost for the Plan consists of the following:

(In thousands)	December 31,	
	2006	2005
Service cost	\$ 148	\$ 109
Interest cost	97	72
Amortization of prior service cost	74	74
Amortization of net (gain) loss	36	8
Net periodic benefit cost	\$ 355	\$ 263

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, 2006	\$ 35	\$ (31)
Effect on total of service and interest cost in 2006	158	(141)

In connection with the Plan, we expect to pay health care net premiums aggregating approximately \$0.4 million during the years 2007 through 2011 and \$0.5 million during the years 2012 through 2016.

Table of Contents

The following table sets forth the amounts of net actuarial loss and prior service cost which have been recognized in other comprehensive income but which have not yet been recognized as components of net periodic benefit cost:

(In thousands)	December 31, 2006
Net actuarial loss	\$ 308
Prior service cost	550
Amount recognized in other comprehensive income	\$ 858

Of these amounts, we expect to recognize approximately \$11,000 and \$74,000 of net actuarial loss and prior service cost, respectively, as components of net periodic benefit cost in 2007.

13. COMMITMENTS AND CONTINGENCIES*Commitments*

We occupy leased facilities under agreements that have expiration dates between 2007 and 2021. We also have leased certain office equipment under operating leases. Rental expense under these arrangements totaled approximately \$5.6 million, \$3.8 million and \$2.5 million for the years ended December 31, 2006, 2005 and 2004, respectively. Future payments under non-cancelable operating leases as of December 31, 2006, are as follows:

(In thousands)	
Year Ending December 31,	
2007	\$ 7,125
2008	4,247
2009	3,587
2010	3,439
2011	3,439
Thereafter	66,413
	\$ 88,250

In July 2006, we entered into agreements to lease two buildings in Redwood City, California, to serve as our corporate headquarters. The largest of the two buildings, the Administration Building, will primarily serve as general office space, while the other will serve as our principal laboratory space (the Lab Building). We took possession of these buildings during the fourth quarter of 2006. We are currently constructing leasehold improvements for both buildings, and we expect to move into the facilities during the second half of 2007.

Our leasehold improvements for the Administrative Building relate to normal tenant improvements of the interior office space. However, more significant leasehold improvements are planned for the Lab Building, which has never been occupied or improved for occupancy. While this building had some electrical systems installed, plumbing, elevators and stairs as of the date of the lease, it lacked a heating and air conditioning system, interior walls and various other improvements that would be necessary for occupancy. We expect to incur approximately \$70 million to \$80 million in leasehold improvements in the Lab Building, and in the case that we fail to complete such improvements, our landlord has the right to draw upon the \$15 million letter of credit we established in connection with the lease agreement (see Cash Equivalents, Restricted Cash, Marketable Securities and Concentration of Credit Risk section of Note 1). Therefore, we have financial risk related to the completed construction of the facility.

Table of Contents

Due to our involvement in and assumed risk during the construction period, as well as the nature of the leasehold improvements for the Lab Building, we are required under Emerging Issues Task Force No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, to reflect the lease of the Lab Building in our financial statements as if we purchased the building. Therefore, we recorded the estimated fair value of the building and a corresponding long-term financing liability, which approximated \$24.7 million, at the time when we took possession of the building. Moreover, we are required to recognize interest expense on our financing liability, which is based on our secured borrowing rate at the time we entered into the lease in July 2006. During the construction period, we will be capitalizing such interest as the building has not yet been placed in service and is classified as construction-in-process on our balance sheet. In addition, since we are not the legal owner of the land, we must assume that we are leasing the land and recognize an amount as ground lease rentals (rental expense) under Financial Accounting Standards Board Staff Position SFAS No. 13-1, *Accounting for Rental Costs Incurred During a Construction Period*. During 2006, we capitalized approximately \$0.4 million in interest expense and we recognized approximately \$0.3 million in rental expense. At December 31, 2006, our financing liability was approximately \$25.4 million.

Since we are financing a substantial amount of the leasehold improvements, the lease of the Lab Building does not qualify for sale-leaseback accounting under SFAS No. 98, *Accounting For Leases*, and therefore, we are required to keep the fair value of the building in our balance sheet throughout the lease term. As a result, after the construction is complete and the Lab Building is placed into service, we expect to depreciate the value of the building using the straight-line method over the term of our lease, and we expect to allocate our lease payments to rental expense for the land, interest expense, and the reduction of the financing liability. Our underlying lease term is approximately 15 years, or through December 31, 2021.

Future payments for the Lab Building as of December 31, 2006, are as follows:

(In thousands)

Year Ending December 31,

2007	\$ 3,259
2008	3,376
2009	3,494
2010	3,616
2011	3,743
Thereafter	41,082
Total	58,570
Less amount representing interest	(16,769)
Less amount representing ground rental expense	(14,445)
Less amount representing future reimbursement of leasehold improvements	(2,000)
 Present value of future payments	 \$ 25,356

In addition, we have minimum purchase commitments related to our contract manufacturing arrangements for both our commercial and clinical products. As of December 31, 2006, such purchase commitments totaled approximately \$16.6 million for 2007 and \$0.4 million for 2008 and \$0.4 million for 2009. Further, during January 2007, we signed an amended agreement with one of our contract manufacturers, under which we are committed to purchases totaling \$12.8 million in 2007, \$4.5 million in 2008 and \$4.5 million in 2009.

Contingencies

As permitted under Delaware law, pursuant to the terms of our bylaws, we have agreed to indemnify our officers and directors and, pursuant to the terms of indemnification agreements we have entered into, we have agreed to indemnify our executive officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving as an officer or director of the Company. While the maximum amount of potential future indemnification is unlimited, we have a director and officer insurance policy that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements and bylaw provisions is minimal, and accordingly, we have not recorded the fair value liability associated with these agreements as of December 31, 2006.

14. LONG-TERM LIABILITIES AND NOTES PAYABLE

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

In September 1999, Fremont Holding L.L.C., our wholly owned subsidiary, obtained a \$10.2 million term loan to purchase two of 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. As of December 31, 2006, the carrying amount of the loan was \$6.8 million. This loan is secured by the two Fremont, California facilities we own and is subject to the terms and covenants of the loan agreement.

Table of Contents

Future minimum payments under the term loan at December 31, 2006 are as follows:

(In thousands)	
Year Ending December 31,	
2007	\$ 1,139
2008	1,139
2009	1,139
2010	1,139
2011	1,139
Thereafter	3,448
Total	9,143
Less amount representing interest	(2,350)
Present value of future payments	6,793
Less current portion	(635)
Non-current portion	\$ 6,158

The fair value of the remaining payments under the loan at December 31, 2006 was \$7.1 million and was estimated using a discounted cash flow analysis, based on our current incremental borrowing rates for similar types of borrowing arrangements.

In addition, our long-term liabilities balance as of December 31, 2006 included \$25.4 million for the financing obligation related to our Lab Building in Redwood City, California, as discussed in Note 13 to the Consolidated Financial Statements, \$3.5 million for a future milestone payment related to our purchase of rights related to the *Cardene* product as discussed in Note 11, \$1.6 million related to the non-current portion of our accumulated postretirement benefit obligation recognized as of December 31, 2006 as discussed in Note 12 and \$0.9 million related to the timing difference between straight-line recognition of rent expenses and actual rent payments.

15. CONVERTIBLE NOTES

In February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of \$250.0 million (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, 2006 was \$2.3 million. The estimated fair value of the 2005 Notes at December 31, 2006 was approximately \$264.1 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.

Table of Contents

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, 2006 was \$4.2 million. The estimated fair value of the 2003 Notes at December 31, 2006 was approximately \$283.4 million based upon publicly available pricing information.

16. REVENUES BY GEOGRAPHIC AREA AND SIGNIFICANT CUSTOMERS

Our chief operating decision-maker is comprised of our executive management. Our chief operating decision-maker 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:

(In thousands)	Years Ended December 31,	
	2006	2005*
<i>Cardene</i>	\$ 109,689	\$ 62,143
<i>Retavase</i>	30,833	32,715
<i>IV Busulfex</i>	24,062	17,417
Total marketed products	164,584	112,275
Off-patent brands	1,117	9,831
Total revenues from product sales, net	\$ 165,701	\$ 122,106

* Represents net product sales generated during the nine-month period since our acquisitions of ESP Pharma and rights to the *Retavase* product on March 23, 2005.

The following table summarizes revenues from our customers and licensees who individually accounted for 10% or more of our total revenues for the years ended December 31, 2006, 2005 and 2004 (as a percentage of total revenues):

	Years Ended December 31,		
	2006	2005	2004
Customers			
Cardinal Health, Inc.	18%	13%	*
AmerisourceBergen Corp.	14%	11%	*
McKesson Corp.	13%	13%	*
Licensees			
Genentech, Inc. (Genentech)	36%	31%	51%
MedImmune, Inc. (MedImmune)	**	12%	30%
Hoffman La-Roche (Roche)	**	**	11%

* Not presented as we did not have product sales prior to 2005.

** Represents less than 10%.

The following table summarizes outstanding accounts receivable from our customers who individually accounted for 10% or more of our total gross accounts receivable (as a percentage of total accounts receivable from product sales):

	December 31,	
	2006	2005
Cardinal Health, Inc.	34%	34%
McKesson Corp.	25%	18%

Table of Contents

Revenues 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. The following table summarizes revenues by geographic area for the years ended December 31, 2006, 2005 and 2004:

(In thousands)	Years Ended December 31,		
	2006	2005	2004
United States	\$ 347,455	\$ 250,480	\$ 84,021
Canada	1,059	888	
Europe	63,696	28,274	11,373
Asia	1,831	525	630
Other	729	402	
Total revenues	\$ 414,770	\$ 280,569	\$ 96,024

17. INCOME TAXES

The provision for income taxes consists of the following:

(In thousands)	Years Ended December 31,		
	2006	2005	2004
Federal	\$ 789	\$ 100	\$
State	(103)	721	20
Foreign	81	47	60
Total provision	\$ 767	\$ 868	\$ 80

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,		
	2006	2005	2004
Tax (benefit) at U.S. statutory rate	\$ (45,438)	\$ (57,998)	\$ (18,074)
Unutilized net operating losses	45,461	30,202	18,074
Federal alternative minimum tax	663		
Nondeductible acquired in-process research and development		27,796	
State taxes	(103)	721	20
Other	126	100	
Foreign taxes	58	47	60
Total	\$ 767	\$ 868	\$ 80

As of December 31, 2006, we had federal and state net operating loss carryforwards of approximately \$428.9 million and \$214.0 million, respectively. We also had federal and California state research and other tax credit carryforwards of approximately \$20.2 million and \$19.5 million, respectively. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in the year 2007 through 2026, if not utilized. The state net operating losses will expire at various dates beginning in 2007 through 2016, if not utilized. The majority of the state tax credits do not expire.

Table of Contents

Utilization of the federal and 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,	
	2006	2005
Deferred tax assets:		
Net operating loss carryforwards	\$ 58,994	\$ 159,549
Net operating loss carryback		10,070
Research and other tax credits	30,408	24,300
SFAS 123 (R) expense	8,591	
Reserves and accruals	14,409	13,586
Capitalized research and development costs	4,121	4,599
Deferred revenue	17,590	5,979
Other	7,223	11,267
Total deferred tax assets	141,336	229,350
Valuation allowance	(110,424)	(144,178)
Total deferred tax assets	30,912	85,172
Deferred tax liabilities:		
Intangible assets	(30,912)	(73,398)
Other		(2,139)
Total deferred tax liabilities	(30,912)	(75,537)
Net deferred tax assets	\$	\$ 9,635

Because of our lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$33.8 million and \$52.6 million for the years ended December 31, 2006 and 2005, respectively. Excess tax benefits from employee stock option exercises of \$97.2 million are included in deferred tax balances at December 31, 2005 as a component of the Company's net operating loss carryovers. The entire balance is offset by a full valuation allowance. As a result of adopting SFAS 123(R), the deferred tax asset balances at December 31, 2006 did not include excess tax benefits from stock option exercises. The amount excluded at December 31, 2006 was \$108.9 million. Equity will be increased by \$108.9 million if and when such excess tax benefits are ultimately realized.

18. LEGAL PROCEEDINGS

Two humanization patents based on the Queen technology were issued to us by the European Patent Office. Eighteen notices of opposition to our first European patent and eight notices of opposition to our second European patent were filed by major pharmaceutical and biotechnology companies, among others, and we are currently in two separate opposition proceedings with respect to these two patents. Five opponents, including Genentech, have withdrawn from the opposition proceedings with respect to the opposition to our first European patent leaving 13 remaining opponents. A description of these two proceedings is set forth below.

Opposition to First European Patent

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

Table of Contents

the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. In August 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to occur in April 2007. Regardless of the Opposition Division's decision on these claims, any resulting 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, which is also being opposed, 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, if the Opposition Division rules against us, that decision could encourage challenges of our related patents in other jurisdictions, including the United States. Such a decision may also 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.

Opposition to Second European Patent

At an oral hearing in February 2005, the Opposition Division of the European Patent Office also 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. The Technical Board of Appeal has not scheduled a date for the appeal hearing.

We intend to vigorously defend our two European Queen patents in these two proceedings. We may not prevail in either of the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of either 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.

Table of Contents

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. as of December 31, 2006 and 2005, and the related consolidated statements of operations, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, 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.

As discussed in Notes 2 and 12 to the consolidated financial statements, in 2006 PDL BioPharma, Inc. changed its methods of accounting for stock-based compensation and for its postretirement benefit plan.

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, 2006, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 23, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

February 23, 2007

Table of Contents**QUARTERLY FINANCIAL DATA (UNAUDITED)**

(In thousands, except per share data)	2006 Quarter Ended ⁽¹⁾			
	December 31	September 30	June 30	March 31
Revenues:				
Product sales	\$ 48,051	\$ 41,064	\$ 39,039	\$ 37,547
Royalties	43,753	42,533	54,021	43,970
License and other	16,038	27,795	11,264	9,695
Total revenues	107,842	111,392	104,324	91,212
Costs and expenses:				
Cost of product sales	24,418	17,433	21,482	22,959
Research and development	65,397	70,880	62,612	61,771
Selling, general and administrative	36,689	26,672	25,336	32,159
Other acquisition-related charges ⁽²⁾	289	2,615	2,177	1,118
Asset impairment charge ⁽³⁾	72,094	1,656	900	
Total costs and expenses	198,887	119,256	112,507	118,007
Operating loss	(91,045)	(7,864)	(8,183)	(26,795)
Interest and other income, net	5,268	5,042	4,064	3,330
Interest expense	(3,605)	(3,693)	(3,122)	(2,650)
Loss before income taxes	(89,382)	(6,515)	(7,241)	(26,115)
Income tax expense	326	208	118	115
Net loss	\$ (89,708)	\$ (6,723)	\$ (7,359)	\$ (26,230)
Net loss per basic and diluted share	\$ (0.78)	\$ (0.06)	\$ (0.06)	\$ (0.23)
Shares used in computation of net loss per basic and diluted share	114,403	113,868	113,539	112,472

(1) The 2006 and 2005 amounts were computed independently for each quarter, and the sum of the quarters may not equal the annual amounts due to rounding.

(2) Represents product sales returns, accounts receivable allowances and other liabilities related to ESP Pharma operations prior to our acquisitions of ESP Pharma and sales returns of *Retavase* from sales made prior to our acquisition of the *Retavase* product in March 2005.

(3) Represents the impairment of product rights. For a description of these charges, see Note 10 to the Consolidated Financial Statements.

Table of Contents

(In thousands, except per share data)	2005 Quarter Ended ⁽¹⁾			
	December 31	September 30	June 30	March 31
Revenues:				
Product sales	\$ 39,012	\$ 43,594	\$ 38,552	\$ 948
Royalties	33,373	26,003	37,528	33,164
License, collaboration and other	11,268	7,536	4,888	4,703
Total revenues	83,653	77,133	80,968	38,815
Costs and expenses:				
Cost of product sales	16,776	22,209	20,135	1,137
Research and development	46,959	49,480	40,339	35,261
Selling, general and administrative	28,119	26,795	19,806	7,666
Acquired in-process research and development ⁽²⁾				79,417
Other acquisition-related charges ⁽³⁾	10,876	6,266	3,207	
Asset impairment charges ⁽⁴⁾	16,044	15,225		
Total costs and expenses	118,774	119,975	83,487	123,481
Operating loss	(35,121)	(42,842)	(2,519)	(84,666)
Interest and other income, net	2,781	2,027	1,873	2,935
Interest expense	(2,655)	(2,671)	(2,709)	(2,142)
Loss before income taxes	(34,995)	(43,486)	(3,355)	(83,873)
Income tax expense (benefit)	(899)	1,680	65	22
Net loss	\$ (34,096)	\$ (45,166)	\$ (3,420)	\$ (83,895)
Net loss per basic and diluted share	\$ (0.31)	\$ (0.43)	\$ (0.03)	\$ (0.87)
Shares used in computation of net loss per basic and diluted share	111,571	105,272	103,705	96,754

- (1) The 2006 and 2005 amounts were computed independently for each quarter, and the sum of the quarters may not equal the annual amounts due to rounding.
- (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 Note 5 to the Consolidated Financial Statements.
- (3) Represents product sales returns, accounts receivable allowances and other liabilities related to ESP Pharma operations prior to our acquisitions of ESP Pharma and sales returns of *Retavase* product from sales made prior to our acquisition of the rights to the *Retavase* product in March 2005.
- (4) Represents the impairment of product rights. For a description of these charges, see Note 10 to the Consolidated Financial Statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures: Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in reaching a reasonable level of assurance that information required to be disclosed by us in the reports that we file or submit 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.

Table of Contents

Management's Annual Report on Internal Control Over Financial Reporting: PDL, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, is responsible for the preparation and integrity of our Consolidated Financial Statements, establishing and maintaining adequate internal control over our financial reporting and all related information appearing in this Annual Report. We employed the Internal Control-Integrated Framework founded by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our 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, 2006.

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.

Our independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report and have issued an audit report on management's assessment of our internal control over financial reporting as well as on the effectiveness of our 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.

Table of Contents

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. maintained effective internal control over financial reporting as of December 31, 2006, 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, 2006, 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, 2006, 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, 2006 and 2005, and the related consolidated statements of operations, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2006 and our report dated February 23, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

February 23, 2007

Table of Contents

Changes in Internal Control Over Financial Reporting: There were no changes in our internal control over financial reporting during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS

The information required by this Item 10 is incorporated by reference from the information provided under the headings Board of Directors, Executive Officers, Audit Committee, Nominating Committee, Code of Ethics, and Compliance with Section 16(a) of the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference from the information provided under the heading Executive Compensation of the Proxy Statement. 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 Equity Compensation Plan Information in Part II, Item 5 of this Annual Report.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this subsection Indebtedness of Management of this Item 13 is incorporated by reference from the information provided under the heading Related Person Transactions of the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated by reference from the information provided under the heading Appointment of Independent Registered Public Accounting Firm of the Proxy Statement.

Table of Contents

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.

Item	Page
<u>Consolidated Balance Sheets</u>	64
<u>Consolidated Statements of Operations</u>	65
<u>Consolidated Statements of Cash Flows</u>	66
<u>Consolidated Statements of Stockholders' Equity</u>	67
<u>Notes to Consolidated Financial Statements</u>	68
<u>Report of Independent Registered Public Accounting Firm</u>	97

(2) The following schedule is filed as part of this Annual Report and should be read in conjunction with the financial statements:
Schedule II Valuation and Qualifying Accounts and Reserves for the year ended December 31, 2006

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

(3) Index to Exhibits

Exhibit Number	Exhibit Title
2.1	Amended and Restated Agreement and Plan of Merger among the Company, Big Dog Bio, Inc. and ESP Pharma Holding Company, Inc., dated 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., and ESP Pharma, Inc., dated January 31, 2005 (incorporated by reference to Exhibit 2.2 to Current Report on Form 8-K filed March 25, 2005)
3.1	Restated Certificate of Incorporation effective March 23, 1993 (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 effective August 21, 2001 (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 effective January 9, 2006 (incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed January 10, 2006)
3.4	Certificate of Designation, Preferences and Rights of the Terms effective August 25, 2006 (incorporated by reference to Exhibit 3.4 to Registration Statement on Form 8-A filed September 6, 2006)
3.5	Amended and Restated Bylaws effective 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, dated July 14, 2003 (incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-3 filed September 11, 2003)

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

- 4.2 Indenture between the Company and J.P. Morgan Trust Company, National Association, dated February 14, 2005 (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed February 16, 2005)
- 4.3 Registration Rights Agreement among the Company and Goldman, Sachs & Co., Citigroup Global Markets Inc. and UBS Securities LLC, dated February 14, 2005 (incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed February 16, 2005)
- 4.4 Rights Agreement, dated August 25, 2006, between the Company and Mellon Investor Services LLC (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed August 29, 2006)
- *10.1 1993 Employee Stock Purchase Plan, as amended June 29, 2000 (incorporated by reference to Exhibit 10.3 to Annual Report on Form 10-K filed March 14, 2002)

Table of Contents

- *10.2 1991 Stock Option Plan, as amended 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)
- *10.3 1991 Stock Option Plan, as amended October 17, 1996 (incorporated by reference to Exhibit 10.2 to Annual Report on Form 10-K filed March 14, 2002)
- *10.4 1999 Nonstatutory Stock Option Plan (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.5 1999 Stock Option Plan, as amended June 14, 2001 (incorporated by reference to Exhibit 10.27 to Annual Report on Form 10-K filed March 14, 2002)
- *10.6 1999 Stock Option Plan, as amended through February 20, 2003 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.7 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 10-Q filed August 14, 2002)
- *10.8 Form of Stock Option Agreement (incentive stock options) under the 1999 Stock Option Plan (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.9 Form of Stock Option Agreement (nonstatutory stock options) under the 1999 Stock Option Plan (incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.10 1999 Nonstatutory Stock Option Plan (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.11 Form of Notice of Grant of Stock Option under the 1999 Nonstatutory Stock Option Plan (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 14, 2002)
- *10.12 Form of Stock Option Agreement under the 1999 Nonstatutory Stock Option Plan (incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.13 2002 Outside Directors Stock Option Plan, as amended June 8, 2005 (incorporated by reference to Exhibit 99.2 to Current Report on Form 8-K filed June 14, 2005)
- *10.14 Form of Nonqualified Stock Option Agreement under the 2002 Outside Directors Plan (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 14, 2002)
- *10.15 2005 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed June 14, 2005)
- *10.16 Form of Notice of Grant of Stock Option under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.17 Form of Stock Option Agreement under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.18 Form of Notice of Grant of Restricted Stock Award under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.19 Form of Restricted Stock Agreement under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to Quarterly Report on Form 10-Q filed August 9, 2006)
- *10.20 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)
- *10.21 Retiree Health Care Plan (incorporated by reference to Exhibit 10.50 to Annual Report on Form 10-K filed March 8, 2004)
- *10.22 Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-1 filed December 16, 1991)
- *10.23 Offer Letter 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)
- *10.24

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

Notice of Grant of Stock Option 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)

- *10.25 Offer Letter between the Company and Ms. Laurie Torres dated September 10, 2003 (incorporated by reference to Exhibit 10.40 to Annual Report on Form 10-K filed March 8, 2004)
- *10.26 Offer Letter between the Company and Mr. Andrew Guggenhime dated February 3, 2006 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 10, 2006)
- 10.27 Agreement of Purchase and Sale between the Company and Ardenstone LLC, effective June 21, 1999 (incorporated by reference to Exhibit 10.46 to Quarterly Report on Form 10-Q filed November 15, 1999)
- 10.28 Promissory Note between Fremont Holding LLC 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)
- 10.29 Deed of Trust and Absolute Assignment of Rents and Leases and Security Agreement (and Fixture Filing) among Fremont Holding LLC, American Securities 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)

Table of Contents

- 10.30 Indenture Agreement between the Company and Chase Manhattan Bank and Trust Company, National Association, dated February 15, 2000 (incorporated by Reference to Exhibit 10.33 to Annual Report on Form 10-K filed March 30, 2000)
- 10.31 Registration Rights Agreement among the Company, CIBC World Markets Corporation, Credit Suisse First Boston Corporation, SG Cowen Securities Corporation, and Warburg Dillon Read LLC, dated February 15, 2000 (incorporated by Reference to Exhibit 10.34 to Annual Report on Form 10-K filed March 30, 2000)
- 10.32 Lease Agreement between the Company and Plymouth Business Center I Partnership, dated February 10, 1992 (incorporated by reference to Exhibit 10.28 to Annual Report on Form 10-K filed March 31, 1993)
- 10.33 Amendment No. 1 to Lease Agreement between the Company and Plymouth Business Center I Partnership, dated July 8, 1993 (incorporated by reference to Exhibit 10.14 to Annual Report on Form 10-K filed March 31, 1994)
- 10.34 Amendment No. 2 to Lease Agreement between the Company and St. Paul Properties, Inc., effective October 25, 1994 (incorporated by reference to Exhibit 10.36 to Annual Report on Form 10-K filed March 31, 1995)
- 10.35 Amendment No. 3 to Lease Agreement between the Company and St. Paul Properties, Inc., effective November 27, 1996 (incorporated by Reference to Exhibit 10.39 to Annual Report on Form 10-K filed February 13, 1997)
- 10.36 Lease Agreement between the Company and St. Paul Properties, Inc., dated May 31, 2001 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 13, 2001)
- 10.37 Lease Agreement among the Company, John Arrillaga (John Arrillaga Survivor's Trust, Successor Trustee), and Richard T. Peery (Richard T. Peery Separate Property Trust, Successor Trustee), dated June 28, 2001 (incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed August 13, 2001)
- 10.38 Lease Agreement between the Company and Abgenix, Inc., dated July 31, 2003 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed November 12, 2003)
- 10.39 Sublease, effective July 6, 2006, between Openwave Systems, Inc. and the Company (for building located at 1400 Seaport Boulevard, Redwood City, California) (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed July 6, 2006)
- 10.40 Triple Net Space Lease, effective July 6, 2006, between Pacific Shores Investors, LLC and the Company (for building located at 1400 Seaport Boulevard, Redwood City, California) (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed July 6, 2006)
- 10.41 Triple Net Space Lease, effective July 6, 2006, between the Pacific Shores Investors, LLC and the Company (for building located at 1500 Seaport Boulevard, Redwood City, California) (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed July 6, 2006)
- 10.42 License Agreement between the Company and the Medical Research Council of the United Kingdom dated July 1, 1989, as amended January 30, 1990 (incorporated by reference to Exhibit 10.10 to Registration Statement on Form S-1 filed December 16, 1991)
- 10.43 Patent Licensing Master Agreement between the Company and Genentech, Inc., dated September 25, 1998 (incorporated by reference to Exhibit 10.10 to Quarterly Report on Form 10-Q filed November 16, 1998)
- 10.44 Amendment No. 1 to Patent Licensing Master Agreement between the Company and Genentech, Inc., dated September 18, 2003 (incorporated by reference to Exhibit 10.45 to Annual Report on Form 10-K filed March 8, 2004)
- 10.45 Amendment No. 2 to Patent Licensing Master Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.46 to Annual Report on Form 10-K filed March 8, 2004)
- 10.46 Amendment No. 1 to the Herceptin® License Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.47 to Annual Report on Form 10-K filed March 8, 2004)
- 10.47 PDL License Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.48 to Annual Report on Form 10-K filed March 8, 2004)
- 10.48 PDL License Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.49 to Annual Report on Form 10-K filed March 8, 2004)
- 10.49 Sublicense and Supply Agreement between Syntex (U.S.A) Inc. 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 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 10, 2005)
- 10.50

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

Letter Agreement dated September 5, 2003 between Roche Palo Alto LLC and ESP Pharma, Inc., amending Sublicense and Supply Agreement (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 10, 2005)

- 10.51 Collaboration Agreement between the Company and Biogen Idec MA Inc., dated September 12, 2005 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed November 8, 2005)
- 10.52 Amended and Restated Co-Development and Commercialization Agreement among the Company, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd dated October 29, 2005 (incorporated by reference to Exhibit 10.54 to Quarterly Report on Form 10-Q filed March 16, 2006.)

Table of Contents

10.53	Second Amended and Restated Worldwide Agreement among the Company, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd dated October 28, 2005 (incorporated by reference to Exhibit 10.55 to Annual Report on Form 10-K filed March 16, 2006)
*10.54	2007 Performance Bonus Program (incorporated by reference to the description under the heading <u>2007 Performance Bonus Program</u> in the Current Report on Form 8-K filed February 21, 2007)
14	See Code of Ethics in Item 10: Executive Officers and Directors, of this Annual Report on Form 10-K
21.1	Subsidiaries of the Company
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)

* Management contract or compensatory plan or arrangement.
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.

Table of Contents**SCHEDULE II****VALUATION AND QUALIFYING ACCOUNTS AND RESERVES**

(In thousands)

(in thousands)	Balance at Beginning of Year	Balance at ESP Pharma Acquisition	Charged to Costs and Expenses	Deductions(1)	Charged to Other Accounts	Balance at End of Year
Year ended December 31, 2006:						
Allowances for accounts receivable	\$ 12,895	\$	\$ 49,682	\$ (49,265)	\$ 397	\$ 13,709
Reserve for excess and obsolete inventory	\$ 1,279	\$	\$ 4,780	\$ (1,014)	\$	\$ 5,045
Year ended December 31, 2005:						
Allowances for accounts receivable	\$	\$ 7,697	\$ 26,944(2)	\$ (22,096)	\$ 350	\$ 12,895
Reserve for excess and obsolete inventory	\$	\$ 1,826	\$ 1,695	\$ (2,242)	\$	\$ 1,279

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

(2) Includes a \$2,847 reclassification made in 2006 for chargeback accrual balance originally recorded as other accrued liabilities in 2005.

Table of Contents

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

Date: March 1, 2007

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

Signature	Title	Date
/s/ MARK McDADE (Mark McDade)	Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2007
/s/ ANDREW L. GUGGENHIME (Andrew L. Guggenhime)	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2007
/s/ MAX LINK (Max Link)	Chairman of the Board of Directors	March 1, 2007
/s/ LAURENCE JAY KORN (Laurence Jay Korn)	Director	March 1, 2007
/s/ JON S. SAXE (Jon S. Saxe)	Director	March 1, 2007
/s/ SAMUEL BRODER (Samuel Broder)	Director	March 1, 2007
/s/ L. PATRICK GAGE (L. Patrick Gage)	Director	March 1, 2007
/s/ KAREN A. DAWES (Karen A. Dawes)	Director	March 1, 2007

Edgar Filing: PDL BIOPHARMA, INC. - Form 10-K

/s/ BRADFORD S. GOODWIN

Director

March 1, 2007

(Bradford S. Goodwin)

/s/ RICH MURRAY

Director

March 1, 2007

(Rich Murray)