
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

CURRENT REPORT

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

Date of report (date of earliest event reported):

February 7, 2005

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

000-19756

(Commission File No.)

94-3023969

(I.R.S. Employer Identification
No.)

34801 Campus Drive

Fremont, California 94555

(Address of principal executive offices)

Registrant's telephone number, including area code:

(510) 574-1400

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition

The following statements include forward looking statements regarding our expectations as to financial results. The actual results are subject to risks and uncertainties including (i) our ability to complete the merger (as defined in Item 9.01 below) and the proposed acquisition of Retavase (as described below), and (ii) the risks as set forth in Exhibit 99.3 attached hereto.

As disclosed in the Summary section of the Preliminary Offering Circular (as defined in Item 8.01 below) attached as Exhibit 99.2 hereto, with respect to the financial performance of PDL, we are confirming our January 12, 2005 financial guidance for 2004 as follows:

We expect our GAAP results for 2004 to include: (a) total revenues in the range of approximately \$93 to \$95 million; (b) interest income for the year of approximately \$10 million and interest expense of approximately \$5 million; (c) total costs and expenses of approximately \$153 to \$158 million; and (d) capital expenditures in the range of approximately \$88 million to \$93 million. As a result, on a GAAP basis, we expect a net loss in 2004 in the range of approximately \$52 million to \$56 million, or approximately \$0.55 to \$0.60 per basic and diluted share.

On a non-GAAP basis, we expect: (a) total revenues in the range of approximately \$93 to \$95 million; (b) interest income for the year of approximately \$10 million and interest expense of approximately \$5 million; (c) total costs and expenses of approximately \$149 to \$154 million (excluding approximately \$2.5 million for amortization of intangible assets, \$1.3 million for stock-based compensation expense and \$0.3 million for restructuring charges); and (d) capital expenditures in the range of approximately \$88 million to \$93 million. As a result, on a non-GAAP basis, we expect a net loss in 2004 in the range of approximately \$48 million to \$52 million, or approximately \$0.50 to \$0.55 per basic and diluted share.

As announced on January 25, 2005, we have entered into a definitive agreement to acquire ESP Pharma Holding Company, Inc., a Delaware corporation ("ESP Pharma"), which generated total net product sales in excess of approximately \$90 million in 2004. The earnings contribution of ESP Pharma to the performance of the combined enterprise on a pro forma basis for 2004 is not expected to be significant. As further announced on February 1, 2005, ESP Pharma entered into an agreement to acquire certain product rights and assets relating to a biologics product known as Retavase® from Centocor, Inc., a biopharmaceutical operating company of Johnson & Johnson. Retavase generated net product sales of approximately \$50 million in 2004.

We expect to provide a review of 2004 as part of our year-end conference call now scheduled for March 14, 2005. In that call we also plan to provide an update on the timing of the closing of the ESP and Retavase transactions as well as 2005 financial guidance for the combined enterprise. In addition to providing more detailed financial information, we anticipate royalty revenue for 2005 will exceed approximately \$100 million, and assuming the closing of

the ESP Pharma acquisition and the related Retavase purchase occur on or before March 31, 2005, we expect to have product revenues in excess of \$110 million for 2005.

To supplement the information that is presented in accordance with U.S. generally accepted accounting principles (“GAAP”), we provide certain non-GAAP financial measures that exclude from the directly comparable GAAP measures certain non-cash charges, including charges related to acquisitions such as acquired in-process research and development and amortization of workforce as well as stock compensation expense. We believe that these non-GAAP measures enhance an investor’s overall understanding of our financial performance and future prospects by reconciling more closely to the actual cash expenses of the Company in its operations as well as excluding expenses that in management’s view are unrelated to our core operations, the inclusion of which may make it more difficult for investors and financial analysts reporting on the Company to compare our results from period to period. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with GAAP, and non-GAAP financial measures as reported by the Company may not be comparable to similarly titled items reported by other companies.

Item 8.01 Other Events.

On February 7, 2005, Protein Design Labs, Inc. (“PDL”) announced the offering of up to \$250 million of convertible senior notes due 2012 in a 144A private placement (the “Notes Offering”). The foregoing matter is discussed in greater detail in PDL’s press release, a copy of which is attached hereto as Exhibit 99.1.

In connection with the Notes Offering, PDL has prepared a preliminary offering circular (the “Preliminary Offering Circular”) to be distributed to certain qualified institutional buyers solely for the purpose of considering the purchase of the notes offered in the Notes Offering. Copies of certain sections of the Preliminary Offering Circular, including previously nonpublic material information, have been attached hereto as Exhibits 99.3 and 99.4.

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Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

As disclosed in the Current Reports on Form 8-K filed with the Commission on January 24, 2005 and February 1, 2005, PDL announced that it had entered into an Agreement and Plan of Merger, dated as of January 24, 2005 and amended as of January 31, 2005 (the “Merger Agreement”), by and among PDL, Big Dog Bio, Inc., a Delaware corporation and a wholly-owned subsidiary of PDL (“Merger Sub”), ESP Pharma and certain other individuals and entities, pursuant to which Merger Sub will be merged with and into ESP Pharma (the “Merger”), with ESP Pharma surviving the Merger as a wholly owned subsidiary of PDL.

See Exhibit 99.5 for the audited financial statements of ESP Pharma for the period from inception (April 15, 2002) to December 31, 2002 and for the year ended December 31, 2003 and the unaudited financial statements for the nine month periods ended September 30, 2004 and 2003.

The sections of Exhibit 99.2 attached hereto set forth under the subheadings "Our Company", "Our Products", "Business and Commercialization Strategy" and "Recent Developments – Agreement to Acquire ESP Pharma" and "– Retavase" are deemed filed under the Securities Exchange Act of 1934.

(b) Pro Forma Financial Statements.

See Exhibit 99.6 for pro forma financial information of PDL for the year ended December 31, 2003 and for the nine month period ended September 30, 2004.

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
99.1	Press Release dated February 7, 2005 regarding PDL’s offering of convertible senior notes due 2012.
99.2	Summary Section as set forth in the Preliminary Offering Circular regarding PDL’s offering of convertible senior notes due 2012.
99.3	Risk Factors as set forth in the Preliminary Offering Circular regarding PDL’s offering of convertible senior notes due 2012.
99.4	Business Section as set forth in the Preliminary Offering Circular regarding PDL’s offering of convertible senior notes due 2012.
99.5	Audited financial statements of ESP Pharma Holding Company, Inc. for the period from inception (April 15, 2002) to December 31, 2002 and for the year ended December 31, 2003 and unaudited financial statements for the nine month periods ended September 30, 2004 and 2003.
99.6	Pro forma financial information of PDL for the year ended December 31, 2003 and for the nine month period ended September 30, 2004.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 7, 2005

PROTEIN DESIGN LABS, INC.

By: /s/ Sergio Garcia-Rodriguez
Sergio Garcia-Rodriguez
Vice President, Legal, General Counsel and
Assistant Secretary

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-36708 and 333-108701), and in the related prospectuses, and on Form S-8 (Nos. 333-44762, 333-87957, 33-65224, 33-50116, 33-50114, 33-96318, 333-68314 and 333-104170), pertaining to the 1993 Employee Stock Purchase Plan, Outside Directors Stock Option Plan, 1991 Stock Option Plan, 1999 Nonstatutory Stock Option Plan, 1999 Stock Option Plan, and 2002 Outside Directors Stock Option Plan of Protein Design Labs, Inc. of our report dated March 12, 2004, with respect to the consolidated financial statements of ESP Pharma Holdings and Subsidiary as of December 31, 2003 and 2002, for the year ended December 31, 2003 and for the period from April 15, 2002 (inception) to December 31, 2002, included in this Current Report (Form 8-K) dated February 7, 2005.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey
February 7, 2005



www.pdl.com

For Immediate Release

Contact:

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Corporate Communications
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**PROTEIN DESIGN LABS ANNOUNCES INTENT
TO OFFER \$250 MILLION OF CONVERTIBLE SENIOR
NOTES IN PRIVATE OFFERING**

Fremont, Calif., February 7, 2005 — Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) announced today that it intends to raise approximately \$250 million through an offering of seven-year notes that are convertible into shares of PDL common stock, subject to market and other conditions. In addition, the initial purchasers have a 30-day option to purchase up to an additional \$50 million in principal amount of seven-year notes from PDL.

PDL expects to use the net proceeds from the offering for working capital and other general corporate purposes, including research and development, capital expenditures and expansion of our manufacturing facilities. PDL may use a portion of the net proceeds to pay for the proposed acquisitions of ESP Pharma Holding Company, Inc. and Retavase®, and to acquire or invest in other complementary businesses, products or technologies.

This press release is neither an offer to sell nor a solicitation of an offer to buy any of the convertible senior notes, nor shall there be any sale of these notes in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

The notes and the common stock issuable upon conversion of the notes have not been registered under the Securities Act of 1933, as amended (the Securities Act) or any state securities laws, and are being offered only to qualified institutional buyers in reliance on Rule 144A under the Securities Act. Unless so registered, the notes and common stock issued upon conversion of the notes may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws.

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The foregoing contains forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those in the forward-looking statements, including but not limited to the ability of PDL to complete the sale of the notes and the ability of PDL to effectively use the proceeds of the sale for the indicated purposes. Factors that may cause such differences are discussed in PDL's Annual Report on Form 10-K for the year ended December 31, 2003, PDL's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, PDL's Form 8-K filed on February 7, 2005, and other filings made with the Securities and Exchange Commission. In addition, PDL may be unable to consummate the acquisition of ESP Pharma Holding Company, Inc. or to develop its or ESP Pharma's products and technologies, may experience failures or delays in preclinical or clinical trials and may be subject to administrative proceedings or disputes regarding its intellectual property. All forward-looking statements included in this press release are based upon information available to PDL as of the date hereof, and PDL assumes no obligation to update any such forward-looking statements.

Protein Design Labs and the PDL logo are registered U.S. trademarks of Protein Design Labs, Inc.

SUMMARY

The following summary may not contain all the information that may be important to you. You should read the entire offering circular, as well as the information incorporated by reference in this offering circular, before making an investment decision. When used in this offering circular, the terms “PDL”, “we”, “our” and “us” refer to Protein Design Labs, Inc. and its consolidated subsidiaries, unless otherwise specified.

Our Company

We are a recognized leader in the discovery and development of humanized monoclonal antibodies for the treatment of disease. Our patented antibody humanization technology is applied to promising mouse antibodies. By making certain modifications to the mouse antibody that make it more like a human antibody, our technology enhances the utility of such antibodies, while retaining their biological activity, for human therapeutic use. We believe our technology for the creation of humanized therapeutic monoclonal antibodies is the most widely validated in our industry. As of December 31, 2004, a total of eight marketed products were licensed under our humanization patents and we are aware of more than 40 humanized antibodies in clinical stage development worldwide by various pharmaceutical and biotechnology companies, of which a large number may be covered under our patent agreements. Based on the strength of our proprietary platform, the number of antibody programs we have in development and the flexibility provided by our current financial position, our goal for our existing pipeline is to launch our first PDL-developed proprietary antibody product into the North American market by the end of 2007.

We license our patents covering numerous humanized antibodies in return for license fees, annual maintenance payments and royalties on product sales. Eight of the nine humanized antibodies currently approved by the U.S. Food and Drug Administration (FDA) are licensed under our patents and seven of these licensed products generated royalties to PDL that were recognized in 2004: Genentech, Inc.’s Herceptin®, Xolair®, Raptiva® and Avastin®; MedImmune, Inc.’s Synagis®; Wyeth Pharmaceuticals’ Mylotarg®; and Hoffmann-La Roche’s Zenapax®. Combined annual worldwide sales of these products exceeded \$2.9 billion in 2004. In 2003, we received \$52.7 million in product royalties, and for the nine month period ended September 30, 2004, we received \$63.9 million in product royalties. Additionally, Elan Corporation, plc entered into a license under our patents for the Tysabri® antibody product, which was approved by the FDA in November 2004. Tysabri is licensed under PDL’s humanization patents and we expect to begin to receive royalties on sales of that humanized antibody product in the first quarter of 2005.

In January 2005, we entered into a definitive agreement with ESP Pharma Holding Company, Inc. (ESP Pharma), a privately held, hospital-focused pharmaceutical company, under which PDL will acquire ESP Pharma for \$300 million in cash and approximately \$175 million in PDL common stock, or an aggregate value of approximately \$475 million, plus the assumption of net debt of approximately \$14 million. In February 2005, this agreement was amended to reflect ESP Pharma’s agreement to acquire from Centocor, Inc. (Centocor), a biopharmaceutical operating company of Johnson & Johnson, rights to manufacture, develop, market and distribute Retavase® (reteplase) in the United States and Canada, including an increase in the purchase price by \$25 million in cash payable to the ESP Pharma stockholders at the closing of the ESP Pharma acquisition. The acquisition price to be paid to Centocor for the rights to Retavase is \$110 million, representing approximately two times net 2004 product sales. Milestone payments of up to \$45 million will be made if additional conditions relating to ongoing clinical trials and manufacturing arrangements are satisfied.

By adding marketed products and sales and distribution capabilities to our antibody development and humanization technology platform, the ESP Pharma acquisition is intended to

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

Our Products

We currently have four antibodies in clinical development for various disease indications, with a near-term emphasis on autoimmune and inflammatory diseases and cancer, specifically inflammatory bowel disease, asthma and solid tumors. Our three lead programs are as follows:

Nuvion (visilizumab, anti-CD3). Nuvion is in a Phase I/II clinical study in patients with intravenous steroid-refractory ulcerative colitis. We plan to conduct a Nuvion end-of-Phase I meeting with the FDA late in the first quarter of 2005. We anticipate that the future registration pathway will be based on the Special Protocol Assessment process. If our discussions with the FDA are successful, we expect to seek approval to initiate Phase III studies by the fourth quarter of 2005 in the intravenous steroid-refractory ulcerative colitis setting. We have received Fast Track status from the FDA for the investigation of Nuvion in patients with intravenous steroid-refractory ulcerative colitis, which is the first PDL program to receive such designation.

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

Effective October 2003, we paid Roche \$80 million in cash for return of exclusive rights to daclizumab in indications other than transplantation. Under the terms of this arrangement, Roche has the right to put these transplant indications as early as 2005 upon six months’ prior written notice to us. If Roche does not exercise its put right, we have the right to acquire these transplant indications, which right is exercisable beginning in the second quarter of 2006 and effective no earlier than six months following the date of notice of the exercise but no later than July 1, 2007. To effectuate the transfer of Zenapax in the transplantation indications, we will pay an additional exercise fee to Roche based on the average annual gross sales of Zenapax during the period from January 1, 2004, through either the calendar quarter prior to the date we exercise our option, or Roche’s notice of its decision to transfer the rights to us prior to our exercise date. If we do not receive transplantation rights, we would pay royalties to Roche on any sales in all diseases other than transplantation, and we would continue to receive royalties on sales of Zenapax in transplantation.

In September 2004, we entered into an agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases. Under the terms of this agreement, we received a \$17.5 million upfront payment and may receive up to

\$187.5 million in milestone payments for successful further development and commercialization of daclizumab. This agreement provides that Roche and PDL will globally co-develop daclizumab in asthma, equally share development expenses and co-promote the product in the United States. Outside the United States, PDL will receive royalties on net sales of the product in asthma and related respiratory diseases.

M200 (volociximab, anti- $\alpha5\beta1$ integrin antibody). Our anti- $\alpha5\beta1$ integrin chimeric antibody program, M200, is in Phase II clinical studies for advanced solid tumors. We have initiated a series of open-label, Phase II clinical trials which are planned to study M200 in the treatment of renal, melanoma, pancreatic, and non-small cell lung cancers. The renal cell carcinoma study initiated in January 2005 is a single agent trial, while the studies in the other three malignancies will be combination studies with standard therapy.

Business and Commercialization Strategy

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

- **Fully-integrated commercial organization.** We believe that our current clinical development programs address areas of significant unmet medical need that could, at least in North America, effectively be serviced with a modest-sized sales force of between 80 to 125 representatives. If our programs are successful in later stage trials, and subsequently gain regulatory approval for therapeutic use in the United States and Canada, our goal is to create a North American hospital-focused sales and marketing operation related to our core therapeutic focus in inflammatory bowel disease by 2007. Prior to that time, we expect to develop a small PDL sales and marketing capability in transplantation in connection with the anticipated reversion of rights to manufacture and market Zenapax, and we believe such infrastructure would be complementary to our potential marketing needs as they relate to Nuvion for ulcerative colitis. In the event the ESP Pharma transaction is completed, we believe the integration of this sales and marketing capability with ESP Pharma's in-line marketing and sales team will help to enable successful commercialization following the reversion of Zenapax transplant rights to PDL.
- **Development of proprietary drugs.** Our most advanced clinical-stage programs are Nuvion antibody product for potential treatment of intravenous steroid-refractory ulcerative colitis (IVSR-UC), and daclizumab for the potential treatment of moderate-to-severe asthma. Additionally, in 2003, we repurchased rights from Roche to market and manufacture daclizumab in indications other than transplantation, and we obtained an option to acquire rights to daclizumab in transplant indications, marketed as Zenapax, by no later than 2007. We believe that the market potential for daclizumab could be expanded beyond the current approved indication in renal transplantation through potential development of this already-marketed antibody in other autoimmune or inflammatory disease indications, such as asthma and multiple sclerosis (MS). In September 2004, we completed an agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases.
- **Licensing arrangements.** While our goal is to market our products in North America, for all our products in development, we may out-license rights, even within the United States, to other biotechnology or pharmaceutical companies with respect to certain indications requiring specific expertise or large development and marketing efforts, such as MS or some oncology indications. For example, we have partnered with Roche for the joint development and commercialization of daclizumab in asthma. We retain worldwide rights to each of the other products we are currently developing. We may receive upfront fees, milestone payments or other types of funding under these arrangements, in addition to possible royalties or other profit-sharing rights on any product sales by such marketing partners.

Recent Developments

Agreement to Acquire ESP Pharma. In January 2005, we entered into a definitive agreement with ESP Pharma, a privately held, hospital-focused pharmaceutical company, under which PDL will acquire ESP Pharma for \$300 million in cash and approximately \$175 million in PDL common stock, or an aggregate value of approximately \$475 million, plus the assumption of net debt of approximately \$14 million. On February 1, 2005, PDL and ESP Pharma agreed to increase the purchase price by \$25 million in cash in connection with ESP Pharma's agreement to acquire Retavase from Centocor.

ESP Pharma has a hospital-focused sales force committed to the acute-care setting. ESP Pharma has grown its sales force from 22 as of September 2002 to 66 field representatives as of January 2005 and intends to employ approximately 85 representatives by the end of 2005. If the Retavase acquisition is completed, ESP Pharma intends to further expand its sales force to approximately 120 representatives. The current sales team allows ESP Pharma to market to approximately 800 hospitals in the U.S. Once inside the hospitals, the ESP Pharma sales force focuses on the Cardiac, Neurological and Intensive Care Unit, or ICU, sections. For the nine months ended September 30, 2004, unaudited net sales and EBITDA (before nonrecurring expenses) for ESP Pharma were approximately \$68 million and \$19.5 million, respectively.

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

- Cardene IV is the only branded, U.S.-approved dihydropyridine class calcium channel blocker delivered intravenously that is indicated for treating short-term treatment of hypertension when oral therapy is not feasible or desirable. The product is patent protected in the United States through November 2009.
- IV Busulfex®, an IV formulation of Busulfan, is a chemotherapeutic agent used as part of a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. IV Busulfex provides antitumor effect to eradicate residual malignancy, ablation of the bone marrow to make space for the new source of stem cells and to provide immunosuppression to prevent graft rejection.

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

Financial Update. With respect to the financial performance of PDL, we are confirming our January 12, 2005 financial guidance for 2004 as follows:

We expect our GAAP results for 2004 to include: (a) total revenues in the range of approximately \$93 to \$95 million; (b) interest income for the year of approximately \$10 million and interest expense of approximately \$5 million; (c) total costs and expenses of approximately \$153 to \$158 million; and (d) capital expenditures in the range of approximately \$88 million to \$93 million. As a

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result, on a GAAP basis, we expect a net loss in 2004 in the range of approximately \$52 million to \$56 million, or approximately \$0.55 to \$0.60 per basic and diluted share.

On a non-GAAP basis, we expect: (a) total revenues in the range of approximately \$93 to \$95 million; (b) interest income for the year of approximately \$10 million and interest expense of approximately \$5 million; (c) total costs and expenses of approximately \$149 to \$154 million (excluding approximately \$2.5 million for amortization of intangible assets, \$1.3 million for stock-based compensation expense and \$0.3 million for restructuring charges); and (d) capital expenditures in the range of approximately \$88 million to \$93 million. As a result, on a non-GAAP basis, we expect a net loss in 2004 in the range of approximately \$48 million to \$52 million, or approximately \$0.50 to \$0.55 per basic and diluted share.

As announced on January 25, 2005, we have entered into a definitive agreement to acquire ESP Pharma, which generated total net product sales in excess of approximately \$90 million in 2004. The earnings contribution of ESP Pharma to the performance of the combined enterprise on a pro forma basis for 2004 is not expected to be significant. As further announced on February 1, 2005, ESP Pharma entered into an agreement to acquire certain product rights and assets relating to a biologics product known as Retavase® from Centocor. Retavase generated net product sales of approximately \$50 million in 2004.

We expect to provide a review of 2004 as part of our year-end conference call now scheduled for March 14, 2005. In that call we also plan to provide an update on the timing of the closing of the ESP and Retavase transactions as well as 2005 financial guidance for the combined enterprise. In addition to providing more detailed financial information, we anticipate royalty revenue for 2005 will exceed approximately \$100 million, and assuming the closing of the ESP Pharma acquisition and the related Retavase purchase occur on or before March 31, 2005, we expect to have product revenues in excess of \$110 million for 2005.

Protein Design Labs, the PDL logo and Nuvion are registered U.S. trademarks, and HuZAF and ZamyI are trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche. Cardene IV, IV Busulfex, Tenex, Sectral, and Ismo are registered trademarks of ESP Pharma. Retavase is a registered U.S. trademark of Centocor. All other company names and trademarks included in this offering circular are trademarks, registered trademarks or trade names of their respective owners.

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RISK FACTORS

An investment in the 2005 Notes involves a high degree of risk. You should carefully consider the following factors, in addition to the other information included and incorporated by reference in this offering circular, in evaluating us, our business and an investment in the 2005 Notes. Any of the following risks, as well as other risks and uncertainties, could harm our business and financial results or condition and cause the value of the 2005 Notes to decline, which in turn could cause you to lose all or part of your investment. Additional risks not currently known to us also may harm our business.

Risks Related To Our Business

We have a history of operating losses and may never achieve sustained profitability.

In general, our expenses have exceeded revenues. As of September 30, 2004, we had an accumulated deficit of approximately \$259 million. We expect our expenses to increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain.

Our commitment of resources to the continued development of our products will require significant additional funds for development. Our operating expenses may also increase as:

- some of our earlier stage potential products move into later stage clinical development;
- additional potential products are selected as clinical candidates for further development;
- we pursue clinical development of our potential products in new indications;
- we invest in additional manufacturing capacity;
- we build commercial infrastructure to market our products in North America;
- we defend or prosecute our patents and patent applications; and
- we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new agreements with third-party business partners, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses and may require additional capital to fully execute our business strategy.

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

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

- the seasonality of sales of licensed products;
- the existence of competing products;

- the market launch of recently licensed products;
- the marketing efforts of our licensees;
- potential reductions in royalties receivable due to credits for prior payments to us;
- the timing of royalty reports, some of which are required quarterly and others semi-annually; and
- our ability to successfully defend and enforce our patents.

We receive royalty revenues on sales of the product Synagis, which product is marketed by MedImmune, Inc. (MedImmune). This product has higher sales in the fall and winter, which to date have resulted in much higher royalties paid to us in our first and second quarters than in other quarters. The seasonality of Synagis sales will contribute to fluctuation of our revenues from quarter to quarter.

License and other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees, payments for manufacturing and clinical development services, and payments for the achievement of milestones under new and existing agreements with third-party business partners. Revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

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

In addition, our expenses or other operating results may fluctuate due to the accounting treatment of securities we own or may purchase or securities we have issued or may issue. For example, we expect to recognize expense for employee stock options beginning in the third quarter of 2005, and as a result, we will incur significantly higher losses. In addition, we hold a \$30 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the change in the value of the Exelixis stock in our financial statements such that changes in the Exelixis stock price contribute to fluctuations of our operating results from quarter to quarter.

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

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

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European antibody humanization patent. We

appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if the opponents are successful, our ability to collect royalties on European sales of antibodies humanized by others would depend on: (i) the scope and validity of our second European patent; and (ii) whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents, and if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to our related patents in other jurisdictions, including the United States. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents.

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

We intend to vigorously defend the European patents in these proceedings. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the European opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

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

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

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

patents, our revenues and financial condition could be adversely affected, and we could be required to undertake additional actions, including litigation, to enforce our rights. Such efforts would increase our expenses and could be unsuccessful.

If we are unable to protect our patents and proprietary technology, we may not be able to compete successfully.

Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology. A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of our patents or result in a significant reduction in the scope of our issued patents.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation in claim scope could reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

We may require additional patent licenses in order to manufacture or sell our potential products.

Other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain

required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or may not be able to market our products at all.

Celltech, for example, has been granted a European patent covering humanized antibodies, which we have opposed. At an oral hearing in September 2000, the Opposition Division of the European Patent Office decided to revoke this patent. Celltech appealed that decision, but the Technical Board of Appeal recently rejected the appeal. As a result, the decision revoking the patent is final; no further appeals are available. However, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. At an oral hearing in January 2005, the Opposition Division decided to revoke this patent. Celltech has filed a notice of appeal. We cannot predict whether Celltech's appeal will be successful, or whether it will be able to obtain the grant of a patent from the pending divisional application with claims broad enough to generally cover humanized antibodies. Celltech has also been issued a corresponding U.S. patent that contains claims that may be considered broader in scope than its first European patent. In addition, Celltech was recently issued a second U.S. patent with claims that may be considered broader than its first U.S. patent. We have entered into an agreement with Celltech providing each company with the right to obtain nonexclusive licenses for up to three antibody targets under the other company's humanization patents. We recently negotiated an extension that has extended the term of the current agreement to December 2014. Notwithstanding this agreement, if our humanized antibodies were covered by Celltech's European or U.S. patents and if we need more than the three licenses under those patents currently available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

In addition, if the Celltech U.S. patent or any related patent applications conflict with our U.S. patents or patent applications, we may become involved in proceedings to determine which company was the first to invent the products or processes contained in the conflicting patents. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation would reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

We do not have a license to an issued U.S. patent assigned to Stanford University and Columbia University, which may cover a process we use to produce our potential products. We have been advised that an exclusive license has been previously granted to a third party, Centocor, under this patent. If our processes were found to be covered by either of these patents, we might be required to obtain licenses or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflicts with these patents or to obtain licenses on acceptable terms.

If our research efforts are not successful, we may not be able to effectively develop efficacious or commercially viable products.

We have not commercialized any antibody products. We are engaged in research activities intended to identify antibody product candidates that we may enter into clinical development. These research activities include efforts to discover and validate new targets for antibodies in our areas of therapeutic focus. We obtain new targets through our own drug discovery efforts and through in-licensing targets from institutions or other biotechnology or pharmaceutical companies. Our success in identifying new antibody product candidates depends upon our ability to discover and validate new targets, either through our own research efforts, or through in-licensing or collaborative

arrangements. In order to increase the possibilities of identifying antibodies with a reasonable chance for success in clinical studies, part of our business strategy is to identify a number of potential targets. Our antibody product candidates are in various stages of development and many are in an early

development stage. If we are unsuccessful in our research efforts to identify and obtain rights to new targets and generate antibody product candidates that lead to the required regulatory approvals and the successful commercialization of products, our ability to develop new products could be harmed.

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

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

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

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

Completion of clinical trials may take several years or more. The length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly according to the type, complexity, novelty and intended use of the product candidate and is difficult to predict. Further, we, the FDA, Investigational Review Boards or data safety monitoring boards may decide to temporarily suspend or permanently terminate ongoing trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to preclinical or clinical trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future. Despite the time and expense incurred, we cannot guarantee that we will successfully

develop commercially viable products that will achieve FDA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

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

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

Early clinical trials such as Phase I and II trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed. We may decide, or the FDA may require us, to make changes in our plans and protocols. Such changes may relate, for example, to changes in the standard of care for a particular disease indication, comparability of efficacy and toxicity of materials where a change in materials is proposed, or competitive developments foreclosing the availability of expedited approval procedures. We may be required to support proposed changes with additional preclinical or clinical testing, which could delay the expected time line for concluding clinical trials.

Larger or later stage clinical trials may not produce the same results as earlier trials. Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials. As an example, the daclizumab Phase II clinical trials in moderate-to-severe ulcerative colitis, which did not meet the primary endpoint in May 2004, were based on earlier Phase I physician-sponsored clinical trials that indicated safety and biological activity for a small number of patients in this indication.

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

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

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

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

Additionally, regulatory review of our clinical trial protocols may cause us in some cases to delay or abandon our planned clinical trials. Our potential inability to commence or continue clinical trials, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of our potential products, further adds to the uncertainty of regulatory approval for our potential products.

Our clinical trial strategy may increase the risk of clinical trial difficulties.

Research, preclinical testing and clinical trials may take many years to complete, and the time required can vary depending on the indication being pursued and the nature of the product. We may at times elect to use aggressive clinical strategies in order to advance potential products through clinical development as rapidly as possible. For example, our current projection for regulatory approval of Nuvion in the United States in 2007 depends upon regulatory approval to initiate Phase III studies in 2005. We anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

We may be unable to enroll sufficient patients in a timely manner in order to complete our clinical trials.

The rate of completion of our clinical trials, and those of our collaborators, is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population;
- perceived risks and benefits of the drug under study;
- availability of competing therapies, including those in clinical development;
- availability of clinical drug supply;
- availability of clinical trial sites;
- design of the protocol;
- proximity of and access by patients to clinical sites;
- patient referral practices of physicians;
- eligibility criteria for the study in question; and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may result in our being unable to successfully achieve our projected development timelines, or potentially even lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication. For example, our current expectations for registrational studies and regulatory approval for Nuvion are dependent on our ability to timely enroll a worldwide clinical program.

Our revenues from licensed technologies depend on the efforts and successes of our licensees.

In those instances where we have licensed rights to our technologies, the product development and marketing efforts and successes of our licensees will determine the amount and timing of royalties we may receive, if any. We have no assurance that any licensee will successfully complete the product

development, regulatory and marketing efforts required to sell products. The success of products sold by licensees will be affected by competitive products, including potential competing therapies that are marketed by the licensees or others.

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

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

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

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

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

commercialization of any resulting products. In these circumstances, our ability to pursue potential products could be severely limited.

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

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

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

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

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with partners. To market products directly, we must establish an internal marketing and sales group, contract for these services, or obtain the assistance of another company. Pursuant to the terms of our revised collaboration agreement with Roche, we have a reversion right, exercisable in 2006, but effective in 2007, to repurchase all rights, including marketing rights, in transplant indications, unless earlier elected by Roche. If we elect to exercise this right, or Roche elects to transfer such rights to us, we will be responsible for the marketing and commercialization of Zenapax in all indications worldwide. While Roche must notify us at least six months prior to a transfer of Zenapax to us, there can be no assurance that we will be able to establish marketing, sales and distribution capabilities for Zenapax in a timely manner. Further, we may not be able to establish such capabilities for our other products or succeed in gaining market acceptance for our products. If we were to enter into co-promotion or other marketing arrangements with pharmaceutical or biotechnology companies, our revenues would be subject to the payment provisions of these arrangements and could largely depend on these partners' marketing and promotion efforts.

If we do not attract and retain key employees, our business could be impaired.

To be successful we must attract additional and retain qualified clinical, manufacturing, scientific and management personnel. If we are unsuccessful in attracting and retaining qualified personnel, our business could be impaired.

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

The manufacture of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. We will need to manufacture such antibody therapeutic products in a facility and by an appropriately validated process that comply

with FDA, European, and other regulations. Our manufacturing operations will be subject to ongoing, periodic unannounced inspection by the FDA and state agencies to ensure compliance with good manufacturing practices. If we are unable to manufacture product or product candidates in accordance with FDA and European good manufacturing practices, we may not be able to obtain regulatory approval for our products.

We intend to continue to manufacture potential products for use in preclinical and clinical trials using our manufacturing facility in accordance with standard procedures that comply with appropriate regulatory standards. The manufacture of sufficient quantities of antibody products that comply with these standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays and/or the inability to produce sufficient quantities of such products in a commercially viable manner. Our collaborative partners and we have experienced some manufacturing difficulties. Product supply interruptions could significantly delay clinical development of our potential products, reduce third-party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization and sales of these products. Manufacturing difficulties can even interrupt the supply of marketed products, thereby reducing revenues and risking loss of market share.

We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture all of our potential products on a commercial scale. To obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to improve and expand our manufacturing capabilities. Our current plans are to validate and use our new manufacturing plant in Brooklyn Park, Minnesota in order to manufacture initial commercial supplies of Nuvion and daclizumab. Our ability to file for, and to obtain, regulatory approvals for such products, as well as the timing of such filings, will depend on our ability to successfully operate our manufacturing plant. We may encounter problems with the following:

- production yields;
- quality control and assurance;
- availability of qualified personnel;
- availability of raw materials;
- adequate training of new and existing personnel;
- on-going compliance with our standard operating procedures;
- on-going compliance with FDA regulations;
- production costs; and
- development of advanced manufacturing techniques and process controls.

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

In addition, as we implement validation of our Brooklyn Park, Minnesota manufacturing facility, we are implementing an enterprise resource management software platform to support our operations, including our new manufacturing facility. These efforts will involve substantial costs and resource commitments. Any construction, validation, or other delays could impair our ability to obtain necessary regulatory approvals and to produce adequate commercial supplies of our potential products on a timely basis. Failure to do so could delay commercialization of some of our products and could impair our competitive position.

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

If we make changes in the manufacturing process, we may be required to demonstrate to the FDA and corresponding foreign authorities that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. Changing the manufacturing site is considered to be a change in the manufacturing process and so moving production to our Brooklyn Park manufacturing facility from our Plymouth facility or from third parties will entail manufacturing changes. Further, any significant manufacturing changes for the production of our product candidates could result in delays in development or regulatory approval or in the reduction or interruption of commercial sales of our product candidates. Our inability to maintain our manufacturing operations in compliance with applicable regulations within our planned time and cost parameters could materially harm our business, financial condition and results of operations.

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

Additionally, when we assume responsibility for manufacturing Zenapax, we may be required to demonstrate that the material manufactured by Roche does not differ significantly from the material we produce at our manufacturing facilities. Showing comparability between the material we produce before and after manufacturing changes, and in the case of Zenapax, between the material produced by Roche and the drug material produced by us, is particularly important if we want to rely on results of prior preclinical studies and clinical trials performed using the previously produced drug material. Depending upon the type and degree of differences between the newer and older drug material, and in the case of Zenapax, between our material and Roche material, we may be required to conduct additional animal studies or human clinical trials to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material. Our ability to successfully market and develop Zenapax, in particular in transplantation, depends upon our success in manufacturing Zenapax at commercial scale. There can be no assurance that we will successfully and in a timely manner be capable of manufacturing Zenapax following the transfer of Zenapax to us by Roche.

We have made manufacturing changes and are likely to make additional manufacturing changes for the production of our products currently in clinical development. These manufacturing changes or an inability to immediately show comparability between the older material and the newer material after making manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

Our revenue may be adversely affected by competition and rapid technological change.

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed, are developing, or may develop technologies that may compete with our antibody technology platform. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our

collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

Any product that our collaborative partners or we succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, markets Simulect® (basiliximab), a product competitive with Zenapax, in the United States and Europe. Novartis has acquired a significant interest in Roche. As a result of Novartis' relationship with Roche, Roche may not devote significant resources to the marketing and sales of Zenapax, which could harm our business.

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

All of our products in development are subject to risks associated with applicable government regulations. The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and non-clinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires a number of years and the expenditure of substantial resources. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

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

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

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

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process and quality control procedures are required to comply with the applicable FDA current good manufacturing practice (cGMP) regulations and other regulatory requirements. Good manufacturing practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities, including our facility, must pass an inspection by the FDA before initiating commercial manufacturing of any product. Pharmaceutical product manufacturing establishments are also subject to inspections by state and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the United States, foreign manufacturing establishments must comply with these FDA approved guidelines. These foreign manufacturing establishments are subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. The FDA enforces post-marketing regulatory requirements, such as cGMP requirements, through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manufacturing operations.

In addition, during 2003 the FDA completed the transfer of regulatory responsibility, review and continuing oversight for many biologic therapeutic products, including antibody therapeutics, from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This transfer of responsibility could result in new regulatory standards, which could result in delays in development or regulatory approvals for our potential products. In addition, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured

by Roche is comparable to the material we produce at our manufacturing facilities. New regulations resulting from the transfer of regulatory responsibility from CBER to CDER could make it more difficult for us to show comparability which could delay development and regulatory approval of Zenapax in new indications or reduce or interrupt commercial sales of Zenapax for the prevention of acute kidney transplant rejection.

For the marketing of pharmaceutical products outside the United States, our collaborative partners and we are subject to foreign regulatory requirements and, if the particular product is manufactured in the United States, FDA and other U.S. export provisions. Requirements relating to the manufacturing, conduct of clinical trials, product licensing, promotion, pricing and reimbursement vary widely in different countries. Difficulties or unanticipated costs or price controls may be encountered by us or our licensees or marketing partners in our respective efforts to secure necessary governmental approvals. This could delay or prevent us, our licensees or our marketing partners from marketing potential pharmaceutical products.

Both before and after approval is obtained, a biologic pharmaceutical product, its manufacturer and the holder of the Biologics License Application (BLA) for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA if applicable regulatory criteria are not satisfied. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which the pharmaceutical product may be marketed. In their regulation of advertising, the FDA, the Federal Trade Commission (FTC) and the Department of Health and Human Services (HHS) may investigate whether particular advertising or promotional practices are false, misleading or deceptive. These agencies may impose a wide array of sanctions on companies for such advertising practices. Additionally, physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of "off-label" use. Companies cannot promote FDA-approved pharmaceutical or biologic products for off-label uses. If our advertising or promotional activities fail

to comply with applicable regulations or guidelines, we may be subject to warnings or enforcement action. In addition, if the ESP Pharma merger is completed, there may be a similar risk with respect to the products currently developed and marketed by ESP Pharma, including Cardene IV and IV Busulfex.

Further, regulatory approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA, the manufacturer continues to be subject to facility inspection and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. If we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including:

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

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

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

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

Physicians will not recommend therapies using our products until such time as clinical data or other factors demonstrate the safety and efficacy of such procedures as compared to conventional drug and other treatments. Even if we establish the clinical safety and efficacy of therapies using our antibody product candidates, physicians may elect not to recommend the therapies for any

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

Our business may be harmed if we cannot obtain sufficient quantities of raw materials.

We depend on outside vendors for the supply of raw materials used to produce our product candidates. Once a supplier's materials have been selected for use in our manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

We may be subject to product liability claims, and our insurance coverage may not be adequate to cover these claims.

We face an inherent business risk of exposure to product liability claims in the event that the use of products during research and development efforts or after commercialization results in adverse effects. This risk will exist even with respect to any products that receive regulatory approval for commercial sale. While we have obtained liability insurance for our products, it may not be sufficient to satisfy any liability that may arise. Also, adequate insurance coverage may not be available in the future at acceptable cost, if at all.

We may incur significant costs in order to comply with environmental regulations or to defend claims arising from accidents involving the use of hazardous materials.

We are subject to federal, state and local laws and regulations governing the use, discharge, handling and disposal of materials and wastes used in our operations. As a result, we may be required to incur significant costs to comply with these laws and regulations. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities which exceed our resources. In addition, we cannot predict the extent of the adverse effect on our business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

Changes in the U.S. and international health care industry could adversely affect our revenues.

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. The FDA and other health care policies may change, and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. Cost containment measures, whether instituted by health care providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in

the purchase of drugs. As a result, third-party payors may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

We may not be able to obtain or maintain our desired price for our products. Our products may not be considered cost effective relative to alternative therapies. As a result, adequate third-party reimbursement may not be available to enable us to maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborative partners. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

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

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. For example, during the period from January 1, 2004 to February 4, 2005, our common stock closed as high as \$27.14 per share and as low as \$15.10 per share. Additionally, the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The following are some of the factors that may have a significant effect on the market price of our common stock:

- our financial results;
- developments or disputes as to patent or other proprietary rights;

- disappointing sales of approved products;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in obtaining regulatory approvals or unfavorable FDA advisory panel recommendations;
- changes in reimbursement policies;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- disputes or disagreements with collaborative partners;
- developments in our relationships with customers;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- initiation, termination or modification of agreements with our collaborative partners;
- loss of key personnel;

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- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and beginning with our annual report on Form 10-K for the year ended December 31, 2004, our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal controls over financial reporting as of the end of 2004. The rules governing the standards that must be met for management to assess the effectiveness of our internal controls over financial reporting are new and complex and require significant documentation, testing and possible remediation. We are currently in the process of reviewing, documenting and testing our internal controls over financial reporting, which has and may continue to result in increased expenses and the devotion of significant management resources. We may encounter problems or delays in completing the implementation of any changes necessary to make a favorable assessment of our internal controls over financial reporting. In addition, in connection with the attestation process by our independent auditors, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment, investor confidence and our stock price could be adversely affected.

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Risks Related to the Acquisition of ESP Pharma

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

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

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

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

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

In January 2005, we entered into a definitive agreement to acquire ESP Pharma, a privately-owned company. If the merger is completed, achieving the benefits of the merger will depend in substantial part on the successful integration of the two companies' technologies, operations and personnel. Prior to the merger, PDL and ESP Pharma have operated independently, each with its own operations, corporate culture, locations, employees and systems. PDL and ESP Pharma now have to operate as a combined organization and begin utilizing common business, information and communication systems, operating procedures, financial controls and human resource practices, including benefits, training and professional development programs. PDL and ESP Pharma will face significant challenges in integrating their organizations and operations in a timely and efficient manner. Some of the challenges and difficulties involved in this integration include:

- demonstrating to the customers of PDL and ESP Pharma that the merger will not result in adverse changes in client service standards or business focus and helping customers conduct business successfully with the combined company;
- coordinating sales and marketing efforts to effectively communicate the capabilities of the combined company;
- coordinating and rationalizing commercialization and development activities to enhance introduction of new products and technologies;
- preserving important relationships of both PDL and ESP Pharma and resolving potential conflicts that may arise;
- management distraction from the business of the combined company;
- incompatibility of corporate cultures;

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- costs and delays in implementing common systems and procedures;
 - consolidating and rationalizing corporate, IT and administrative infrastructures;
 - integrating and documenting processes and controls in conformance with the requirements of the Sarbanes-Oxley Act of 2002; and
 - operating the combined company at multiple sites in the U.S.

Any one or all of these factors may increase operating costs or lower anticipated financial performance. In addition, the combined company may lose distributors, suppliers, manufacturers and employees. Many of these factors are also outside the control of the company. Achieving anticipated synergies and the potential benefits underlying the two companies' reasons for the merger will depend on successful integration of the two companies. The failure to integrate PDL and ESP Pharma successfully would have a material adverse effect on our business, financial condition and results of operations.

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

The issuance of shares of PDL common stock in the merger will substantially reduce the percentage interests that holders of the 2005 Notes would receive upon conversion of the 2005 Notes, and the registered sale of these shares could decrease the market value of our common stock.

Upon completion of the merger, the shares of ESP Pharma preferred stock, common stock and options therefor will be converted into the right to receive up to \$325 million in cash and up to approximately 9,855,000 shares of PDL common stock. Based on this estimated number of PDL shares to be issued in the acquisition of ESP Pharma, former ESP Pharma stockholders will own approximately 9% of the combined company's outstanding common

stock following the completion of the merger. We have granted registration rights covering the PDL shares to be issued in the acquisition of ESP Pharma, which could result in the registered sale of a substantial number of shares of our common stock and which could lead to a decrease in the market price of our common stock. The issuance of these shares in connection with the merger will cause a significant reduction in the relative percentage interests in earnings, voting power, liquidation value and book and market value of all holders of common stock and securities convertible into common stock, including without limitation our unsecured 2.75% Convertible Subordinated Notes due August 16, 2023 (the 2003 Notes), the 2005 Notes and the PDL common stock issuable thereunder.

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

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

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

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

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

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

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

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

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

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

In accordance with U.S. generally accepted accounting principles, the combined company will account for the merger using the purchase method of accounting, which will result in charges to

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

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

PDL estimates that it will incur transaction costs of approximately \$5 million associated with the merger, which will be included as a part of the total purchase costs for accounting purposes. These amounts are estimates and could increase. In addition, we believe that the combined entity may incur charges to operations, in amounts that are not currently reasonably estimable, in the quarter in which the merger is completed or in subsequent quarters, to reflect

costs associated with integrating the two companies. The combined company may incur additional material charges in subsequent quarters to reflect additional costs associated with the merger. These significant costs associated with the merger could adversely affect the future liquidity and operating results of the combined company.

Risks Related to the Business of ESP Pharma

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

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

Cardene IV accounts for a significant portion of the operating income and growth in sales for ESP Pharma. Cardene IV faces a competitive marketplace with branded and generic intravenous anti-hypertensive products being marketed in the United States and it may be harder to continue to penetrate this market at the current rate of growth. While we expect to maintain and increase committed sales and marketing presence in order to ensure the continued growth of Cardene IV, there can be no assurance that we can continue the rapid growth rate that ESP Pharma has achieved in the past 29 months. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for Cardene IV to continue its success, we will have to maintain and expand its position in the marketplace against these competitors' drugs.

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

Retavase is expected to account for a significant portion of our operating income and growth in cash flow from operations. Retavase is sold into the thrombolytic market that has recently been declining due to the more widespread use of stents and the introduction of gpIIb/IIIa inhibitor products. Moreover, Retavase competes for use in the management of acute myocardial infarction

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with TNKase and Activase from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we currently have available. While we believe our planned investment in additional sales and promotional efforts may increase the market acceptance of Retavase, there can be no assurance that we can increase the market share of Retavase, or that even if we are able to increase our market share, that the anti-thrombolytic market will not decline significantly regardless of our efforts. In addition, the product currently is marketed on behalf of Centocor by Scios, Inc. (Scios), a Johnson & Johnson company. We will require the cooperation of Centocor and Scios to successfully transfer the product to us and there can be no assurance that our sales and marketing efforts will be implemented in a timely manner or that we will be successful in achieving our projected sales levels.

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

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

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

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

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

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

ESP Pharma was founded in April 2002. While ESP Pharma was profitable in 2003 and expects to be profitable for the year ended December 31, 2004, it has a short operating history and there can be no assurance that it will continue to achieve profitable results as

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part of the combined companies. PDL has incurred losses since inception and expects to continue to incur losses until, at the earliest, 2008, the currently anticipated date in which PDL could complete its first full year of sales of its antibody products. In order for the combined companies to achieve a cash flow positive rate by 2007, ESP Pharma's products must continue to grow in accordance with the internal projections of the companies.

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

ESP Pharma sells its products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the quarter ended September 30, 2004, revenues from the sales of ESP Pharma products to its three largest U.S. wholesalers totaled approximately 83% of its net revenues. ESP Pharma's reliance on a small number of wholesalers and distribution partners could cause its revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners. In addition, as of September 30, 2004, these three U.S. wholesalers represented approximately 95% of ESP Pharma's outstanding accounts receivable. If any of these wholesalers or international partners fails to pay ESP Pharma on a timely basis or at all, ESP Pharma's financial position and results of operations could be materially adversely affected.

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

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

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

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

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

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

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

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

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

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

As of September 30, 2004, approximately 42% of the ESP Pharma net product sales resulted from the sale of the off-patent products Tenex, Sectral, Ismo and Declomycin. These products have accounted for a majority of the cash flow from operations of ESP Pharma. If sales of Cardene IV do not perform as planned and we are unable to maintain the cash flow returns from these off-patent products, our ability to achieve positive cash flow from operations by 2007 could be delayed.

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

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

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

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

Risks Related to the 2003 Notes

We may not have the ability to repurchase the 2003 Notes upon a repurchase event or a repurchase date under the indenture.

In August 2010, August 2013 and August 2018, 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.

BUSINESS

Overview

We are a recognized leader in the discovery and development of humanized monoclonal antibodies for the treatment of disease. Our patented antibody humanization technology is applied to promising mouse antibodies. By making certain modifications to the mouse antibody that make it more like a human antibody, our technology enhances the utility of such antibodies, while retaining their biological activity, for human therapeutic use. We believe our technology for the creation of humanized therapeutic monoclonal antibodies is the most widely validated in our industry. As of December 31, 2004, a total of eight marketed products were licensed under our humanization patents and we are aware of more than 40 humanized antibodies in clinical stage development worldwide by various pharmaceutical and biotechnology companies, of which a large number may be covered under our patent agreements.

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

Since our founding in 1986, we have actively licensed our antibody humanization technology to, and performed humanization services for, pharmaceutical and biotechnology partners. To date, we have entered into numerous patent licensing agreements, and the resulting fees, milestones and related royalty revenues currently are the primary source of our revenues. For the nine month period ended September 30, 2004, we recognized total royalties of approximately \$63.9 million on seven licensed antibody products. Licensed antibody products for which we have recognized revenue in 2004 include Zenapax, Mylotarg, Synagis, Herceptin, Avastin, Raptiva and Xolair. Zenapax, Mylotarg and Synagis are marketed by Roche, Wyeth, and MedImmune, respectively, and Herceptin, Avastin, Raptiva and Xolair are marketed by Genentech and Genentech's partners. Genentech exercised licenses for its Raptiva and Avastin antibody products, which were approved by the FDA in October 2003 and February 2004, respectively. As royalty revenue is recognized one quarter following the quarter in which sales occurred, we began to receive royalties on sales of Raptiva beginning in the first quarter of 2004 and on sales of Avastin in the second quarter of 2004. In addition, the FDA approved Tysabri antibody product from Elan/Biogen Idec in the fourth quarter of 2004. Tysabri is licensed under PDL's humanization patents and we expect to begin to receive royalties on sales of that humanized antibody product in the first quarter of 2005.

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

Based on the strength of our proprietary platform, the number of antibody programs we have in development and the flexibility provided by our current financial position, our goal for our existing

pipeline is to launch our first PDL-developed proprietary antibody product into the North American market by the end of 2007. We believe that our ability to achieve positive cash flow from operations based upon revenues consisting of royalties, license and other income and product sales would be accelerated by the acquisition of ESP Pharma. Accordingly, our ability to achieve a cash-flow positive position based on our proprietary products is anticipated to be accelerated to 2007, provided the ESP Pharma transaction is completed successfully.

PDL Products in Clinical Stage Development

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

Antibody Product	Indication(s)	Status
Nuvion (visilizumab, anti-CD3)	Intravenous steroid-refractory ulcerative colitis	Phase I/II
Zenapax (daclizumab, anti-IL-2 receptor)	Prevention of acute kidney transplant rejection	Marketed/Roche
	Asthma	Phase II
M200 (volociximab, anti- $\alpha 5\beta 1$ integrin)	Advanced solid tumors	Phase II
HuZAF (fontolizumab, anti-gamma-interferon)	Crohn's disease	Phase II

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

Nuvion is being evaluated in patients with ulcerative colitis that is refractory to treatment with intravenous steroids. This refractory patient population has no approved medical alternatives and generally requires surgery. We have completed a 32-patient Phase I clinical trial in which patients received one intravenous injection of Nuvion on two consecutive days. The two dose cohorts tested were at 15 and 10 $\mu\text{g}/\text{kg}$. In the 15 $\mu\text{g}/\text{kg}$ dose cohort, all 8 patients achieved remission. At the 10 $\mu\text{g}/\text{kg}$ dose level, 19 of 24 patients responded and 13 achieved remission. The antibody was demonstrated an appropriate safety profile for these patients for whom there are no approved medical treatments.

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

Interim findings from the Phase I portion of this study were presented at the United European Gastroenterology Week meeting in Prague in September 2004. We have now seen clinical responses at all dose levels tested to date, although we did not see significant differences in safety or activity among the lower doses being studied in the current trial.

In each of the studies reported to date, the most common adverse events have been associated with the cytokine release syndrome, which generally consists of flu-like symptoms and is

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

We have received Fast Track status from the FDA for the investigation of Nuvion in patients with intravenous steroid-refractory ulcerative colitis, which is the first PDL program to receive such designation.

We currently plan to conduct a Nuvion end-of-Phase I meeting with the FDA late in the first quarter of 2005. We anticipate that the future registration pathway will be based on the Special Protocol Assessment process. If our discussions with the FDA are successful, we expect to seek approval to initiate Phase III studies by the fourth quarter of 2005 in the intravenous steroid-refractory ulcerative colitis setting.

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

Effective October 2003, we paid \$80 million in cash for return of exclusive rights to daclizumab in indications other than transplantation. Under the transfer agreement, PDL is to assume manufacturing responsibility for Zenapax. PDL is undertaking strategies to facilitate future Zenapax manufacture, and these strategies are subject to certain technical and regulatory risks which may impact timing of the manufacturing transfer. In connection with this arrangement, Roche has the right to put these transplant indications as early as 2005 upon six months prior written notice to us. If Roche does not exercise its put right, we have the right to acquire these transplant indications, which right is exercisable beginning in the second quarter of 2006 and effective no earlier than six months following the date of notice of the exercise but no later than July 1, 2007. To effectuate the transfer of Zenapax in the transplantation indications, we will pay an additional exercise fee to Roche based on the average annual gross sales of Zenapax during the period from January 1, 2004, through either the calendar quarter prior to the date we exercise our option, or Roche's notice of its decision to transfer the rights to us prior to our exercise date. If we do not receive transplantation rights, we would pay royalties to Roche on any sales in all diseases other than transplantation, and we would continue to receive royalties on sales of Zenapax in transplantation.

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

Daclizumab binds to the IL-2 receptor on immune system cells known as T cells. IL-2 is a cytokine, one of the substances released by cells as part of the normal immune response as well

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

Positive results from a Phase II trial of daclizumab in moderate-to-severe persistent asthma were reported in March 2004 at the American Academy of Allergy, Asthma & Immunology meeting. This Phase II randomized, double blind, placebo controlled clinical trial treated 115 patients who suffer from chronic, persistent asthma and whose disease is not well controlled with high doses of inhaled corticosteroids. We reported that statistically significant treatment differences ($p=0.05$) were observed in treatment period one for the primary endpoint, which was the percent change in FEV₁ (Forced Expiratory Volume in one second) from baseline to 12 weeks, or day 84. Secondary clinical endpoints also supported these findings. Treatment with daclizumab was generally well tolerated. We expect that the next trial of daclizumab in asthma will be a single-dose, Phase I clinical trial in healthy volunteers, intended to gather additional experience with the PDL-manufactured subcutaneous formulation of daclizumab. This single-dose subcutaneous study should begin in the first quarter of 2005. This single-dose trial is expected to be followed by a multiple-dose Phase I study. We anticipate that a subsequent Phase IIb clinical trial in moderate-to-severe persistent asthma could begin in the first quarter of 2006.

In a pilot study conducted in 2002 and 2003 through the National Institutes of Health, daclizumab was evaluated in combination with interferon-beta therapy in patients with relapsing remitting MS who had partially or completely failed to respond to interferon-beta therapy. In that study, daclizumab was well tolerated and led to a greater than 75% reduction in inflammatory activity in the majority of patients, as measured by reduction in contrast enhanced

MRI-scanned lesions. We believe that the resources and market expertise of a collaborative partner experienced in MS could facilitate the late-stage development and marketing of daclizumab in this indication. Consequently, we are seeking to establish a collaboration with such a partner for development of daclizumab in MS. A PDL-sponsored Phase II study of daclizumab in MS is expected to be initiated in the first quarter of 2005.

We evaluated daclizumab in a Phase II clinical study in patients with moderate-to-severe ulcerative colitis. This randomized, placebo controlled Phase II clinical trial enrolled approximately 150 patients. In May 2004, we reported that daclizumab did not meet primary or secondary endpoints in the study, and that we do not plan further development of daclizumab in ulcerative colitis.

M200 (volociximab, anti- $\alpha 5\beta 1$ integrin antibody). Our anti- $\alpha 5\beta 1$ integrin chimeric antibody program, M200, is in Phase II clinical studies for advanced solid tumors. M200 is a direct anti-endothelial cell antibody that inhibits angiogenesis. Agents that inhibit angiogenesis are intended to block formation of blood vessels in tumors, thereby leading to slower tumor growth, cell death or inhibition of metastasis. M200 targets the activated subset of endothelial cells. These activated cells are found in the lining of blood vessels undergoing angiogenesis, and by inhibiting the binding of fibronectin to $\alpha 5\beta 1$ integrin receptors, angiogenesis is inhibited. *In vitro* studies have shown that the antibody inhibits angiogenesis, including vessel formation induced by vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF), as well as other pro-angiogenic growth factors. As a result, the antibody may prove effective in treating tumors in which one or more growth factors contribute to angiogenesis.

In September 2004, we presented interim clinical data from the Phase I study of M200. In the Phase I trial, 16 men and women between the ages of 29 and 81 (mean 58 years) with various solid tumor types refractory to standard therapy had been enrolled. Tumor types included colorectal, melanoma, hepatic, pancreatic and non-small cell lung cancers. The study data showed that adverse events were generally mild to moderate in intensity and included fatigue, nausea,

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constipation, headache, and anorexia. There were no severe or serious adverse events that were dose limiting or considered by investigators to be related to M200. In addition, 10 of 15 evaluable patients had stable disease as their best response, and five of six patients treated at the highest dose level reported, 10 mg/kg, achieved stable disease. Four patients with stable disease after 5 doses of M200 in the Phase I study continued treatment with M200 in a Phase I extension study. Three of these patients maintained stable disease for greater than 16 weeks over the two studies.

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

HuZAF \hat{O} (fontolizumab, anti-gamma interferon). Fontolizumab targets gamma interferon, a protein that stimulates several types of white blood cells and that has been shown by academic researchers to play a role in certain autoimmune diseases.

This humanized antibody has completed two Phase II studies in a total of approximately 329 patients with Crohn's disease, a form of inflammatory bowel disease. These two randomized, placebo controlled, double blind Phase II trials were designed to better define the activity of this antibody in Crohn's disease. The first trial explored an initial intravenous dose of fontolizumab given as 1 mg/kg or 4 mg/kg, followed by additional lower subcutaneous doses. In the second trial, patients received up to two intravenous doses of fontolizumab given at 4 mg/kg or 10 mg/kg. In March 2004, we reported results of these two trials of HuZAF in Crohn's disease. The primary endpoint for both trials was the response to the initial intravenous dose. HuZAF did not meet the primary endpoint in either trial following administration of a single intravenous dose. We did, however, in subset analysis of C-Reactive Protein (CRP)-elevated patients, identify very strong signals of activity. Based on the recent success of our pipeline and the allocation of resources to higher priority programs, we currently are seeking to partner HuZAF before initiating additional development in Crohn's disease or other autoimmune indications, such as systemic lupus and rheumatoid arthritis.

Business and Commercialization Strategy

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

Our most advanced clinical-stage programs are Nuvion (visilizumab) antibody product for potential treatment of intravenous steroid-refractory ulcerative colitis (IVSR-UC), and daclizumab (Zenapax) humanized antibody for potential treatment of moderate-to-severe asthma. Additionally, in 2003, we reacquired rights from Roche to market and manufacture daclizumab in indications other than transplantation, and we obtained an option to acquire rights to daclizumab in transplant indications, marketed as Zenapax, by no later than 2007. We believe that the market potential for daclizumab could be expanded beyond the current approved indication in renal transplantation through potential development of this already-marketed antibody in other autoimmune or inflammatory disease indications, such as asthma and MS. In September 2004, we completed an agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases. We received a \$17.5 million upfront payment and may receive up to \$187.5 million in milestone payments for successful further development and commercialization of daclizumab. Roche and PDL will globally co-develop daclizumab in asthma, equally share development expenses and co-promote the product in the United States. Outside of

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the United States, we will receive royalties on net sales of the product in asthma and related respiratory diseases.

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

transaction is completed, we believe the integration of this sales and marketing capability with ESP Pharma's in-line marketing and sales team will help to enable a successful commercialization following the reversion of Zenapax transplant rights to PDL.

We have partnered with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and related respiratory diseases. We retain worldwide rights to each of the other products we are currently developing. While our goal is to market our products in North America, for all our products in development, we may out-license rights, even within the United States, to other biotechnology or pharmaceutical companies with respect to certain indications requiring specific expertise or large development and marketing efforts, such as MS or some oncology indications. For example, we have partnered with Roche for the joint development and commercialization of daclizumab in asthma. We retain worldwide rights to each of the other products we are currently developing. We may receive upfront fees, milestone payments or other types of funding under these arrangements, in addition to possible royalties or other profit-sharing rights on any product sales by such marketing partners.

Current Sources of Revenue

Royalties. We license our patents covering numerous humanized antibodies in return for license fees, annual maintenance payments and royalties on product sales. Eight of the nine humanized antibodies currently approved by the FDA are licensed under our patents and seven of these licensed products generated royalties to PDL that were recognized in 2004: Genentech's Herceptin, Xolair; Raptiva and Avastin; MedImmune's Synagis; Wyeth's Mylotarg; and Roche's Zenapax. Combined annual worldwide sales of these products exceeded \$2.9 billion in 2004. Additionally, Elan entered into a license under our patents for the Tysabri antibody product, which was approved by the FDA in November 2004. As royalty revenue is recognized one quarter following the quarter in which sales occurred, we expect to receive royalties on sales of Tysabri beginning in the first quarter of 2005.

Patent licensing, humanization agreements and outlicensing. We have patent license or patent rights agreements with numerous other companies for humanized antibodies they are developing, and we will seek to enter into additional agreements on an ongoing basis.

We humanize antibodies for other companies in return for upfront fees, milestone payments and royalties on any product sales. In some cases, we also receive the right to co-promote these products in designated territories.

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

Agreement to Acquire ESP Pharma

In January 2005, we entered into a definitive agreement with ESP Pharma, a privately held, hospital-focused pharmaceutical company, under which PDL will acquire ESP Pharma for \$300 million in cash and approximately \$175 million in PDL common stock, or an aggregate value of approximately \$475 million, plus the assumption of net debt of approximately \$14 million. On February 1, 2005, PDL and ESP Pharma agreed to increase the purchase price by \$25 million in cash in connection with ESP Pharma's agreement to acquire Retavase from Centocor.

ESP Pharma has a hospital-focused sales force committed to the acute-care setting. ESP Pharma has grown its sales force from 22 as of September 2002 to 66 field representatives as of January 2005 and intends to employ approximately 85 representatives by the end of 2005. The current sales team allows ESP Pharma to market to approximately 800 hospitals in the U.S. Once inside the hospitals, the ESP Pharma sales force focuses on the Cardiac, Neurological and Intensive Care Unit, or ICU, sections. For the nine months ended September 30, 2004, unaudited net sales and EBITDA (before nonrecurring expenses) for ESP Pharma were approximately \$68 million and \$19.5 million, respectively.

ESP Pharma has actively pursued a strategy for identifying, acquiring and maximizing the potential of approved and late-stage development specialty therapeutics. ESP Pharma began operations in May 2002 when it acquired the U.S. rights to four cardiovascular products from Wyeth: Cardene IV, Sectral, Tenex and Ismo. The key product of the acquisition was Cardene IV, a patented drug that is the only U.S.-approved intravenous calcium channel blocker indicated for the treatment of hypertension. Sectral, Tenex, and Ismo are "off-patent brands" which are cash flow positive despite no active promotion.

In 2003, ESP Pharma acquired the following marketed products:

- worldwide rights (excluding Australia) to IV Busulfex, an acute care oncology drug, from Orphan Medical; and
- worldwide marketing rights for an antibiotic, declomycin, from Wyeth.

ESP Pharma's sales force concentrates its efforts on Cardene IV and IV Busulfex, which was re-launched in September 2003. Currently, ESP Pharma does not have and is not expected to have a dedicated sales force to sell or market declomycin or its other off-patent brands.

Cardene IV. Cardene IV is the only branded, U.S.-approved dihydropyridine class calcium channel blocker delivered intravenously that is indicated for treating hypertension. Cardene IV is approved for short-term treatment of hypertension when oral therapy is not feasible or desirable. The product is patent protected through November 2009. This patent is a process patent which protects the active ingredient, Nicardipine Hydrochloride, being used in injectable form.

Based on recent estimates, up to 75% of surgical patients develop hypertension during or following surgery. Patients receive Cardene IV to reduce high blood pressure during or after surgery. Competing products also reduce blood pressure, but are either not as effective in stabilizing blood pressure predictably, or are more toxic than Cardene IV. The primary driver in future growth of Cardene IV will be the effective marketing to approximately 800 currently targeted hospitals in the United States plus potential new specialty dosing formulations and indications.

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

IV Busulfex. ESP Pharma acquired IV Busulfex from Orphan Medical in June 2003 for \$29.3 million, plus the purchase of existing inventory. IV Busulfex, an IV formulation of Busulfan, is a chemotherapeutic agent used as part of a conditioning regimen prior to bone marrow transplantation. IV Busulfex suppresses the immune system so the patient does not reject bone marrow grafts. Furthermore, it provides antitumor effect to eradicate residual malignancy, ablation of the bone marrow to make space for the new source of stem cells and to provide immunosuppression to prevent graft rejection. It is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. Its U.S. patent expires in 2015. IV Busulfex competes with other unapproved conditioning regimens including oral busulfan tablets, which are cumbersome in their dosing and have a slower onset of action compared to IV Busulfex.

Currently, approximately 75% of sales are in the United States and Canada. ESP Pharma launched IV Busulfex in Europe in the 4th quarter of 2003 through its marketing partner, Pierre Fabre. In Japan, IV Busulfex is in the approval process and is expected to be launched via Kirin Pharmaceuticals in early 2005.

Retavase. ESP Pharma and PDL have amended the definitive merger agreement to increase the purchase price by \$25 million in connection with ESP Pharma's agreement to acquire certain rights to Retavase from Centocor, a biopharmaceutical operating company of Johnson & Johnson. The Retavase product currently is marketed by Scios, another Johnson & Johnson company. The acquisition price for the product from Centocor is \$110 million, representing approximately two times net 2004 product sales. Milestone payments of up to \$45 million will be made if additional conditions relating to ongoing clinical trials and manufacturing arrangements are satisfied. ESP Pharma's acquisition of Retavase includes U.S. and Canadian distribution, manufacturing and marketing rights, all relevant intellectual property and approximately two years supply of inventory plus certain manufacturing equipment.

First introduced into the U.S. market in 1997, Retavase belongs to the fibrinolytic or thrombolytic class of pharmaceutical agents used in the acute-care setting to dissolve coronary blood clots and improve blood flow in AMI patients. Each year, in the United States, more than one million people suffer AMI.

Retavase is indicated for use in the management of AMI in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. The product can be administered within a 30-minute time window by a double-bolus injection without dose adjustment for patient weight compared to other thrombolytics requiring longer duration intravenous infusions or dosing adjustments based on weight.

Off-Patent Brands

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

- Tenex is a centrally-acting alpha-blocking agent for use in the treatment of hypertension.
- Sectral is a cardioselective beta-blocker for the treatment of hypertension and ventricular arrhythmia.

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

ESP Pharma has increased sales by using selective price increases to offset declining unit volumes.

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

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

ESP Pharma's Operations

Customers. ESP Pharma's products are sold through wholesale distributors to roughly 800 hospitals. ESP Pharma's sales force consists of 8 sales managers and 66 representatives in the field. The field representatives focus primarily on approximately 800 hospitals across the United States.

Facilities. ESP Pharma maintains leased offices consisting of approximately 23,000 square feet for administrative and sales purposes in Edison, New Jersey. Specialty Pharmaceutical Services (formerly Cord), a subsidiary of Cardinal Health (Specialty Pharmaceutical), handles a number of tasks for ESP Pharma including: warehousing, distribution, receiving orders from customers, invoicing and collection of receivables. All inventory is shipped directly from Specialty Pharmaceutical's third-party warehouse located in Tennessee.

PDL'S Technology

Antibody Background Information

Antibodies are protective proteins released by the immune system's B cells, a type of white blood cell, in response to the presence of a foreign substance in the body, such as a virus, or due to an irregular autoimmune response. B cells produce millions of different kinds of antibodies, which have slightly different shapes that enable them to bind and, as a result, inactivate different targets. Antibodies that have identical molecular structure that bind to a specific target are called monoclonal antibodies.

Typically, mice have been used to produce monoclonal antibodies to a wide range of targets, including targets to which the human body does not normally produce antibodies. Specifically, many mouse antibodies have been developed as potential therapeutics to inhibit immune function, destroy cancer cells or neutralize viruses.

Although mouse monoclonal antibodies are relatively easy to generate, they have significant drawbacks as therapeutics. Mouse antibodies have a relatively short half-life in human patients,

requiring them to be administered frequently. In addition, mouse antibodies are not adapted to work effectively with the human immune system and therefore often have limited ability to destroy the target, such as cancer cells. Most importantly, when injected into humans, a mouse antibody is usually recognized by the body's immune system as foreign. The immune system therefore responds with a human anti-mouse antibody, or HAMA, response, which rapidly neutralizes the mouse antibody and renders it ineffective for further therapy. These problems have largely prevented mouse antibodies from fulfilling their promise as therapeutics.

More recently, improved forms of antibodies, such as humanized, human and chimeric antibodies, have been developed using recombinant DNA and other technologies. These new antibodies can minimize or avoid many of the problems associated with mouse antibodies and have led to a resurgence of interest in antibody therapeutics by the pharmaceutical and biotechnology industries. As a result of these advances, many monoclonal antibodies are now progressing into clinical trials. In particular, we are aware of approximately 40 humanized antibodies in clinical trials, including several antibodies addressing large markets. Fifteen human, humanized or chimeric antibodies have already been approved for marketing by the FDA, of which eight are humanized and licensed under our patents.

Our Antibody Technology Platform

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

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

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

Our Research

Our research efforts are focused on creating and developing humanized antibodies for the treatment of autoimmune diseases, inflammatory conditions and cancer. Following our acquisition of Eos in April 2003, we significantly restructured and redefined our research to combine the target and biology expertise of Eos with the advanced protein engineering skills of PDL, with the aim of generating an average of one new antibody IND candidate per year after 2004. We have significant research activities aimed at the discovery of new antibodies and utilize various state-of-the-art research tools intended to optimize the efficiency of antibodies that may be useful for the treatment of certain diseases. These activities are intended to provide antibody product candidates for further preclinical and clinical development in our core disease areas. We use a variety of sophisticated methods to discover these targets. In addition, we have obtained or in-licensed targets, or rights to targets or antibodies, through collaborative research agreements, from academic institutions or other biotechnology or pharmaceutical companies. We may in-license rights to additional targets or antibodies in the future.

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

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

Our Antibody Manufacturing

Antibodies for use as human therapeutics are generally manufactured through the culture of mammalian cell lines, which produce the antibodies. We maintain facilities and personnel in California and Minnesota for the production and characterization of such cell lines. We also engage in process development activities intended to improve the productivity and other characteristics of such cell lines. We believe our knowledge and capabilities in this area provide a significant degree of competitive advantage over those companies that currently lack such fully integrated operations. In particular, we have more than a decade of manufacturing experience based upon a serum-free and protein-free production process, and we believe that this approach is a significant competitive advantage.

We manufacture antibodies for use as clinical trial material in an approximately 45,000 square-foot manufacturing facility in Plymouth, Minnesota, which we have leased since 1992. We currently manufacture Nuvion, fontolizumab and other preclinical antibodies in that facility. We renovated this facility in 2002 and early 2003 to make it potentially licensable by regulatory agencies in the United States and other countries for supply of commercial antibodies. We resumed manufacturing of antibodies in the first half of 2003. Our current plans are to reduce or close operations in this facility in 2006.

We are validating a new commercial manufacturing facility in Brooklyn Park, Minnesota, approximately nine miles from our Plymouth location. Physical construction of our approximately 22,000-liter capacity manufacturing facility was completed in December 2004. We currently expect to be able to produce antibodies for clinical use from this facility by 2006 and for commercial sale

in 2007. Antibodies currently in our clinical stage pipeline that may be made in this facility include Nuvion, fontolizumab, daclizumab and volociximab, the anti- $\alpha 5\beta 1$ integrin antibody.

Humanization and Patent Licensing Rights Agreements

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

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

Manufacturing and Facilities

We manufacture our products for clinical development, other than M200. M200 is currently supplied by ICOS Corporation as part of a manufacturing agreement related to our 2003 acquisition of Eos Biotechnology, Inc. However, we intend to change over from ICOS supply to our own supply as soon as is reasonably practicable, subject to regulatory and physical constraints.

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

We own two buildings comprising approximately 92,000 square feet of research and development and general office space in Fremont, California. As of September 30, 2004, we have a mortgage of approximately \$8 million on these facilities. In addition, we lease approximately 100,000 square feet of adjacent research and development and general office space in Fremont, California. Our lease terms for these facilities will expire on December 31, 2006 and February 28, 2007.

In Plymouth, Minnesota, we lease a total of approximately 75,000 square feet of manufacturing, laboratory and office space in three separate buildings. The lease terms will expire on February 28, 2009, subject to our option to extend the lease for an additional five-year term. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and have built a new commercial manufacturing plant on this property that is currently being validated. In January 2005, we entered

into an agreement to purchase approximately 6 acres adjacent to our existing Brooklyn Park facility to permit further expansion of our existing site if we deem this necessary in the future.

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

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

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

Patents and Proprietary Technology

We have been issued patents in the United States, Europe and Japan, which we believe cover many humanized antibodies. Some of these patents also cover other aspects of our antibody technology platform. We have filed similar patent applications in other countries. Our U.S. humanization patents, known generally as the Queen, et. al. patents, expire in 2014.

Our two humanization patents issued by the European Patent Office apply in the United Kingdom, Germany, France, Italy and 17 other European countries. The European Patent Office procedures provide for an opposition period in which other parties may submit arguments as to why a patent was incorrectly granted and should be withdrawn or limited. Eighteen notices of opposition to our first European patent were filed during the opposition period for the patent, including oppositions by major pharmaceutical and biotechnology companies. Five opponents, including Genentech, have withdrawn from the opposition proceedings.

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims in our first European patent. We subsequently appealed the Opposition Division's decision to the Technical Board of Appeal at the European Patent Office. In November 2003, the Technical Board of Appeal upheld our appeal and set aside the Opposition Division's initial decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. We believe that such claims, if upheld by the Opposition Division, would cover the production of many humanized antibodies.

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

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

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

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

We intend to vigorously defend our patents in these proceedings. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

Our success depends significantly on our ability to obtain and maintain patent protection for our products and technologies, to preserve our trade secrets and to operate without infringing on the proprietary rights of third parties. While we file and prosecute patent applications to protect our inventions, our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology.

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents. Additionally, other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or may not be able to market our products at all.

The scope, enforceability and effective term of patents issued to companies, universities and research institutions can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. We cannot assure you that the patents we obtain or the unpatented proprietary technology we hold will afford us significant commercial protection.

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CONSOLIDATED FINANCIAL STATEMENTS

ESP Pharma Holdings and Subsidiary

September 30, 2004

ESP Pharma Holdings and Subsidiary
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
ESP Pharma Holdings and Subsidiary

We have audited the accompanying consolidated balance sheets of ESP Pharma Holdings and Subsidiary as of December 31, 2003 and 2002 and the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2003 and for the period from April 15, 2002 (inception) to December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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, 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. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing our opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ESP Pharma Holdings and Subsidiary at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for the year ended December 31, 2003 and for the period from April 15, 2002 (inception) to December 31, 2002, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

March 12, 2004

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ESP Pharma Holdings and Subsidiary

Consolidated Balance Sheets

	December 31	
	2003	2002

Assets

Current assets:

Cash and cash equivalents	\$ 29,507,156	\$ 5,938,706
Accounts receivable, net	6,140,579	3,426,265
Inventories	3,465,543	702,745
Prepaid expenses and other current assets	2,922,494	129,159
Deferred tax asset	1,034,078	—
Total current assets	<u>43,069,850</u>	<u>10,196,875</u>
Property and equipment, net	1,056,438	515,548
Non-marketable investments	1,600,000	400,000
Product rights, net	70,245,851	27,285,844
Deferred tax assets	2,558,964	310,000
Restricted cash	—	418,739
Deferred financing costs	1,289,838	—
Total assets	<u>\$ 119,820,941</u>	<u>\$ 39,127,006</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,472,001	\$ 1,463,820
Accrued expenses	4,493,485	1,239,789
Other current liabilities	4,860,069	1,410,223
Income taxes payable	883,737	38,000
Current portion of long-term debt	10,761,301	—
Total current liabilities	<u>23,470,593</u>	<u>4,151,832</u>
Long-term debt	42,738,699	9,500,000
Stockholders' equity:		
Series A convertible preferred stock; \$0.0001 par value; 28,200,000 shares authorized, issued and outstanding as of December 31, 2003 and 2002, respectively (minimum liquidation preference of \$28,200,000)	27,404,602	27,404,602
Series B convertible preferred stock; \$0.0001 par value; 12,500,000 shares authorized, issued and outstanding as of December 31, 2003 (minimum liquidation preference of \$20,000,000)	19,943,210	—
Common stock; \$0.0001 par value; 36,300,000 shares authorized, 6,588,708 and 6,775,000 issued and outstanding at December 31, 2003 and 2002, respectively	659	678
Additional paid-in capital	98,055	9,339
Notes receivable – related parties	(152,904)	(146,564)
Retained earnings (accumulated deficit)	6,408,418	(1,792,881)
Other comprehensive income	(90,391)	—
Total stockholders' equity	<u>53,611,649</u>	<u>25,475,174</u>
Total liabilities and stockholders' equity	<u>\$ 119,820,941</u>	<u>\$ 39,127,006</u>

See accompanying notes.

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ESP Pharma Holdings and Subsidiary

Consolidated Statements of Operations

	Year ended December 31, 2003	Period from April 15, 2002 (inception) to December 31, 2002
Revenue	\$ 62,544,565	\$ 14,746,464
Cost of goods sold	<u>20,610,249</u>	<u>6,757,594</u>
Gross profit	41,934,316	7,988,870
Selling and marketing	13,778,859	3,223,071
General and administrative	11,587,033	4,126,881
Research and development	586,993	—
Other operating expenses	2,279,505	2,043,459
Income (loss) from operations	<u>13,701,926</u>	<u>(1,404,541)</u>
Interest expense	(1,211,695)	(441,399)
Interest income	107,613	53,059
Income (loss) before provision for income taxes	<u>12,597,844</u>	<u>(1,792,881)</u>
Provision for income taxes	4,396,545	—
Net income (loss)	<u>\$ 8,201,299</u>	<u>\$ (1,792,881)</u>

See accompanying notes.

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ESP Pharma Holdings and Subsidiary

Consolidated Statements of Stockholders' Equity

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable	Retained Earnings (Accumulated Deficit)	Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at April 15, 2002 (inception)	—	\$ —	—	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of Series A Preferred Stock, net of issuance costs	28,200,000	27,404,602									27,404,602
Issuance of common stock					6,775,000	678	163,172				163,850
Shares subject to repurchase rights							(153,833)				(153,833)
Issuance of notes receivable								(146,564)			(146,564)
Net loss									(1,792,881)		(1,792,881)
Balance at December 31, 2002	28,200,000	27,404,602	—	—	6,775,000	678	9,339	(146,564)	(1,792,881)	—	25,475,174
Issuance of Series B Preferred Stock, net of issuance costs			12,500,000	19,943,210							19,943,210
Issuance of common stock					50,375	5	26,075	(8,669)			17,411
Shares no longer subject to repurchase rights								51,119			51,119
Options issued to non-employees								13,865			13,865
Return of unvested shares to reserve					(236,667)	(24)	(2,343)	2,329			(38)
Comprehensive income:											
Net income									8,201,299		8,201,299
Other comprehensive income, net of tax										(90,391)	(90,391)
Total comprehensive income											8,110,908
Balance at December 31, 2003	28,200,000	\$ 27,404,602	12,500,000	\$ 19,943,210	6,588,708	\$ 659	\$ 98,055	\$ (152,904)	\$ 6,408,418	\$ (90,391)	\$ 53,611,649

See accompanying notes.

ESP Pharma Holdings and Subsidiary

Consolidated Statements of Cash Flows

	Year ended December 31, 2003	Period from April 15, 2002 (inception) to December 31, 2002
Operating activities		
Net income (loss)	\$ 8,201,299	\$ (1,792,881)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation	167,406	44,829
Amortization of product rights	8,925,294	4,214,156
Interest rate swap	(90,391)	—
Non-cash expense associated with non-employee options	13,865	—
Deferred tax assets	(3,283,042)	(310,000)
Changes in operating assets and liabilities:		
Accounts receivable	(2,328,185)	(3,426,265)
Inventories	(2,762,798)	(702,745)
Prepaid expenses and other current assets	(2,793,335)	(129,159)
Accounts payable	1,008,181	1,463,820
Accrued expenses	3,304,777	1,239,789
Other current liabilities and income tax payable	5,357,677	1,294,930
Deferred financing costs	(1,289,838)	—
Net cash provided by operating activities	14,430,910	1,896,474
Investing activities		
Additions to fixed assets	(708,296)	(560,377)
Restricted cash	418,739	(418,739)
Purchase of non-marketable investments	(1,200,000)	(400,000)
Purchase of product rights	(51,885,301)	(22,000,000)
Net cash used in investing activities	(53,374,858)	(23,379,116)
Financing activities		
Proceeds from the issuance of long-term debt, net	52,051,777	—
Payment of note payable	(9,500,000)	—
Proceeds from issuance of common stock	17,411	16,746

Proceeds from issuance of preferred stock, net of issuance costs	19,943,210	27,404,602
Net cash provided by financing activities	<u>62,512,398</u>	<u>27,421,348</u>
Net increase in cash and cash equivalents	23,568,450	5,938,706
Cash and cash equivalents at beginning of period	5,938,706	—
Cash and cash equivalents at end of period	<u>\$ 29,507,156</u>	<u>\$ 5,938,706</u>
Supplemental disclosures of cash flow information		
Cash paid during the year for interest	<u>\$ 1,205,453</u>	<u>\$ 412,124</u>
Cash paid during the year for taxes	<u>\$ 4,503,141</u>	<u>\$ 190,000</u>
Other non-cash activities		
Deferred tax assets	<u>\$ 2,424,233</u>	<u>\$ 310,000</u>
Note issued for product rights	<u>\$ —</u>	<u>\$ 9,500,000</u>
Shares issued for notes	<u>\$ 3,997</u>	<u>\$ 146,564</u>

See accompanying notes.

ESP Pharma Holdings and Subsidiary
Notes to Consolidated Financial Statements
December 31, 2003

1. Organization and Description of Business

ESP Pharma Holdings and Subsidiary (the “Company”) was incorporated on April 15, 2002 (inception) in the State of Delaware for the purpose of selling and marketing specialty pharmaceutical products. Immediately following its inception, the Company secured financing in the amount of \$27.4 million and acquired the sales and marketing rights to four cardiovascular products from Wyeth Pharmaceuticals Inc. Since its inception, the Company has focused its efforts primarily on building the infrastructure required to support the sales and marketing of its products, and expanding its product portfolio.

2. Significant Accounting Policies

Consolidation

The financial statements include the accounts of ESP Pharma Holdings and Subsidiary and its wholly-owned subsidiary, ESP Pharma, Inc. Intercompany transactions and balances are eliminated in consolidation.

Reclassification

Certain prior year balances have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions. Assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities are affected by such estimates and assumptions. The most significant assumptions are employed in estimates used in determining allowances for doubtful accounts, values of inventories and intangible assets, accruals for rebates, returns and chargebacks, as well as estimates used in applying the revenue recognition policy. The Company is subject to risks and uncertainties that may cause actual results to differ from those estimates.

Fair Value of Financial Instruments

The Company’s financial instruments consist primarily of cash, accounts payable, accrued compensation and related benefits, an interest rate swap, long-term debt, non-marketable investments and other accrued liabilities. The Company believes the carrying value of all of its financial instruments approximates fair value. The fair value of the Company’s debt approximates fair value because of its variable interest rate.

Concentration of Credit Risk and Major Sources of Revenue

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents, accounts receivable, and revenue. The Company places its cash and cash equivalents with high-credit quality financial institutions. Concentrations of credit risk, with respect to these financial instruments, exist to the extent of the amounts presented in the financial statements.

The following table outlines customers with revenues and/or accounts receivable that individually exceed 10% of the Company’s total revenues and/or accounts receivable during the year ended December 31, 2003 and for the period ended December 31, 2002 (in thousands):

2003			2002		
Cardinal	AmeriSource Bergen	McKesson	Cardinal	AmeriSource Bergen	McKesson

Accounts receivable	\$	675	\$	4,336	\$	1,441	\$	2,021	\$	965	\$	494
Revenue		18,734		20,766		19,547		4,084		4,073		3,408

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in, first-out method. If the cost of the inventories exceeds their expected market value, provisions are recorded currently for the difference between the cost and the market value. Inventories consist of finished goods, raw materials (active pharmaceutical ingredients), and work-in-process.

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Property and Equipment

Furniture and equipment, including computer equipment and software, are stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets, generally three to five years, using the straight-line method. Leasehold improvements are capitalized as incurred and are amortized over the estimated life of the assets or related lease term, whichever is shorter.

Non-Marketable Investments

The Company has an investment in a strategic partner whose securities are not publicly traded. Because these securities are not publicly traded, the Company reviews these investments periodically for impairment by using information acquired from industry trends, the management of the investee, financial statements, and other external sources. The Company records an investment impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary. No impairment charges were recorded or deemed necessary through December 31, 2003.

Derivative Instrument

The Company uses a derivative to hedge its exposure to changes in interest rates. At December 31, 2003, the Company designated \$26,750,000 in notional value of its derivative as a cash flow hedge. The derivative is in a loss position at December 31, 2003 with the liability classified in other current liabilities and the net unrealized loss recorded as a component of other comprehensive income. There was no impact on earnings during the period resulting from hedge ineffectiveness since the hedges qualify for the "short-cut method" assumption of no ineffectiveness under the provisions of SFAS 133.

Intangible Assets

Intangible assets represent the value of product rights purchased from Wyeth Pharmaceuticals and Orphan Medical, Inc. In accordance with FAS 142, these intangible assets are being amortized on a straight-line basis over their estimated useful lives and are reviewed for impairment in accordance with FAS 144. The Company uses the remaining patent life as its estimated useful life or three years, for generic pharmaceuticals. No impairment charges were recorded or deemed necessary for the year ended December 31, 2003 or for the period ended December 31, 2002.

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Deferred Financing Costs

Deferred financing costs related to the term loan are being amortized over five years, the term of the facility. Total accumulated amortization of deferred financing costs was \$311,715 at December 31, 2003.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than their carrying amount. Impairment, if any, is assessed using discounted cash flows. No impairment charges were recorded or deemed necessary for the year ended December 31, 2003 and for the period ended December 31, 2002.

Accruals for Rebates, Returns, and Chargebacks

The Company establishes accruals for rebates, returns, and chargebacks in the same period the Company recognizes the related sales and reduces revenues for these accruals. Accrued rebates include amounts due under Medicaid, and other commercial contractual rebates. The Company estimates accrued rebates based on a percentage of selling price determined from historical experience. With respect to accruals for estimated Medicaid rebates, the Company evaluates historical rebate payments by product as a percentage of historical sales, product pricing and current contracts. At the time of rebate payment, which generally occurs with a delay after the related sale, the Company records a reduction to accrued expenses and, at the end of each period, adjust accrued expenses for any differences between estimated and actual payments. Due to estimates and assumptions inherent in determining the amount of the rebate, rebate payments remain subject to retroactive adjustment. Returns are accrued based on historical and industry experience and is currently estimated at two percent of net sales. Chargebacks are based on the estimated days of unprocessed claims using historical experience. In all cases, judgment is required in estimating these reserves, and actual claims for rebates, returns and chargebacks could be different from the estimates.

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Revenue Recognition

Revenue is recognized when title and risk of loss are transferred to customers, collection of sales is reasonably assured, and the Company has no further performance obligations. This is generally at the time products are received by the customer. Accruals for estimated discounts, returns, rebates and chargebacks, determined based on historical experience, reduce revenues at the time of sale.

Cost of Goods Sold

Cost of goods sold includes manufacturing costs and allocated costs including packaging materials, labor and overhead, royalty costs, and amortization of intangible assets associated with the products rights acquisition. The Company is required to pay royalties on its marketed products Cardene I.V., Ismo, IVBusulfex, and Declomycin. Royalty expenses directly related to product sales are classified as cost of sales and range from 12-21% of net product sales. Royalties are paid on a quarterly basis and are included as a component of cost of goods sold when the expense is incurred.

Advertising and Promotion

The Company engages in promotional activities, which typically take the form of detail aids, industry publications, journal ads, hospital grants, exhibits, speaker programs, and other forms of media. In accordance with procedures defined under Statement of Position ("SOP") 93-7, *Reporting on Advertising Costs*, advertising and promotion expenditures are expensed as incurred. Total advertising costs incurred during the year ended December 31, 2003 and for the period ended December 31, 2002 were \$6,429,822 and \$1,420,892, respectively.

Stock-Based Compensation

The Company grants stock options for a fixed number of shares to employees with an exercise price equal to the fair value of the shares at the date of grant. The Company accounts for stock option grants in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations as permitted under Financial Accounting Standards Board Statement ("FASB") No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) which requires the use of option valuation models that were not developed for use in valuing employee stock options.

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The following table illustrates the effect on net income if the Company had applied the fair value recognition provisions of SFAS 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation:

	Year ended December 31, 2003	Period from April 15, 2002 (inception) to December 31, 2002
Net income (loss), as reported	\$ 8,201,299	\$ (1,792,881)
Add total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(174,621)	(15,142)
Pro forma net income (loss)	<u>\$ 8,026,678</u>	<u>\$ (1,808,023)</u>

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and the Emerging Issues Task Force in 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*, which require that such equity instruments are recorded at their fair value on the measurement date, which is typically the date the services are performed and such equity instruments may be subject to periodic revaluation over the vesting term.

Other Operating Expenses

Other operating expenses consists principally of technology transfer costs and other start-up costs that are expensed as incurred. These expenses are separately classified as the Company does not consider these costs to be a recurring component of operating expenses.

Income Taxes

The Company accounts for income taxes under the asset and liability method whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

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Research and Development Costs

Research and development costs are expensed as incurred. Upfront payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval.

Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, requires components of other comprehensive income, including unrealized gains and losses on available-for-sale securities and other components of comprehensive income, to be included as part of total comprehensive income. The components of comprehensive income are typically included in the statements of stockholders' equity. Through December 31, 2003, the Company recorded \$90,391, net of tax in comprehensive income reflecting the non-cash impact of the interest rate swap.

In December 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities* ("FIN 46-R") to address certain FIN 46 implementation issues. The effective dates and impact of FIN 46 and FIN 46-R are as follows:

- (i) Special purpose entities ("SPEs") created prior to February 1, 2003. The Company must apply either the provisions of FIN 46 or early adopt the provisions of FIN 46-R at the end of the first interim or annual reporting period ending after December 15, 2003.
- (ii) Non-SPEs created prior to February 1, 2003. The Company is required to adopt FIN 46-R at the end of the first interim or annual reporting period ending after March 15, 2004.
- (iii) All entities, regardless of whether a SPE, that were created subsequent to January 31, 2003. The provisions of FIN 46 were applicable for variable interest in entities obtained after January 31, 2003. The Company is required to adopt FIN 46-R at the end of the first interim or annual reporting period ending after March 15, 2004.

The adoption of FIN 46 is not expected to have a material impact.

On November 21, 2002, the EITF reached a consensus on Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, regarding whether an arrangement involving multiple deliverables contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting in an arrangement. For contracts including multiple deliverables meeting the separation criteria of EITF 00-21, the Company will allocate the total arrangement consideration to each separate unit of accounting based on the relative fair values of the deliverables in each unit of accounting and recognizes revenue based on the Company's revenue recognition policy applicable to each separate unit of accounting. In general, EITF 00-21 limits the amount of revenue allocated to an individual deliverable under an agreement to the lesser of its relative fair value or the amount not contingent on the Company's delivery of other elements under the agreement, regardless of the probability of the Company's performance. The adoption of EITF 00-21 did not impact the financial statements of the Company.

3. Product Rights Acquisitions

Immediately following its inception in April 2002, the Company purchased the sales and marketing rights to four commercialized cardiovascular pharmaceutical products from Wyeth Pharmaceuticals for an aggregate purchase price of \$31.5 million, including \$22.0 million in cash and a \$9.5 million note (see Note 6).

On June 10, 2003, the Company acquired from Orphan Medical, Inc. the worldwide sales and marketing rights (excluding Australia) and existing inventory of IVBusulfex for an aggregate purchase price of \$29.3 million in cash. On October 3, 2003, the Company acquired from Wyeth Pharmaceuticals the U.S. rights to Declomycin for a net purchase price of \$22.6 million in cash.

These acquisitions were accounted for as asset acquisitions. The products and medical indications are summarized below:

Product Name	Product Indication
Cardene I.V.	For short-term treatment of hypertension when oral therapy is not feasible or desirable
IVBusulfex	For use as a conditioning regimen prior to bone marrow transplantation for chronic myelogenous leukemia
Declomycin	For use as an antibiotic in treating numerous bacterial infections
Sectral	For chronic treatment of hypertension and ventricular arrhythmias
Tenex	For chronic treatment of hypertension
Ismo	For the prevention of angina pectoris due to coronary artery disease

The fair value of the product rights acquisition was allocated based on discounted cash flow projections. The following tables summarize the gross carrying amount of the assets acquired and estimated useful lives at the date of acquisition with accumulated amortization through December 31, 2003 and 2002 (in thousands):

Product Name	Gross Carrying Amount	Accumulated Amortization	Estimated Useful Life (Years)
December 31, 2003			
Cardene I.V.	\$ 25,626	\$ (6,441)	7
IVBusulfex	29,300	(1,424)	12
Declomycin	22,585	(1,848)	3
Sectral	2,685	(1,567)	3
Tenex	2,421	(1,412)	3
Ismo	768	(448)	3
Total	<u>\$ 83,385</u>	<u>\$ (13,140)</u>	
December 31, 2002			
Cardene I.V.	\$ 25,626	\$ (2,746)	7
Sectral	2,685	(671)	3
Tenex	2,421	(605)	3

Ismo	768	(192)	3
Total	<u>\$ 31,500</u>	<u>\$ (4,214)</u>	

The estimated amortization expense for the next five years is as follows (in thousands):

For the year ending December 31:		
2004	\$	15,571
2005		14,103
2006		11,735
2007		6,103
2008		6,103
Thereafter		16,630

4. Property and Equipment

Property and equipment consisted of the following:

	December 31	
	2003	2002
Office equipment	\$ 578,915	\$ 242,862
Furniture and fixtures	472,933	229,457
Computer equipment and software	216,825	88,058
	<u>1,268,673</u>	<u>560,377</u>
Less accumulated depreciation and amortization	212,235	44,829
Property, plant and equipment, net	<u>\$ 1,056,438</u>	<u>\$ 515,548</u>

Depreciation expense was \$167,406 and \$44,829 for the year ended December 31, 2003 and for the period ended December 31, 2002, respectively.

5. Non-Marketable Investments

On September 25, 2002, the Company entered into two agreements (the "Hydralazine Agreements") with Barbeau Pharma, Inc. (Evanston, IL). Under the terms of the Hydralazine Agreements, Barbeau Pharma, Inc. provided to the Company the exclusive rights to market a new formulation of hydralazine hydrochloride ("Hydralazine"), and a derivative compound in late-stage development both for treating severe hypertension in pregnancy, a potentially life-threatening condition. Additionally, Barbeau Pharma, Inc. is responsible for preparing an NDA for submission to the FDA for the approval to market Hydralazine. The fair value of these rights was not deemed significant at the date of acquisition. In accordance with these arrangements, the Company purchased 900 shares of Series A cumulative preferred stock for \$900,000 in a series of transactions between

September 2002 and November 2003. Upon approval of Hydralazine by the FDA, the Company will owe Barbeau Pharma, Inc. an additional payment ranging from \$750,000 to \$2,000,000 based on the extent of marketing exclusivity inherent in such approval.

In June 2003, the Company entered into two additional agreements (the "BP104 Agreements") with Barbeau Pharma, Inc. whereby Barbeau Pharma, Inc. provided the Company with exclusive rights to develop and market an injectable form of an anti-emetic ("BP104") for the treatment of chemotherapy induced nausea and vomiting and post operative nausea and vomiting. Barbeau Pharma, Inc. is responsible for preparing an NDA for submission to the FDA for the approval to market BP104. The Company purchased 700 shares of Series A cumulative preferred stock for \$700,000 in a series of transactions. The fair value of these rights was not deemed significant at the date of acquisition. Under the BP104 Agreements the Company is obligated to make additional investments in Barbeau Pharma, Inc. preferred stock of \$600,000. Further, the Company may be required to pay an additional \$1,200,000 upon the clinical data review by the FDA, and an additional \$1,000,000 upon approval by the FDA. As of December 31, 2003, the Company had less than 10% ownership of Barbeau Pharma, Inc. and, as such, the investment is accounted for under the cost method.

6. Debt

In connection with the 2002 products rights acquisition discussed in Note 3, the Company issued a \$9.5 million Senior Secured Promissory Note. Principal payments were due annually, commencing April 25, 2004. Interest accrued on the unpaid principal amount at a variable rate and was payable semiannually. This note was paid in full in October, 2003 with a portion of the proceeds of a Credit Facility (as further described below).

On October 3, 2003, in connection with the acquisition of Declomycin, the Company entered into a long-term financing arrangement (the "Credit Facility") with a group of financial institutions. The Credit Facility is comprised of: (i) a \$6.5 million Revolving Credit Facility (the "Revolver"), and (ii) a \$53.5 million Term Loan ("Term Loan"). The Credit Facility is secured by substantially all of the tangible and intangible assets of the Company.

Under the terms of the Revolver, through October 3, 2008, the Company may borrow on a revolving basis up to \$6.5 million where amounts repaid may be re-borrowed. The Revolver includes a \$1.0 million letter of credit sub-facility and a \$1.0 million Swingline sub-facility. Through December 31, 2003, there were no draws on the Revolver.

The Company borrowed \$53.5 million under the Term Loan which fully matures on October 3, 2008. Scheduled principal payments of \$2.7 million are required on a quarterly basis commencing on September 30, 2004 with the balance due at the maturity date. Additionally, the Term Loan also includes annual mandatory principal payments commencing in April, 2004 in amounts based on a percentage of the Company's excess cash flow as defined in the Credit Facility. These mandatory principal payments are classified as a current liability.

Borrowings under the Credit Facility bear interest, which is payable monthly, at a floating rate equal to the Base Rate (as defined in the Credit Facility) plus a margin of 1.25%, or at a rate equal to LIBOR plus a margin of 3.75% based on the type of borrowing. Additionally, a fee of 0.50% is charged on the average daily unused amount of the Revolver, and a fee of 3.75% is charged on the amount of any issued letters of credit. Under the terms of the Credit Facility, the Company was required to execute an interest rate swap for half of the principal balance converting the variable rate note to a fixed rate (see Note 2).

The Credit Facility contains limitations and restrictions concerning, among other things, additional indebtedness, acquisitions and dispositions of assets, dividend payments and transactions with affiliates. In addition, the Credit Facility requires the Company to maintain certain ratios (as defined therein). The Company believes it is in compliance with all financial covenants at December 31, 2003.

The following is a summary of the scheduled principal payments of the Term Loan for the next five years and does not include the annual mandatory principal payments as such amounts are contingent on future operations:

2004	\$	10,761,301
2005		10,700,000
2006		10,700,000
2007		10,700,000
2008		10,638,699
Total principal payments	\$	<u>53,500,000</u>

7. Stockholders' Equity

Convertible Preferred Stock

In April and May of 2002, the Company issued 28.2 million shares of Series A convertible preferred stock for proceeds of \$27.4 million.

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In April 2003, the Company completed its Series B convertible stock financing, which raised \$19.9 million through the sale of 12.5 million shares. The Series B preferred stock preferences are the same as the Series A convertible preferred stock.

Conversion

Each share of preferred stock is, at the option of the holder, convertible into shares of common stock on a one-for-one basis, subject to certain adjustments for dilution, if any, resulting from future stock issuances. The initial conversion price for the preferred stock is \$1.00 per share. The convertible preferred stock shall be automatically converted into common stock upon (a) the consummation of an IPO at an offering price which is not less than \$3 per share in an offering with aggregate proceeds to the Company of not less than \$40,000,000 or (b) the vote of a two-thirds interest of the convertible preferred stock voting together as a single class.

Dividend Rights

Convertible preferred shareholders are entitled to cumulative dividends at an annual rate of 8% per share if and when declared by the Board of Directors. Dividends will be paid only out of legally available funds. No dividends have been declared or paid as of or for any period ended December 31, 2003. The amount of cumulative dividends in arrears related to the preferred stock is \$4,855,459 as of December 31, 2003.

Liquidation Preferences

In the event of any liquidation, sale or merger, or winding up of the Company, the preferred shareholders are entitled to receive, in preference to the holders of common stock, an initial preference equal to one times the original purchase price per share plus all accrued and unpaid dividends declared, then for any remaining assets, shall participate with the holders of common stock on an as-converted basis, until the preferred shareholders receive a total of three times their purchase price per share, plus all accrued and unpaid dividends declared.

Voting Rights

The preferred shareholders will vote together with the common shareholders and not as a separate class except as specifically provided in the investment agreement or required by law. Specifically, the preferred and common stock will vote separately on mergers, acquisitions,

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sale of all, or substantially all assets, and transactions that would result in a change of control. Each share of preferred shall have a number of votes equal to the number of shares of common stock then issuable upon conversion of such share of preferred.

Common Stock and Common Stock Options

Restricted Common Stock Purchases

Prior to closing of the Company's Series A Preferred Stock financing, the Company issued 6,065,000 shares of \$0.0001 par value restricted common stock to founders and other advisors at a price of \$0.01 per share. The Company issued additional shares totaling 710,000 to management and other employees at

\$0.16 per share. All common shares issued to Company employees were purchased with cash or with full recourse loans with an average interest rate of 4.75%, and have certain restrictions in connection with the ownership of such shares.

The restricted founders shares vest (i.e. have a lapsing forfeiture provision) as follows: a) 33.33% of the common stock vests on the date each founder commences employment with the Company, b) 16.67% vests on the first anniversary of the date of employment, c) the remaining 50% vests in equal monthly installments over a three year period beginning the month following the first anniversary. The vesting accelerates upon an approved sale or a liquidating event.

The Company will, at all times, reserve and keep available from its authorized but unissued shares of common stock, sufficient shares to be issued upon the conversion of the shares of the convertible preferred stock and upon the exercise of the stock options. As of December 31, 2003, the Company reserved 29,525,000 shares of common stock for future issuance pursuant to its equity compensation plan.

Stock Options

In June 2002, the Company's Board of Directors and shareholders approved the Company's 2002 Stock Option Plan (the "2002 Plan"). The 2002 Plan provides for the granting of options to purchase common stock in the Company to employees, advisors and consultants at a price to be determined by the Company's Board of Directors. The Options may be incentive stock options or non-statutory stock options. Under the provisions of the 2002 Plan, no option will have a term in excess of 10 years. At December 31, 2003, the Company reserved up to 3,025,000 shares for issuance upon exercise of options.

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The 2002 Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business and is administered by the Board of Directors or a committee consisting of members of the Board. The Board or committee is responsible for determining the individuals to be granted options, the number of options each individual will receive, the option price per share and the exercise period of each option. Options granted pursuant to the 2002 Plan generally vest 25% after the first year, and the remaining 75% vest equally over the next three years.

The following table summarizes information about stock options outstanding at December 31, 2003 and 2002.

	Shares Available for Grant	Restricted Stock	Options Outstanding		
			Number of Shares	Option Price Per Share Range	Weighted-Average Exercise Price
Balance at April 15, 2002 (inception)	—	—	—	\$ —	\$ —
Shares authorized	1,325,000	—	—	—	—
Options granted	(223,500)	—	223,500	0.16	0.16
Options exercised	—	—	—	—	—
Options forfeited	—	—	—	—	—
Balance at December 31, 2002	1,101,500	—	223,500	0.16	0.16
Shares authorized	1,700,000	—	—	—	—
Shares issued	(20,000)	20,000	—	—	—
Options granted	(2,652,200)	—	2,652,200	0.16-0.46	0.28
Options exercised	—	—	(30,375)	0.16	0.16
Options forfeited	103,625	—	(103,625)	0.16	0.16
Balance at December 31, 2003	232,925	20,000	2,741,700	\$ 0.16-0.46	\$ 0.21

The following table summarizes information about stock options outstanding at December 31, 2003:

Exercise Price	Options Outstanding	Options Vested	Weighted-Average Remaining Contractual Life
\$ 0.16	1,154,250	136,438	4.00
0.22	462,500	7,500	4.25
0.25	1,083,500	10,000	4.50
0.46	41,450	5,000	4.75
	2,741,700	158,938	

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At December 31, 2003, the average remaining contractual life of outstanding options was approximately 4 years. The weighted-average fair value of options granted since inception was approximately \$0.32.

If compensation cost had been determined based on the fair value of the options at the grant dates for those options for which no compensation cost has been recognized, consistent with the method of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), the Company's net income per share would have decreased. Such pro forma disclosures (see Note 2) may not be representative of future compensation expense because options vest over several years and additional grants may be made each year. The fair value of these options was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions for 2003:

Employee Share Options

Expected life	5 years
Risk-free interest rate	3.5%
Volatility	100%
Dividend yield	0%

8. Income Taxes

Significant components of the state and federal income tax provision (benefit) for income taxes are as follows:

	Year ended December 31	
	2003	2002
Current provision:		
Federal	\$ 5,941,000	\$ 235,000
State	1,690,000	75,000
Total current provision	7,631,000	310,000
Deferred benefit:		
Federal	(2,856,000)	(946,000)
State	(378,000)	(174,000)
Total deferred benefit	(3,234,000)	(1,120,000)
Valuation allowance	—	810,000
Net deferred benefit	(3,234,000)	(310,000)
Total income tax provision	\$ 4,397,000	\$ —

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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets for financial reporting and the amount used for income tax purposes. At December 31, 2002, a valuation allowance was recorded to partially offset the net deferred tax assets. At December 31, 2003, the Company believed it was more likely than not that it would realize its deferred tax assets and reduced the valuation allowance to zero. The change in the valuation allowance for the year ended December 31, 2003 and the period ended December 31, 2002 was approximately (\$810,000) and \$810,000, respectively. Significant components of the Company's deferred tax assets as of December 31, 2003 and 2002 are as follows:

	December 31	
	2003	2002
Deferred tax assets:		
Accounts receivable allowances	\$ 1,642,000	\$ 394,000
Amortization of intangible assets	1,767,000	452,000
Amortization of start-up costs	231,000	270,000
Other	(47,000)	4,000
Total deferred tax assets	3,593,000	1,120,000
Less valuation allowance	—	(810,000)
Net deferred tax asset	\$ 3,593,000	\$ 310,000

The net deferred tax asset included a current portion of \$1,034,078 at December 31, 2003 and a long-term portion of \$2,558,964 at December 31, 2003.

9. Operating Leases and Commitments

Minimum annual rental commitments under non-cancelable operating leases, primarily office facilities in effect at December 31, 2003 are as follows:

2004	\$ 403,440
2005	432,066
2006	433,328
2007	433,328
2008	36,111

Operating lease rental expense aggregated \$305,578 and \$199,030 for the year ended December 31, 2003 and for the period ended December 31, 2002, respectively.

Letter of Credit

In accordance with the terms of the Company's leasing arrangement, the Company is required to maintain an irrevocable letter of credit in the amount of \$309,000. Through December 31, 2003, there were no draws on the letter of credit.

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10. Employee Benefit Plan

The Company has established a defined contribution pension plan (the "Plan") covering all eligible employees. Employees are eligible to participate in the Plan on the first quarterly entry date following date of hire, as defined in the Plan document. Employees can contribute from 1% to 60% of eligible pay, subject to the annual Federal Tax Law limits. The Company matches 100% of the first 3% of employee contributions and may also elect to make a discretionary non-matching contribution to the Plan on behalf of all eligible employees. Total expenses incurred for the year ended December 31, 2003 and the period ended December 31, 2002 was approximately \$87,700 and \$68,000, respectively.

12. Related Party Transactions

As permitted under the Stock Plan, certain purchasers of restricted stock and option grants signed full recourse promissory notes for the value of their shares and options at the date of grant. Under the terms of these notes, the principal balance and all unpaid interest is at various dates through 2007. Both interest and principal can be prepaid without penalty. At December 31, 2003 and 2002, notes and accrued interest receivable of \$152,904 and \$146,564, respectively, remain outstanding and are classified in stockholders' equity.

Two of the officers of ESP Pharma are members of the Board of Directors for a company that ESP Pharma has non-marketable investments.

13. Subsequent Events

On March 3, 2004 the Company entered into a License and Supply Agreement with Orphan Therapeutics, LLC which gives the Company the exclusive license and other intellectual property related to marketing an injectible pharmaceutical product for treatment of complications related to liver disease ("ESP303") once approved by the FDA. In consideration of the rights to ESP303, the Company paid Orphan Therapeutics \$2 million upon signing the License and Supply Agreement which was charged as a Research and Development expense. The Company is obligated to make additional payments totaling \$4.2 million contingent on the achievement of certain milestones, including the approval of a New Drug Application by the U.S. Food and Drug Administration.

ESP Pharma Holdings and Subsidiary

Consolidated Balance Sheets

	September 30, 2004 (unaudited)	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,001,667	\$ 29,507,156
Accounts receivable, net of reserves of \$3,045,000 and \$2,071,000 as of September 30, 2004 and December 31, 2003, respectively	11,345,627	6,140,579
Inventories	5,429,181	3,465,543
Prepaid expenses and other current assets	2,346,358	2,922,494
Deferred tax asset	3,374,574	1,034,078
Total current assets	<u>56,497,407</u>	<u>43,069,850</u>
Property and equipment, net	1,065,207	1,056,438
Non-marketable investments	—	1,600,000
Product rights, net	58,554,117	70,245,851
Deferred tax assets	3,711,298	2,558,964
Deferred financing costs	1,159,589	1,289,838
Total assets	<u>\$ 120,987,618</u>	<u>\$ 119,820,941</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,235,977	\$ 2,472,001
Accrued expenses	7,851,965	4,493,485
Other current liabilities	8,805,818	4,860,069
Income taxes payable	269,635	883,737
Current portion of long-term debt	10,700,000	10,761,301
Total current liabilities	<u>28,863,395</u>	<u>23,470,593</u>
Long-term debt	37,300,000	42,738,699
Series A convertible preferred stock; \$0.0001 par value; 28,200,000 shares authorized, issued and outstanding as of September 30, 2004 and December 31, 2003, respectively (minimum liquidation preference of \$28,200,000)	27,404,602	27,404,602
Series B convertible preferred stock; \$0.0001 par value; 12,500,000 shares authorized, issued and outstanding as of September 30, 2004 and December 31, 2003 (minimum liquidation preference of \$20,000,000)	19,943,210	19,943,210
Stockholders' equity		
Common stock; \$0.0001 par value; 36,300,000 shares authorized, 6,578,024 and 6,588,708 issued and outstanding at September 30, 2004 and 2003, respectively	658	659
Additional paid-in capital	307,034	98,055
Notes receivable - related parties	(140,912)	(152,904)
Deferred compensation	(156,876)	—
Retained earnings	7,457,376	6,408,418
Other comprehensive income (loss)	9,131	(90,391)
Total stockholders' equity	<u>7,476,411</u>	<u>6,263,837</u>
Total liabilities and stockholders' equity	<u>\$ 120,987,618</u>	<u>\$ 119,820,941</u>

See accompanying notes.

ESP Pharma Holdings and Subsidiary

Consolidated Statements of Income

	Nine months ended September 30	
	2004	2003
	(unaudited)	
Revenue	\$ 67,615,685	\$ 39,235,747
Cost of goods sold	26,397,941	11,898,631
Gross profit	41,217,744	27,337,116
Selling and marketing	16,802,028	10,165,112
General and administrative	12,062,013	8,255,858
Research and development	4,819,136	400,107
Other operating expenses	3,369,905	1,118,963
Income from operations	4,164,662	7,397,076
Interest expense	(2,441,684)	(480,486)
Interest income	117,299	74,959
Income before provision for income taxes	1,840,277	6,991,549
Provision for income taxes	791,319	2,351,652
Net income	\$ 1,048,958	\$ 4,639,897

See accompanying notes.

ESP Pharma Holdings and Subsidiary

Consolidated Statements of Stockholders' Equity

	Common Stock				Notes Receivable	Deferred Compensation Amount	Retained Earnings (Accumulated Deficit)	Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount							
Balance at									
December 31, 2002	6,775,000	\$ 678	\$ 9,339	\$ 9,339	\$ (146,564)	\$ —	\$ (1,792,881)	\$ —	\$ (1,929,428)
Issuance of common stock	50,375	5	26,075	26,075	(8,669)				17,411
Shares no longer subject to repurchase rights			51,119	51,119					51,119
Options issued to non-employees			13,865	13,865					13,865
Return of unvested shares to reserve	(236,667)	(24)	(2,343)	(2,343)	2,329				(38)
Comprehensive income:									
Net income							8,201,299		8,201,299
Other comprehensive income, net of tax								(90,391)	(90,391)
Total comprehensive income									8,110,908
Balance at									
December 31, 2003	6,588,708	659	98,055	98,055	(152,904)	—	6,408,418	(90,391)	6,263,837
Issuance of common stock	34,625	3	7,375	7,375					7,378
Shares no longer subject to repurchase rights			175,800	33,046					33,046
Deferred compensation related to stock options, net of forfeitures				175,800		(175,800)			—
Amortization of deferred compensation						18,924			18,924
Return of unvested shares to reserve	(45,309)	(4)	(7,242)	(7,242)	11,992				4,746
Comprehensive income:									
Net income							1,048,958		1,048,958
Other comprehensive income, net of tax								99,522	99,522
Total comprehensive income									1,148,480
Balance at	6,578,024	\$ 658	\$ 307,034	\$ 307,034	\$ (140,912)	\$ (156,876)	\$ 7,457,376	\$ 9,131	\$ 7,476,411

See accompanying notes.

ESP Pharma Holdings and Subsidiary
Consolidated Statements of Cash Flows

	Nine months ended September 30	
	2004	2003
	(unaudited)	
Operating activities		
Net income	\$ 1,048,958	\$ 4,639,897
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	219,891	112,394
Amortization of product rights	11,691,734	5,028,049
Change in interest rate swap	99,522	—
Non-cash expense associated with non-employee options	—	13,865
Deferred tax assets	(3,492,830)	(162,285)
Amortization of deferred compensation	18,924	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,205,048)	(3,887,125)
Inventories	(1,963,638)	(2,949,538)
Prepaid expenses and other current assets	576,136	(3,762,586)
Accounts payable	(1,236,024)	369,743
Accrued expenses	3,396,272	6,075,288
Other current liabilities and income tax payable	3,331,647	1,556,571
Deferred financing costs	130,249	—
Net cash provided by operating activities	<u>8,615,793</u>	<u>7,034,273</u>
Investing activities		
Additions to fixed assets	(228,660)	(749,914)
Non-cash write-off of investment	2,200,000	—
Purchase of non-marketable investments	(600,000)	(600,000)
Purchase of product rights	—	(29,300,000)
Net cash provided by (used in) investing activities	<u>1,371,340</u>	<u>(30,649,914)</u>
Financing activities		
Payment of note payable	(5,500,000)	—
Proceeds from issuance of common stock	7,378	17,411
Proceeds from issuance of preferred stock, net of issuance costs	—	19,943,210
Net cash (used in) provided by financing activities	<u>(5,492,622)</u>	<u>19,960,621</u>
Net increase (decrease) in cash and cash equivalents	4,494,511	(3,655,020)
Cash and cash equivalents at beginning of period	29,507,156	5,938,706
Cash and cash equivalents at end of period	<u>\$ 34,001,667</u>	<u>\$ 2,283,686</u>
Supplemental disclosures of cash flow information		
Cash paid during the period for interest	\$ 330,729	\$ 2,143,095
Cash paid during the period for taxes	<u>\$ 1,780,179</u>	<u>\$ 4,839,723</u>

See accompanying notes.

ESP Pharma Holdings and Subsidiary
Notes to Consolidated Financial Statements

1. Organization and Description of Business

ESP Pharma Holdings and Subsidiary (the "Company") was incorporated on April 15, 2002 (inception) in the State of Delaware for the purpose of selling and marketing specialty pharmaceutical products. Immediately following its inception, the Company secured financing in the amount of \$27.4 million and acquired the sales and marketing rights to four cardiovascular products from Wyeth Pharmaceuticals Inc. Since its inception, the Company has focused its efforts primarily on building the infrastructure required to support the sales and marketing of its products, and expanding its product portfolio.

2. Significant Accounting Policies

Consolidation

The financial statements include the accounts of ESP Pharma Holdings and Subsidiary and its wholly-owned subsidiary, ESP Pharma, Inc. Intercompany transactions and balances are eliminated in consolidation.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. In the opinion of management, the accompanying financial statements include all adjustments considered necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented.

The results of operations for the nine month period ended September 30, 2004 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2004. These consolidated financial statements should be read in conjunction with the audited financial statements included in the Company's consolidated financial statements for the year ended December 31, 2003.

Reclassification

Certain prior year balances have been reclassified to conform to the current year presentation.

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Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions. Assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities are affected by such estimates and assumptions. The most significant assumptions are employed in estimates used in determining allowances for doubtful accounts, values of inventories and intangible assets, accruals for rebates, returns and chargebacks, as well as estimates used in applying the revenue recognition policy. The Company is subject to risks and uncertainties that may cause actual results to differ from those estimates.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, accounts payable, accrued compensation and related benefits, an interest rate swap, long-term debt, non-marketable investments and other accrued liabilities. The Company believes the carrying value of all of its financial instruments approximates fair value. The fair value of the Company's debt approximates fair value because of its variable interest rate.

Concentration of Credit Risk and Major Sources of Revenue

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents, accounts receivable, and revenue. The Company places its cash and cash equivalents with high-credit quality financial institutions. Concentrations of credit risk, with respect to these financial instruments, exist to the extent of the amounts presented in the financial statements.

The following table outlines customers with revenues and/or accounts receivable that individually exceed 10% of the Company's total revenues and/or accounts receivable during the nine month period ended September 30, 2004 and the year ended December 31, 2003 (in thousands):

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	2004			2003		
	Cardinal	AmeriSource Bergen	McKesson	Cardinal	AmeriSource Bergen	McKesson
Accounts receivable	\$ 2,875	\$ 1,499	\$ 6,457	\$ 675	\$ 4,336	\$ 1,441
Revenue	22,354	12,223	21,463	18,734	20,766	19,547

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in, first-out method. If the cost of the inventories exceeds their expected market value, provisions are recorded currently for the difference between the cost and the market value. Inventories consist of finished goods, raw materials (active pharmaceutical ingredients), and work-in-process.

	September 30, 2004 (unaudited)	December 31, 2003
Raw material	\$ 1,836,689	\$ 363,658
Work in process	—	148,000
Finished goods	3,887,678	3,009,997
Less: Inventory reserves	295,186	56,112
Total inventories	\$ 5,429,181	\$ 3,465,543

Property and Equipment

Furniture and equipment, including computer equipment and software, are stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets, generally three to five years, using the straight-line method. Leasehold improvements are capitalized as incurred and are amortized over the estimated life of the assets or related lease term, whichever is shorter.

Non-Marketable Investments

The Company has an investment in a strategic partner whose securities are not publicly traded. Because these securities are not publicly traded, the Company reviews this investment periodically for impairment by using information acquired from industry trends, the management of the investee, financial statements, and other external sources. The Company records an investment impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary. The investment was evaluated as of September 30, 2004 for net realizable value and a reserve was established as of that time for the total amount of the investment.

Derivative Instrument

The Company uses a derivative to hedge its exposure to changes in interest rates. At September 30, 2003, the Company designated \$26,750,000 in notional value of its derivative as a cash flow hedge. The derivative is in a net gain position at September 30, 2004 with the asset classified as an offset to other current liabilities and the net unrealized gain recorded as a component of other comprehensive income. There was no impact on earnings during the period resulting from hedge ineffectiveness since the hedges qualify for the "short-cut method" assumption of no ineffectiveness under the provisions of SFAS 133.

Intangible Assets

Intangible assets represent the value of product rights purchased from Wyeth Pharmaceuticals and Orphan Medical, Inc. In accordance with FAS 142, these intangible assets are being amortized on a straight-line basis over their estimated useful lives and are reviewed for impairment in accordance with FAS 144. The Company uses the remaining patent life as its estimated useful life or three years, for generic pharmaceuticals. No impairment charges were recorded or deemed necessary for the period ended September 30, 2004 and the year ended December 31, 2003.

Deferred Financing Costs

Deferred financing costs related to the term loan are being amortized into interest expense over five years, the term of the facility. Total accumulated amortization of deferred financing costs was \$334,264 at September 30, 2004.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than their carrying amount. Impairment, if any, is assessed using discounted cash flows. Consequently, the investment in a strategic partner was evaluated as of September 30, 2004 for net realizable value and a reserve was established as of that time for the total amount of the investment.

Accruals for Rebates, Returns, and Chargebacks

The Company establishes accruals for rebates, returns, and chargebacks in the same period the Company recognizes the related sales and reduces revenues for these accruals. Accrued rebates include amounts due under Medicaid, and other commercial contractual rebates. The Company estimates accrued rebates based on a percentage of selling price determined from historical experience. With respect to accruals for estimated Medicaid rebates, the Company evaluates historical rebate payments by product as a percentage of historical sales, product pricing and current contracts. At the time of rebate payment, which generally occurs with a delay after the related sale, the Company records a reduction to accrued expenses and, at the end of each period, adjust accrued expenses for any differences between estimated and actual payments. Due to estimates and assumptions inherent in determining the amount of the rebate, rebate payments remain subject to retroactive adjustment. Returns are accrued based on historical and industry experience and is currently estimated at two percent of net sales. Chargebacks are based on the estimated days of unprocessed claims using historical experience. In all cases, judgment is required in estimating these reserves, and actual claims for rebates, returns and chargebacks could be different from the estimates.

Revenue Recognition

Revenue is recognized when title and risk of loss are transferred to customers, collection of sales is reasonably assured, and the Company has no further performance obligations. This is generally at the time products are received by the customer. Accruals for estimated discounts, returns, rebates and chargebacks, determined based on historical experience, reduce revenues at the time of sale.

Cost of Goods Sold

Cost of goods sold includes manufacturing costs, including packaging materials, labor and overhead, royalty costs, and amortization of intangible assets associated with the products rights acquisition. The Company is required to pay royalties on its marketed products Cardene I.V., Ismo, IV Busulfex, and Declomycin. Royalty expenses directly related to product sales are classified as cost of sales and range from 12-30% of net product sales. Royalties are paid on a quarterly basis and are included as a component of cost of goods sold when the expense is incurred.

Advertising and Promotion

The Company engages in promotional activities, which typically take the form of detail aids, industry publications, journal ads, hospital grants, exhibits, speaker programs, and other forms of media. In accordance with procedures defined under Statement of Position ("SOP") 93-7, *Reporting on Advertising Costs*, advertising and promotion expenditures are expensed as incurred. Total advertising costs incurred during the nine month periods ended September 30, 2004 and 2003 were \$8,868,979 and \$4,247,328, respectively.

Stock-Based Compensation

The Company grants stock options for a fixed number of shares to employees with an exercise price equal to the fair value of the shares at the date of grant. The Company accounts for stock option grants in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations as permitted under Financial Accounting Standards Board Statement ("FASB") No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), which requires the use of option valuation models that were not developed for use in valuing employee stock options.

The following table illustrates the effect on net income if the Company had applied the fair value recognition provisions of SFAS 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation:

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	Nine months ended September 30	
	2004	2003
	(unaudited)	
Net income, as reported	\$ 1,048,958	\$ 4,639,897
Add non-cash employee compensation as reported	18,924	—
Deduct total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(82,008)	(130,966)
Pro forma net income	\$ 985,874	\$ 4,508,931

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and the Emerging Issues Task Force in 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*, which require that such equity instruments are recorded at their fair value on the measurement date, which is typically the date the services are performed and such equity instruments may be subject to periodic revaluation over the vesting term.

Other Operating Expenses

Other operating expenses consist principally of technology transfer costs and other start-up costs that are expensed as incurred. These expenses are separately classified as the Company does not consider these costs to be a recurring component of operating expenses. In addition, the investment in a strategic partner was evaluated as of September 30, 2004 for net realizable value and a reserve of \$2,200,000 was established as of that time for the total amount of the investment. This amount is included with other operating expenses in the statement of income for the nine months ended September 30, 2004.

Income Taxes

The Company accounts for income taxes under the asset and liability method whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect

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for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Research and Development Costs

Research and development costs are expensed as incurred. Upfront payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval.

Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, requires components of other comprehensive income, including unrealized gains and losses on available-for-sale securities and derivatives used to hedge exposure to interest rates, and other components of comprehensive income, to be included as part of total comprehensive income. The components of comprehensive income are typically included in the statements of stockholders' equity. For the nine months ended September 30, 2004, the Company recorded \$99,522, net of tax in comprehensive income reflecting the non-cash impact of the interest rate swap.

Recently Issued Accounting Standards

Exposure Draft on Stock Compensation

The FASB recently issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, an Amendment of FASB Statements No. 123 and 95. The change in accounting would replace existing requirements under FAS 123, *Accounting for Stock-Based Compensation*, and APB Opinion No. 25, *Accounting for Stock Issued to Employees*.

The statement covers a wide range of equity-based compensation arrangements. Under the Board's statement, all forms of share-based payments to employees, including employee stock options, would be treated the same as other forms of compensation by recognizing the related cost in the income statement. The expense of the award would generally be measured at fair value at the grant date.

On October 13, 2004, the FASB concluded that Statement 123R would be effective for public companies (except small business issuer as defined in SEC Regulation S-B) for interim or annual periods beginning after June 15, 2005. Retroactive application of the requirements of Statement 123 (not Statement 123R) to the beginning of the fiscal year that includes the effective date would be permitted but not required. Early adoption of Statement 123R is encouraged.

A calendar-year company therefore would be required to apply Statement 123R beginning July 1, 2005 (that is adopt Statement 123R in its financial statements for the quarter ended September 30, 2005), and could choose to apply Statement 123 retroactively from January 1, 2005 to June 30, 2005 (that is, restate the year-to-date period in its third quarter 2005 Form 10-Q to account for all share-based payments under the fair value method from January 1, 2005; under Statement 123 for the first six months and under Statement 123R thereafter). The cumulative effect of adoption, if any, would be measured and recognized on July 1, 2005. Further, the Company could choose to early adopt the proposed Statement at the beginning of its first quarter ended March 31, 2005 (or even in the fourth quarter of 2004 if the FASB issues the final Statement prior to the issuance of those financial statements).

Inventory Costs

The FASB issued FASB No. 151, *Inventory Costs*, amendment of ARB No. 43. This statement classifies the following items as current period charges, regardless of whether they met the criterion of "so abnormal" as required under ARB 43: idle facility expense, excessive spoilage, double freight, and re-handling costs. A final standard when issued will achieve more comparability in cross-border financial reporting through convergence to a single set of high-quality accounting standards. Inventory costs was an area identified in which the FASB and IASB could improve accounting by converging their standards. The statement is applicable to inventory costs incurred during periods beginning after the adoption date (i.e. no cumulative effect upon adoption) and effective for fiscal years beginning on or after December 15, 2004.

3. Product Rights Acquisitions

Immediately following its inception in April 2002, the Company purchased the sales and marketing rights to four commercialized cardiovascular pharmaceutical products from Wyeth Pharmaceuticals for an aggregate purchase price of \$31.5 million, including \$22.0 million in cash and a \$9.5 million note.

On June 10, 2003, the Company acquired from Orphan Medical, Inc. the worldwide sales and marketing rights (excluding Australia) and existing inventory of IVBusulfex for an aggregate purchase price of \$29.3 million in cash. On October 3, 2003, the Company acquired from Wyeth Pharmaceuticals the U.S. rights to Declomycin for a net purchase price of \$22.6 million in cash.

These acquisitions were accounted for as asset acquisitions. The products and medical indications are summarized below:

<u>Product Name</u>	<u>Product Indication</u>
Cardene I.V.	For short-term treatment of hypertension when oral therapy is not feasible or desirable
IVBusulfex	For use as a conditioning regimen prior to bone marrow transplantation for chronic myelogenous leukemia
Declomycin	For use as an antibiotic in treating numerous bacterial infections
Sectral	For chronic treatment of hypertension and ventricular arrhythmias
Tenex	For chronic treatment of hypertension
Ismo	For the prevention of angina pectoris due to coronary artery disease

The fair value of the product rights acquisition was allocated based on discounted cash flow projections. The following tables summarize the gross carrying amount of the assets acquired and estimated useful lives at the date of acquisition with accumulated amortization through September 30, 2004 and December 31, 2003 (in thousands):

<u>Product Name</u>	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Estimated Useful Life (Years)</u>
September 30, 2004			
Cardene I.V.	\$ 25,626	\$ (9,152)	7
IVBusulfex	29,300	(3,256)	12
Declomycin	22,585	(7,528)	3
Sectral	2,685	(2,238)	3
Tenex	2,421	(2,038)	3
Ismo	768	(619)	3
Total	\$ 83,385	\$ (24,831)	
December 31, 2003			
Cardene I.V.	\$ 25,626	\$ (6,441)	7

IVBusulfex	29,300	(1,424)	12
Declomycin	22,585	(1,848)	3
Sectral	2,685	(1,567)	3
Tenex	2,421	(1,412)	3
Ismo	768	(448)	3
Total	\$ 83,385	\$ (13,140)	

The estimated amortization expense for the next five years is as follows (in thousands):

For the year ending December 31:		
2005		\$ 14,103
2006		11,735
2007		6,103
2008		6,103
2009		3,357
Thereafter		13,273

In April, 2004, the Company learned that Impax Laboratories, Inc.'s ("Impax") Abbreviated New Drug Application to manufacture and distribute Demeclocycline Hydrochloride, a generic form of Declomycin, was approved by the FDA. Impax announced that it planned to immediately commence marketing Demeclocycline Hydrochloride through its Global Pharmaceutical division. ESP is currently implementing several strategic responses to this announcement and is determining the short-term and long-term impact on the operations of the Company.

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As part of the Company's strategic response, an agreement was finalized in June 2004 with Stiefel Laboratories, Inc. to sell a generic version of Declomycin through its Glades Pharmaceutical division ("Glades"). As part of the arrangement, the Company will realize profit in the sale of brand product to Glades, plus share in the gross profit of Demeclocycline sold through Glades' distribution channel. On September 9, 2004, Glades began receiving products from the Company.

4. Property and Equipment

Property and equipment consisted of the following:

	September 30, 2004	December 31, 2003
Office equipment	\$ 728,148	\$ 578,915
Furniture and fixtures	268,629	472,933
Computer equipment and software	500,556	216,825
	<u>1,497,333</u>	<u>1,268,673</u>
Less accumulated depreciation and amortization	432,126	212,235
Property, plant and equipment, net	<u>\$ 1,065,207</u>	<u>\$ 1,056,438</u>

Depreciation expense was \$219,891 and \$112,394 for the nine month period ended September 30, 2004 and 2003, respectively.

5. Non-Marketable Investments

On September 25, 2002, the Company entered into two agreements (the "Hydralazine Agreements") with Barbeau Pharma, Inc. (Evanston, IL). Under the terms of the Hydralazine Agreements, Barbeau Pharma, Inc. provided to the Company the exclusive rights to market a new formulation of hydralazine hydrochloride ("Hydralazine"), and a derivative compound in late-stage development both for treating severe hypertension in pregnancy, a potentially life-threatening condition. Additionally, Barbeau Pharma, Inc. is responsible for preparing an NDA for submission to the FDA for the approval to market Hydralazine. The fair value of these rights was not deemed significant at the date of

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acquisition. In accordance with these arrangements, the Company purchased 900 shares of Series A cumulative preferred stock for \$900,000 in a series of transactions between September 2002 and November 2003.

In June 2003, the Company entered into two additional agreements (the "BP104 Agreements") with Barbeau Pharma, Inc. whereby Barbeau Pharma, Inc. provided the Company with exclusive rights to develop and market an injectable form of an anti-emetic ("BP104") for the treatment of chemotherapy induced nausea and vomiting and post operative nausea and vomiting. Barbeau Pharma, Inc. is responsible for preparing an NDA for submission to the FDA for the approval to market BP104. The Company purchased 1,300 shares of Series A cumulative preferred stock for \$1,300,000 in a series of transactions. The fair value of these rights was not deemed significant at the date of acquisition.

Under the Hydralazine and BP104 Agreements, the Company may be required to pay an additional \$800,000 to \$3.8 million, depending upon the achievement of certain developmental and regulatory milestones. As of September 30, 2004, the Company's ownership (fully diluted) was approximately 10% of Barbeau Pharma, Inc. The investment in Barbeau Pharma was evaluated as of September 30, 2004 for net realizable value and a reserve was established as of that time for the total amount of the investment, effectively writing down the investment to zero.

6. Debt

On October 3, 2003, in connection with the acquisition of Declomycin, the Company entered into a long-term financing arrangement (the "Credit Facility") with a group of financial institutions. The Credit Facility is comprised of: (i) a \$6.5 million Revolving Credit Facility (the "Revolver"), and (ii) a \$53.5 million Term Loan ("Term Loan"). The Credit Facility is secured by substantially all of the tangible and intangible assets of the Company.

Under the terms of the Revolver, through October 3, 2008, the Company may borrow on a revolving basis up to \$6.5 million where amounts repaid may be re-borrowed. The Revolver includes a \$1.0 million letter of credit sub-facility and a \$1.0 million Swingline sub-facility. Through September 30, 2004 there were no draws on the Revolver.

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The Company borrowed \$53.5 million under the Term Loan which fully matures on October 3, 2008. Scheduled principal payments of \$2.7 million are required on a quarterly basis commencing on September 30, 2004 with the balance due at the maturity date. Additionally the Term Loan also includes annual mandatory principal payments commencing in April 2004 in amounts based on a percentage of the Company's excess cash flow as defined in the Credit Facility. On April 10, 2004, the Company made a \$5,411,301 payment pursuant to this excess cash flow requirement, plus a voluntary payment of \$88,699 (\$5,500,000 in total).

Borrowings under the Credit Facility bear interest, which is payable monthly, at a floating rate equal to the Base Rate (as defined in the Credit Facility) plus a margin of 1.25%, or at a rate equal to LIBOR plus a margin of 3.75% based on the type of borrowing. Additionally, a fee of 0.50% is charged on the average daily unused amount of the Revolver, and a fee of 3.75% is charged on the amount of any issued letters of credit. Under the terms of the Credit Facility, the Company was required to execute an interest rate swap for half of the principal balance converting the variable rate note to a fixed rate (see Note 2).

The Credit Facility contains limitations and restrictions concerning, among other things, additional indebtedness, acquisitions and dispositions of assets, dividend payments and transactions with affiliates. In addition, the Credit Facility requires the Company to maintain certain ratios (as defined therein). The Company believes it is in compliance with all financial covenants at September 30, 2004.

The following is a summary of the scheduled principal payments of the Term Loan for the next five years and does not include the annual mandatory principal payments as such amounts are contingent on future operations:

October 1 through December 31, 2004	\$ 5,350,000
2005	10,700,000
2006	10,700,000
2007	10,700,000
2008	10,550,000
Total principal payments	<u>\$ 48,000,000</u>

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7. Stockholders' Equity

Convertible Preferred Stock

In April and May of 2002, the Company issued 28.2 million shares of Series A convertible preferred stock for proceeds of \$27.4 million.

In April 2003, the Company completed its Series B convertible stock financing, which raised \$19.9 million through the sale of 12.5 million shares. The Series B preferred stock preferences are the same as the Series A convertible preferred stock.

Conversion

Each share of preferred stock is, at the option of the holder, convertible into shares of common stock on a one-for-one basis, subject to certain adjustments for dilution, if any, resulting from future stock issuances. The initial conversion price for the Series A preferred stock is \$1.00 per share. The initial conversion price for the Series B preferred stock is \$1.60 per share. The convertible preferred stock shall be automatically converted into common stock upon (a) the consummation of an IPO at an offering price which is not less than \$3 per share in an offering with aggregate proceeds to the Company of not less than \$40,000,000 or (b) the vote of a two-thirds interest of the convertible preferred stock voting together as a single class.

Dividend Rights

Convertible preferred shareholders are entitled to cumulative dividends at an annual rate of 8% per share if and when declared by the Board of Directors. Dividends will be paid only out of legally available funds, subject to restrictions set forth in the Credit Facility. No dividends have been declared or paid as of or for any period ended September 30, 2004. Dividends may be paid either in cash or by the issuance of additional shares of common stock (determined by the then fair market value) at the option of the preferred shareholders. The amount of cumulative dividends in arrears related to the preferred stock is \$7,879,333 as of September 30, 2004.

Liquidation Preferences

In the event of any liquidation, sale or merger, or winding up of the Company, the preferred shareholders are entitled to receive, in preference to the holders of common stock, an initial preference equal to on times the original purchase price per share

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plus all accrued and unpaid dividends declared, then for any remaining assets, shall participate with the holders of common stock on an as-converted basis, until the preferred shareholders receive a total of three times their purchase price per share, plus all accrued and unpaid dividends declared.

Voting Rights

The preferred shareholders will vote together with the common shareholders and not as a separate class except as specifically provided in the investment agreement or required by law.

Specifically, the preferred and common stock will vote separately on mergers, acquisitions, sale of all, or substantially all assets, and transactions that would result in a change of control. Each share of preferred shall have a number of votes equal to the number of shares of common stock then issuable upon conversion of such share of preferred.

Common Stock and Common Stock Options

Restricted Common Stock

Prior to closing of the Company's Series A Preferred Stock financing, the Company issued 6,065,000 shares of \$0.0001 par value restricted common stock to founders and other advisors at a price of \$0.01 per share. In 2002, the Company issued additional shares totaling 710,000 to management and other employees at \$0.16 per share. Subsequently, there have been a number of grants, forfeitures upon termination from the Company and exercises of options impacting the number of outstanding shares. All common shares issued to Company employees were purchased with cash or with full recourse loans with an average interest rate of 4.75%, and have certain restrictions in connection with the ownership of such shares.

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The outstanding shares are as follows:

		Shares Granted	Shares Forfeited	Options Exercised	Total Common Shares	Average Price
Inception through December 31, 2002	Founders	6,065,000	—	—	—	\$.01
	Management and other employees	710,000				.16
Balance, December 31, 2002		6,775,000	—	—	6,775,000	.03
Twelve months ended December 31, 2003	Directors	20,000			20,000	.46
	Founders		(236,667)		(236,667)	.01
	Employees			30,375	30,375	.21
Balance, December 31, 2003		6,795,000	(236,667)	30,375	6,588,708	.03
Nine months ended September 30, 2004	Employees		(45,309)	34,625	(45,309)	.16
	Employees				34,625	.18
Balance, September 30, 2004		6,795,000	(281,976)	65,000	6,578,024	\$.03

The restricted founders shares vest (i.e. have a lapsing forfeiture provision) as follows: a) 33.33% of the common stock vests on the date each founder commences employment with the Company, b) 16.67% vests on the first anniversary of the date of employment, c) the remaining 50% vests in equal monthly installments over a three year period beginning the month following the first anniversary. The vesting accelerates upon an approved sale or a liquidating event.

The Company will, at all times, reserve and keep available from its authorized but unissued shares of common stock, sufficient shares to be issued upon the conversion of the shares of the convertible preferred stock and upon the exercise of the stock options. As of September 30, 2004, the Company reserved 40,700,000 shares of common stock for future issuance for the potential conversion of preferred shares.

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Stock Options

In June 2002, the Company's Board of Directors and shareholders approved the Company's 2002 Stock Option Plan (the "2002 Plan"). The 2002 Plan provides for the granting of options to purchase common stock in the Company to employees, advisors and consultants at a price to be determined by the Company's Board of Directors. The Options may be incentive stock options or non-statutory stock options. Under the provisions of the 2002 Plan, no option will have a term in excess of 10 years. At September 30, 2004, the Company reserved up to 143,151 shares for issuance upon exercise of options.

The 2002 Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business and is administered by the Board of Directors or a committee consisting of members of the Board. The Board or committee is responsible for determining the individuals to be granted options, the number of options each individual will receive, the option price per share and the exercise period of each option. Options granted pursuant to the 2002 Plan generally vest 25% after the first year, and the remaining 75% vest equally over the next three years.

The following table summarizes information about stock options outstanding at September 30, 2004 and December 31, 2003.

	Shares Available for Grant	Restricted Stock	Number of Shares	Options Outstanding	
				Option Price Per Share Range	Weighted-Average Exercise Price
Balance at December 31, 2002	1,101,500		223,500	\$ 0.16	\$ 0.16
Shares authorized	1,700,000		—	—	—
Shares issued	(20,000)	20,000	—	—	—
Common stock forfeited	236,667		—	—	—
Options granted	(2,652,200)		2,652,200	0.16-0.46	0.28
Options exercised	—		(30,375)	0.16	0.16
Options forfeited	103,625		(103,625)	0.16	0.16
Balance at December 31, 2003	469,592	20,000	2,741,700	0.16-0.46	0.21
Shares authorized	—		—	—	—
Common stock forfeited	45,309		—	0.16	0.16
Options granted	(455,200)		455,200	0.46-2.63	0.91
Options exercised	—		(34,625)	0.16-0.25	0.18
Options forfeited	83,450		(83,450)	0.16-1.75	0.26
Balance at September 30, 2004	143,151	20,000	3,078,825	\$ 0.16 - 2.63	\$.31

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The following table summarizes information about stock options outstanding at September 30, 2004:

Exercise Price	Options Outstanding	Options Vested	Weighted-Average Remaining Contractual Life
\$ 0.16	1,097,750	378,500	3.25
0.22	456,250	118,750	3.50
0.25	1,044,875	261,125	3.75
0.46	329,300	7,113	4.00
0.77	15,750	—	4.50
1.75	105,400	—	4.75
2.63	29,500	—	5.00
	<u>3,078,825</u>	<u>765,488</u>	

At September 30, 2004, the average remaining contractual life of outstanding options was approximately 4 years. The weighted-average fair value of options granted since inception was approximately \$0.31.

If compensation cost had been determined based on the fair value of the options at the grant dates for those options for which no compensation cost has been recognized, consistent with the method of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), the Company's net income per share would have decreased. Such pro forma disclosures (see Note 2) may not be representative of future compensation expense because options vest over several years and additional grants may be made each year. The fair value of these options was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions for 2004:

Employee Share Options

Expected life	5 years
Risk-free interest rate	3.5%
Volatility	100%
Dividend yield	0%

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8. Income Taxes

Significant components of the state and federal income tax provision (benefit) for income taxes are as follows:

	Nine months ended September 30	
	2004	2003
	(unaudited)	
Current provision:		
Federal	\$ 3,721,321	\$ 1,760,604
State	562,828	753,333
Total current provision	<u>4,284,149</u>	<u>2,513,937</u>
Deferred benefit:		
Federal	(3,040,418)	(142,811)
State	(452,412)	(19,474)
Total deferred benefit	<u>(3,492,830)</u>	<u>(162,285)</u>
Net deferred benefit	<u>(3,492,830)</u>	<u>(162,285)</u>

Total income tax provision	\$ 791,319	\$ 2,351,652
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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets for financial reporting and the amount used for income tax purposes. At December 31, 2003, the Company believed it was more likely than not that it would realize its deferred tax assets and reduced the valuation allowance to zero. The change in the valuation allowance for the year ended December, 2003 was (\$810,000). Significant components of the Company's deferred tax assets as of September 30, 2004 and December 31, 2003 are as follows:

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	September 30, 2004	December 31, 2003
	(unaudited)	
Deferred tax assets:		
Accounts receivable allowances	\$ 3,464,000	\$ 1,642,000
Amortization of intangible assets	3,779,000	1,767,000
Amortization of start-up costs	156,000	231,000
Other	(313,000)	(47,000)
Total deferred tax assets	<u>7,086,000</u>	<u>3,593,000</u>
Less valuation allowance	—	—
Net deferred tax asset	<u>\$ 7,086,000</u>	<u>\$ 3,593,000</u>

The net deferred tax asset included a current portion of \$3,374,574 and \$1,034,078 at September 30, 2004 and December 31, 2003 respectively and a long-term portion of \$3,711,298 and \$2,558,964 at September 30, 2004 and December 31, 2003 respectively.

9. Operating Leases and Commitments

Minimum annual rental commitments under non-cancelable operating leases, primarily office facilities in effect at September 30, 2004 are as follows:

2005	\$ 434,785
2006	433,328
2007	433,328
2008	433,328
Thereafter	36,111

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Operating lease rental expense aggregated \$317,495 and \$272,871 for the nine months ended September 30, 2004 and 2003, respectively.

Letter of Credit

In accordance with the terms of the Company's leasing arrangement, the Company is required to maintain an irrevocable letter of credit in the amount of \$230,000. Through September 30, 2004, there were no draws on the letter of credit.

10. Employee Benefit Plan

The Company has established a defined contribution pension plan (the "Plan") covering all eligible employees. Employees are eligible to participate in the Plan on the first quarterly entry date following date of hire, as defined in the Plan document. Employees can contribute from 1% to 60% of eligible pay, subject to the annual Federal Tax Law limits. The Company matches 100% of the first 3% of employee contributions and may also elect to make a discretionary non-matching contribution to the Plan on behalf of all eligible employees. Total expenses incurred for the nine months ended September 30, 2004 and 2003 was approximately \$ 251,785 and \$133,214 respectively.

11. Related Party Transactions

As permitted under the Stock Plan, certain purchasers of restricted stock and option grants signed full recourse promissory notes for the value of their shares and options at the date of grant. Under the terms of these notes, the principal balance and all unpaid interest is at various dates through 2007. Both interest and principal can be prepaid without penalty. At September 30, 2004 and December 31, 2003, notes and accrued interest receivable of \$140,912 and \$152,904, respectively, remain outstanding and are classified in stockholders' equity.

Two of the officers of ESP Pharma are members of the Board of Directors for a company that ESP Pharma has non-marketable investments.

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PRO FORMA INFORMATION

The unaudited pro forma condensed combined financial statements present financial information for PDL giving effect to the acquisition of the net assets of ESP Pharma (ESP) and the planned sale of our \$250 million convertible notes on or about February 2005. The unaudited pro forma condensed combined balance sheet as of September 30, 2004 is presented as if the acquisition and sale of convertible notes occurred on that date. The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2003 is presented as if the acquisition and sale of convertible notes had occurred on January 1, 2003, and the unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2004 is presented as if the acquisition and sale of convertible notes had occurred on January 1, 2004. PDL expects to account for the acquisition of ESP as a business combination pursuant to Financial Accounting Standards Board No. 141, "Business Combinations."

The pro forma adjustments represent, in the opinion of management, all adjustments necessary to present PDL's pro forma results of operations and financial position in accordance with Article 11 of SEC Regulation S-X and are based upon available information and certain assumptions considered reasonable under the circumstances. The estimated purchase price has been allocated to the acquired assets and liabilities assumed based on a preliminary determination of their respective fair values.

The pro forma information may not necessarily be indicative of PDL's results of operations or financial position had the transaction been in effect as of or for the periods presented, nor is such information necessarily indicative of PDL's results of operations or financial position for any future period or date. Furthermore, no effect has been given in the unaudited pro forma condensed combined statements of operations for synergies that may be realized through the combination of PDL and ESP or costs that may be incurred in integrating their operations. The unaudited pro forma condensed combined financial statements should be read in conjunction with PDL's audited consolidated financial statements and notes thereto included in PDL's annual report on Form 10-K for the year ended December 31, 2003, the unaudited consolidated condensed financial statements and notes thereto included in PDL's quarterly reports on Form 10-Q for the quarters ended March 31, 2004, June 30, 2004 and September 30, 2004, and the historical financial statements, including the notes thereto, of ESP, included as Exhibit 99.5 to this Current Report on Form 8-K.

PROTEIN DESIGN LABS, INC.
PRO FORMA CONDENSED COMBINED BALANCE SHEET
(unaudited)
(In thousands, except per share amounts)

	September 30, 2004			
	Protein Design Labs, Inc.	ESP Pharma	Pro forma adjustments	Pro forma
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 130,900	\$ 34,002	\$ (131,300)(A)	\$ 33,602
Marketable securities, including \$6.8 million of restricted investments at September 30, 2004	288,209	—	—	288,209
Accounts receivable, net of reserves of \$3.0 million	—	11,345	—	11,345
Inventories	—	5,429	—	5,429
Other current assets	5,911	5,721	(3,709)(B)	9,109
			1,186(E)	
Total current assets	425,020	56,497	(133,823)	347,694
Land, property and equipment, net	227,027	1,065		228,092
Intangible assets, net	31,972	58,554	(58,554)(B)	401,872
			369,900(B)	
Restricted investments	6,688	—	—	6,688
Goodwill	—	—	61,527(B)	61,527
Other assets	7,073	4,871	(4,856)(B)	14,202
			7,114(E)	
Convertible note receivable	30,000	—	—	30,000
Total assets	<u>\$ 727,780</u>	<u>\$ 120,987</u>	<u>\$ 241,308</u>	<u>\$ 1,090,075</u>
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$ 4,444	\$ 1,236	\$ —	\$ 5,680
Accrued compensation	7,245	2,477	—	9,722
Accrued clinical trial costs	850	—	—	850
Accrued interest	874	752	(752)(B)	874
Other accrued liabilities	14,169	13,152	5,290(C)	32,611
Deferred revenue	17,760	546	(546)(B)	17,760
Current portion of long-term obligations	1,048	10,700	(10,700)(D)	1,048
Total current liabilities	46,390	28,863	(6,708)	68,545
Convertible subordinated notes	249,998	—	250,000(E)	499,998
Other long-term debt	7,675	37,300	(37,300)(D)	7,675
Convertible preferred stock	—	47,348	(47,348)	—
Commitments and contingencies (Notes 2 and 10)				
Stockholders' equity:				

Preferred stock, par value \$0.01 per share, 10,000 shares authorized; no shares issued and outstanding	—	—	—	—
Common stock, par value \$0.01 per share, 250,000 shares authorized; 95,402 issued and outstanding	954	1	(1)(F) 88(G)	1,043
Additional paid-in capital	682,110	307	(307)(F) 171,142(G)	853,252
Notes receivable – related parties	—	(141)	141(H)	—
Deferred stock-based compensation	—	(157)	157(I)	—
Retained earnings (accumulated deficit)	(258,950)	7,457	(7,457)(J) (81,100)(K)	(340,050)
Accumulated other comprehensive income (loss)	(397)	9	—	(388)
Total stockholders' equity	423,717	7,476	82,664	513,857
Total liabilities and stockholders' equity	\$ 727,780	\$ 120,987	\$ 241,308	\$ 1,090,075

See notes to pro forma condensed combined financial statements.

PROTEIN DESIGN LABS, INC.
PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

(unaudited)

(In thousands, except per share amounts)

	Nine months ended September 30, 2004			
	Protein Design Labs, Inc.	ESP Pharma	Pro forma adjustments	Pro forma
Revenues:				
Royalties	\$ 63,872	\$ —	\$ —	\$ 63,872
Product sales, net	—	67,616	—	67,616
License and other	9,323	—	—	9,323
Total revenues	73,195	67,616	—	140,811
Costs and expenses:				
Cost of goods sold	—	26,398	16,479(L)	42,877
Selling and marketing	—	16,802	—	16,802
Research and development	92,364	4,819	—	97,183
General and administrative	23,182	12,062	—	35,244
Other operating expenses	—	3,370	—	3,370
Acquired in-process research and development	—	—	81,100(M)	81,100
Total costs and expenses	115,546	63,451	97,579	276,576
Operating income (loss)	(42,351)	4,165	(97,579)	(135,765)
Interest and other income, net	7,689	117	(1,969)(N)	5,837
Interest expense	(3,929)	(2,442)	(3,604)(O)	(9,975)
Income (loss) before income taxes	(38,591)	1,840	(103,152)	(139,903)
Provision for income taxes	68	791	(791)(P)	68
Net income (loss)	\$ (38,659)	\$ 1,049	\$ (102,361)	\$ (139,971)
Basic and diluted net loss per share	\$ (0.41)			\$ (1.35)
Shares used in computation of basic and diluted net loss per share	94,771		8,868(Q)	103,639

See notes to pro forma condensed combined financial statements.

PROTEIN DESIGN LABS, INC.
PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

(unaudited)

(In thousands, except per share amounts)

	Year ended December 31, 2003			
	Protein Design Labs, Inc.	ESP Pharma	Pro forma adjustments	Pro forma
Revenues:				
Royalties	\$ 52,704	\$ —	\$ —	\$ 52,704
Product sales, net	—	62,545	—	62,545
License and other	13,982	—	—	13,982
Total revenues	66,686	62,545	—	129,231

Costs and expenses:				
Cost of goods sold	—	20,610	28,636(R)	49,246
Selling and marketing	—	13,779	—	13,779
Research and development	82,732	587	—	83,319
General and administrative	27,613	11,587	—	39,200
Other operating expenses	—	2,280	—	2,280
Acquired in-process research and development	85,993	—	81,100(S)	167,093
Total costs and expenses	196,338	48,843	109,736	354,917
Operating income (loss)	(129,652)	13,702	(109,736)	(225,686)
Interest and other income, net	9,831	108	(2,626)(T)	7,313
Interest expense	(9,770)	(1,212)	(6,849)(U)	(17,831)
Impairment loss on investment	(150)	—	—	(150)
Income (loss) before income taxes	(129,741)	12,598	(119,211)	(236,354)
Provision for income taxes	73	4,397	(4,397)(V)	73
Net income (loss)	\$ (129,814)	\$ 8,201	\$ (114,814)	\$ (236,427)
Basic and diluted net loss per share	\$ (1.40)	—	—	\$ (2.33)
Shares used in computation of basic and diluted net loss per share	92,478	—	8,868(W)	101,346

See notes to pro forma condensed combined financial statements.

NOTES TO PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

Basis of Presentation

On January 24, 2005, Protein Design Labs, Inc. (PDL) and ESP Pharma Holding, Inc. (ESP) entered into a definitive agreement under which PDL will acquire ESP for \$300 million in cash and approximately \$175 million in PDL common stock, or an aggregate value of approximately \$475 million, plus the assumption of net debt of approximately \$14 million, as filed with the Commission on Form 8-K on January 25, 2005. On February 1, 2005, PDL and ESP agreed to increase the purchase price payable to the ESP shareholders at the closing of the ESP acquisition by \$25 million in cash in connection with the Retavase acquisition from Centocor, Inc. announced by ESP on February 1, 2005, as filed with the Commission on Form 8-K on February 1, 2005. The closing of the acquisition of ESP is subject to various conditions, including the receipt of antitrust and other regulatory approvals, and is not anticipated to close until late in the first quarter of 2005. PDL expects to account for the acquisition of ESP as a business combination pursuant to Financial Accounting Standards Board Statement No. 141, "Business Combinations."

The unaudited pro forma condensed combined financial statements present financial information for PDL giving effect to the acquisition of the assets and assumption of liabilities of ESP and the planned sale of our \$250 million convertible notes on or about February 2005. The unaudited pro forma condensed combined balance sheet as of September 30, 2004 is presented as if the acquisition and sale of convertible notes occurred on that date. The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2003 is presented as if the acquisition and sale of convertible notes had occurred on January 1, 2003, and the unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2004 is presented as if the acquisition and sale of convertible notes had occurred on January 1, 2004.

For purposes of the unaudited pro forma condensed combined financial statements, PDL assumed an aggregate preliminary purchase price of \$501 million, including cash to be paid to the ESP stockholders of \$325 million, \$171 million in common stock to be issued to the ESP shareholders and estimated transaction costs of \$5.3 million. The \$171 million is calculated based on 8,868,393 shares of PDL's common stock to be issued to ESP shareholders and the average closing price of PDL's common stock from two days before to two days after the public announcement of the agreement. The unaudited pro forma condensed combined financial statements reflect adjustments that are based upon preliminary estimates of the allocation of the purchase price to the acquired assets and liabilities assumed of ESP based on available information and certain assumptions that PDL believes are reasonable in the circumstances.

PDL anticipates a portion of the purchase price (currently estimated to be \$501 million) to be allocated to acquired in-process research and development due to ESP's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of that date. The preliminary value of the in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 17% which is based on PDL's estimated weighted average cost of capital taking into account the risks associated with the projects acquired.

This charge will be recorded as of the acquisition date and included in PDL's statement of operations for the quarter ending March 31, 2005. In reaching this determination, PDL considered, among other factors, the stage of development of each potential product acquired, the time and resources needed to complete each product, expected income and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals and risks related to the viability of and potential alternative treatments in any future target markets.

The final allocation of the purchase price, which may be different from the current estimate, will be based upon an appraisal prepared by an independent third party and a comprehensive evaluation of the fair value of the acquired intangible and tangible assets and liabilities, including in-process research and development and liabilities assumed as of the closing date. The final determination of tangible and intangible assets purchased may result in future depreciation and amortization expenses that are different from the preliminary estimates of these amounts. As a result of these uncertainties, the exact amount of the final purchase price and allocation of such purchase price may differ from the amounts assumed in the unaudited pro forma condensed combined financial statements.

Unaudited Pro Forma Adjustments

Pro Forma Condensed Combined Balance Sheet as of September 30, 2004

(A) Reflects the cash proceeds from the planned sale of \$250 million convertible notes offset against the cash payment of \$325 million for purchase of ESP's outstanding stock, the payment of ESP's debt of \$48 million, and the payment of an estimated \$8.3 million in debt issuance costs.

(B) Adjustments to the historical amounts of ESP's net assets to reflect the estimated fair values of identifiable tangible and intangible assets and liabilities of ESP acquired, including deferred tax assets. The book value of ESP intangible assets, \$58.6 million, is eliminated since these assets are recorded at fair value in connection with the acquisition. The fair value of these product rights, or \$369.9 million, will be amortized over 7-12 years, the estimated useful lives of these assets.

(C) Reflects the estimated liability for costs and expenses directly related to this transaction, including investment banking, legal and accounting fees which have been included as part of the purchase consideration.

(D) Reflects the 100% payoff of all ESP debt obligations.

(E) Reflects the planned sale of \$250 million convertible notes, including the capitalization of estimated debt issuance costs of \$8.3 million.

(F) Reflects the elimination of ESP's equity accounts.

(G) Reflects the issuance of 8,868,393 shares of PDL common stock in connection with the purchase of ESP.

(H) Reflects the repayment of ESP notes receivable in connection with the acquisition.

(I) Elimination of all remaining ESP deferred stock-based compensation resulting from the acceleration of vesting of all ESP employee stock options in connection with the acquisition.

(J) Reflects the elimination of ESP's retained earnings.

(K) Reflects the estimated acquired in-process research and development charge of \$81.1 million related to the acquisition.

Pro Forma Condensed Combined Statement of Operations for the nine months ended September 30, 2004

(L) Reflects the amortization of \$28.2 million of the acquired intangible assets based on their estimated fair values and estimated useful lives assigned to these assets at the date of acquisition, partially offset by the elimination of ESP's amortization expense of \$11.7 million.

(M) Reflects the estimated acquired in-process research and development charge of \$81.1 million related to the acquisition.

(N) Reflects the decrease in interest income related to the decrease in the cash and marketable securities balances related to the purchase of ESP.

(O) Reflects the additional interest expense related to the planned sale of the \$250 million convertible notes assuming an interest rate of 2.75 %, including the amortization of debt issuance costs, partially offset against the reduction in interest expense for the payment of ESP's debt.

(P) Adjustment to eliminate ESP's provision for income taxes, as the combined company is in a loss position on a pro forma basis.

(Q) Reflects the issuance of 8,868,393 shares of PDL common stock outstanding as a result of the acquisition.

Pro Forma Condensed Combined Statement of Operations for the year ended December 31, 2003

(R) Reflects the amortization of \$37.6 million of the acquired intangible assets based on their estimated fair values and estimated useful lives assigned to these assets at the date of acquisition, partially offset by the elimination of ESP's amortization expense of \$8.9 million.

(S) Reflects the estimated acquired in-process research and development charge of \$81.1 million related to the acquisition.

(T) Reflects the decrease in interest income related to the decrease in the cash and marketable securities balances related to the purchase of ESP.

(U) Reflects the additional interest expense related to the planned sale of the \$250 million convertible notes assuming an interest rate of 2.75 %, including the amortization of debt issuance costs, partially offset against the reduction in interest expense for the payment of ESP's debt.

(V) Adjustment to eliminate ESP's provision for income taxes, as the combined company is in a loss position on a pro forma basis.

(W) Reflects the issuance of 8,868,393 shares of PDL common stock outstanding as a result of the acquisition.
