
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**Amendment No. 1
to
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

PROTEIN DESIGN LABS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3023969
(IRS Employer
Identification No.)

**34801 Campus Drive
Fremont, California 94555
(510) 574-1400**
(Address, including zip code, and telephone number, including area code, of
registrant's principal executive offices)

**Mark McDade
Chief Executive Officer
PROTEIN DESIGN LABS, INC.
34801 Campus Drive
Fremont, California 94555
(510) 574-1400**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.



The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated March 25, 2005

PRELIMINARY PROSPECTUS

9,853,770 Shares



Common Stock

This prospectus relates to the public offering, which is not being underwritten, of shares of the common stock of Protein Design Labs, Inc. (the "Company" or "PDL"). The shares of PDL common stock may be offered by the selling stockholders named in this prospectus. We will receive no part of the proceeds of any sales made under this prospectus. All expenses of registration incurred in connection with this offering are being borne by us, but all selling and other expenses incurred by the selling stockholders will be borne by the selling stockholders. None of the shares offered by this prospectus has been registered prior to the filing of the registration statement of which this prospectus is a part.

The common stock offered in this prospectus may be offered and sold by the selling stockholders directly or through broker-dealers or underwriters acting solely as agents. In addition, the broker-dealers and underwriters may acquire the common stock as principals. The distribution of the common stock may be effected in one or more transactions. These transactions may take place through the Nasdaq National Market, privately negotiated transactions, underwritten public offerings, or a combination of any such methods of sale. These transactions may be made at market prices prevailing at the time of sale, prices related to the prevailing market price or negotiated prices. Usual and customary or specially negotiated brokerage fees or commissions may be paid by the selling stockholder in connection with these sales. See "Plan of Distribution" on page 33 for more information.

The shares of PDL are included for quotation in the Nasdaq National Market under the symbol "PDLI." On March 21, 2005, the reported last sale price of PDL common stock in the Nasdaq National Market was \$16.48 per share.

See "Risk Factors" on pages 7 to 33 for factors that should be considered before investing in the shares of PDL.

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE
SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES
OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY
REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is March , 2005.

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You should rely on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of the prospectus or of any sale of the common stock.

PROSPECTUS SUMMARY

The following summary may not contain all the information that may be important to you. You should read the entire prospectus, as well as the information incorporated by reference in this prospectus, including our financial statements and the notes thereto, before making an investment decision. When used in this prospectus, 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 late November 2004 and was marketed until the end of February 2005, when Tysabri® was voluntarily withdrawn from the market by Elan and Biogen-Idc and is currently pending review for further clinical trial use as well as marketing and commercial sale.

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 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 closed in the first quarter of 2005. 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- α 5b1 integrin antibody*). Our anti- α 5b1 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.

Pursuant to the terms of our acquisition of ESP Pharma, we are registering a maximum of 9,853,770 shares of common stock in this offering for the accounts of the selling stockholders. The selling stockholders acquired the shares of common stock in connection with our acquisition of ESP Pharma.

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 myelomgenous 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.

2005 Notes. On February 9, 2005, we announced that we had priced our private placement under Rule 144A in an aggregate principal amount of \$250 million of our convertible senior notes due 2012 (the "2005 Notes"). The 2005 Notes will be convertible into PDL common stock at a price of approximately \$23.69 per share, subject to adjustment in certain circumstances, which represents a 30% premium over the closing price of our stock on February 8, 2005. The 2005 Notes bear an interest rate of 2% per annum and will have a seven-year term. The offering closed on February 14, 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, and Declomycin are registered trademarks owned by or licensed to ESP Pharma. Retavase is a registered U.S. trademark of Centocor. All other company names and trademarks included in this prospectus are trademarks, registered trademarks or trade names of their respective owners.

We were incorporated in Delaware in 1986. Our corporate headquarters are located at 34801 Campus Drive, Fremont, California 94555 and our telephone number is (510) 574-1400. We maintain a home page at www.pdl.com.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-3 under the Securities Act of 1933, as amended, with the Securities and Exchange Commission ("SEC"). This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules which are a part of the registration statement. For further information with respect to us and our common stock, please refer to the registration statement and the exhibits and schedules filed with it.

You may read and copy all or any portion of the registration statement, reports, statements or other information in the files at the public reference facility of the SEC located at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549. You can request copies of these documents upon payment of a duplicating fee by writing to the SEC. You may call the SEC at 1-800-SEC-0330 for further information on the operation of its public reference room. Our filings including the registration statement, will also be available to you on the web site maintained by the SEC at <http://www.sec.gov>.

We are also subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended. We file reports, proxy statements, and other information with the SEC to comply with the Exchange Act. These reports, proxy statements, and other information are available for inspection at the SEC's public reference facility and its web site, which are described above.

You may obtain a free copy of our most recent annual report on Form 10-K, quarterly report on Form 10-Q and proxy statement on our website on the World Wide Web at <http://www.pdl.com>. Additionally, you may obtain a free copy of these filings, as well as our current reports on Form 8-K and any other reports or filings we have filed with the SEC, including any amendment to those reports we have filed with, or furnished to, the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as practicable after we have electronically filed such material with, or furnished it to, the SEC, by contacting the Corporate Communications Department at our corporate offices by calling (510) 574-1406.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus. Any information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any additional documents we file with the SEC. This registration statement incorporates by reference the documents listed below that we have previously filed with the SEC. They contain important information about us and our financial condition.

The following documents filed with the SEC are incorporated by reference into this prospectus:

- Our annual report or Form 10-K for the year ended December 31, 2004;
- Our current reports on Form 8-K filed on February 1, 2005, February 4, 2005, February 9, 2005, February 16, 2005, February 25, 2005 and March 17, 2005;
- The information set forth under Item 8.01 and in Exhibits 23.1, 99.1, 99.3, 99.4, 99.5 and 99.6 of our current report on Form 8-K filed on February 7, 2005; and
- The description of our common stock in our registration statement on Form 8-A filed with the SEC on December 23, 1991, as amended on Form 8-A/A filed with the SEC on January 22, 1992.

All documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of the offering of securities contemplated by this prospectus shall be deemed to be incorporated by reference in this prospectus. Those documents shall be considered to be a part of this prospectus from the date of filing of such documents. Any statement contained in a document incorporated by reference or deemed to be incorporated by reference into this prospectus shall be deemed to be modified or superseded for all purposes of this prospectus and the registration statement to the extent that a statement contained in this prospectus, in any document incorporated by reference or in any subsequently filed document which also is incorporated or deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom a copy of this prospectus has been delivered a copy of any and all of the documents referred to above which have been or may be incorporated in this prospectus by reference and were not delivered with this prospectus. We will not deliver exhibits to such documents, unless such exhibits are specifically incorporated by reference. We will provide this information upon written or oral request by a person to whom we delivered a copy of the prospectus. Requests for such copies should be directed to our principal executive offices located at 34801 Campus Drive, Fremont, California 94555, Attention: Secretary. Our general telephone number is (510) 574-1400.

FORWARD LOOKING INFORMATION

This prospectus includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including any financial information any statements of the plans and objectives of management for future operations, including the proposed acquisition of ESP Pharma Holding Company, Inc. and the proposed acquisition of certain rights to the Retavase product, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "believes," "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent assumptions, risks and uncertainties, including but not limited to the risk factors set forth in this prospectus, and for the reasons described elsewhere in

this prospectus. All forward-looking statements and reasons why results may differ included in this prospectus are made as of the date hereof, and we assume no obligation to update or revise any forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

RISK FACTORS

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

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

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

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

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

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive

of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon:

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

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

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

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

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

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

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

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European antibody humanization patent. We appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if the opponents are successful, our ability to collect royalties on European sales of antibodies humanized by others would depend on: (i) the scope and validity of our second European patent; and (ii) whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents, and if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to our related patents in other jurisdictions, including the United States. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents.

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

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

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

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

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

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

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

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

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

Other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or 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 therefore moving production to our Brooklyn Park manufacturing facility from our Plymouth facility or from third parties will entail manufacturing changes. Further, any significant manufacturing changes for the production of our product candidates could result in delays in development or regulatory approval or in the reduction or interruption of commercial sales of our product candidates. Our inability to maintain our manufacturing operations in compliance with applicable regulations within our planned time and cost parameters could materially harm our business, financial condition and results of operations.

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

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

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

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

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed, are developing, or may develop technologies that may compete with our antibody technology platform. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

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

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

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

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

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

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

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process and quality control procedures are required to comply with the applicable FDA current good manufacturing practice (cGMP) regulations

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

In addition, during 2003 the FDA completed the transfer of regulatory responsibility, review and continuing oversight for many biologic therapeutic products, including antibody therapeutics, from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This transfer of responsibility could result in new regulatory standards, which could result in delays in development or regulatory approvals for our potential products. In addition, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured by Roche is comparable to the material we produce at our manufacturing facilities. New regulations resulting from the transfer of regulatory responsibility from CBER to CDER could make it more difficult for us to show comparability which could delay development and regulatory approval of Zenapax in new indications or reduce or interrupt commercial sales of Zenapax for the prevention of acute kidney transplant rejection.

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

Both before and after approval is obtained, a biologic pharmaceutical product, its manufacturer and the holder of the 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 March 21, 2005, our common stock closed as high as \$27.14 per share and as low as \$13.85 per share. Additionally, the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The following are some of the factors that may have a significant effect on the market price of our common stock:

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

- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of 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.

Risks Related to the Acquisition of ESP Pharma

The following risks may arise as a result of acquisition of ESP Pharma.

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

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

Any one or all of these factors 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.

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

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

For the nine months ended 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.

Risks Related to the 2005 Notes

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

At December 31, 2004, we would have had approximately \$508.4 million of outstanding debt as adjusted for the offering of the 2005 Notes (assuming no exercise by the initial purchasers of their option to purchase up to \$50 million of additional 2005 Notes). In addition to the 2005 Notes, approximately \$250 million in principal remains outstanding under our 2003 Notes, and we have debt service obligations related thereto (see "—Risks Related to the 2003 Notes" above). The 2005 Notes do not restrict our future incurrence of indebtedness and we may incur additional indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

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

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

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

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

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

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

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

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

USE OF PROCEEDS

PDL will not receive any proceeds from the sale of common stock by the selling stockholders. See "Selling Stockholders" and "Plan of Distribution."

SELLING STOCKHOLDERS

A maximum of 9,853,770 shares of common stock are being registered in this offering for the accounts of the selling stockholders. The selling stockholders acquired the shares of common stock in connection with our acquisition of ESP Pharma Holding Company, Inc. The number of shares to be registered in this offering, and the number of shares acquired by the selling stockholders may be adjusted downward, in accordance with the terms of our acquisition of ESP Pharma. These shares are being registered pursuant to the terms of that transaction. Throughout this prospectus, we may refer to the stockholders and their pledgees, donees, transferees or other successors in interest as the "selling stockholders." The following table sets forth information known to us with respect to the selling stockholders for whom we are registering the shares for resale to the public. The shares being registered under the registration statement of which this prospectus is a part will be sold, if at all, by the selling stockholders listed below. The selling stockholders collectively own approximately nine percent of our outstanding common stock.

| Name of Selling Stockholder(1) | Number of Shares Beneficially Owned Prior to the Offering | Maximum Number of Shares That May Be Sold(2) | Shares Beneficially Owned After the Offering |
|---|---|--|--|
| AMF YoYo, LLC | 0 | 45,823 | 0 |
| Apax Excelsior VI, L.P. | 0 | 2,018,283 | 0 |
| Apax Excelsior VI-A C.V. L.P. | 0 | 164,976 | 0 |
| Apax Excelsior VI-B C.V. L.P. | 0 | 109,905 | 0 |
| Louis P. Berardi | 0 | 163,003 | 0 |
| Ernest S. Biczak, M.D. | 0 | 43,468 | 0 |
| Claremont Delaware Trust | 0 | 61,181 | 0 |
| Domain Partners V, L.P. | 0 | 2,309,003 | 0 |
| DP V Associates, L.P. | 0 | 54,545 | 0 |
| Andrew J. Einhorn | 0 | 11,038 | 0 |
| NEA Ventures 2002, Limited Partnership | 0 | 6,520 | 0 |
| New Enterprise Associates 10, Limited Partnership | 0 | 2,275,527 | 0 |
| Ronald Nordmann | 0 | 10,867 | 0 |
| Patricof Private Investment Club III, L.P. | 0 | 70,385 | 0 |
| Anthony A. Rascio | 0 | 21,734 | 0 |
| Roxiticus Ventures, LLC | 0 | 5,433 | 0 |
| S. Douglas Sheldon | 0 | 56,523 | 0 |
| Sheldon Family Trust | 0 | 47,814 | 0 |
| Joe Smith | 0 | 2,173 | 0 |
| John T. Spitznagel | 0 | 135,836 | 0 |
| Spitznagel Family Limited Partnership | 0 | 233,638 | 0 |
| Sundance AP, LLC | 0 | 347,740 | 0 |
| Thoma Cressey Friends Fund VII, L.P. | 0 | 20,919 | 0 |
| Thoma Cressey Fund VII, L.P. | 0 | 1,337,442 | 0 |
| Howard J. Weisman | 0 | 129,866 | 0 |
| WFG AP, LLC | 0 | 170,128 | 0 |
| Total | 0 | 9,853,770 | 0 |

This registration statement also shall cover any additional shares of common stock which become issuable in connection with the shares registered for sale hereby by reason of any stock dividend, stock split, recapitalization or other similar right, or transaction effected without the receipt of consideration which results in an increase in the number of our outstanding shares of common stock.

PLAN OF DISTRIBUTION

We have been advised by the selling stockholders that they may sell all or a portion of their shares of common stock. The selling stockholders plan to sell on the Nasdaq National Market, or otherwise. The selling stockholders or their pledges, donees, transferees or other successors-in-interest selling shares received from the selling holders as a gift, partnership distribution or other non-sale related transfers after the date of this prospectus (collectively, the "selling stockholders"), may sell their shares at prices and on terms prevailing at the time of sale, at prices related to the then current market price, or in negotiated transactions. The selling stockholders may sell in one or more of, or a combination of, the following methods:

- block trades in which the broker or dealer so engaged will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its own account pursuant to this prospectus;
- on over-the-counter distribution in accordance with the rules of the Nasdaq National Market;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- privately negotiated transactions;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In effecting sales, broker-dealers engaged by the selling stockholder may arrange for other broker-dealers to participate in the resales.

The selling stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In these transactions, broker-dealers may engage in short sales of the shares in the course of hedging the positions they assume with the selling stockholders.

The selling stockholders also may sell shares short and redeliver the shares to close out such short positions. The selling stockholders may enter into options or other transactions with broker-dealers that require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer such shares covered by this prospectus. The selling stockholders also may loan or pledge the shares to a broker-dealer. The broker-dealer may sell the shares so loaned, or upon default the broker-dealer may sell the pledged shares under this prospectus. Broker-dealers or agents may also receive compensation in the form of commissions, discounts or concessions from the selling stockholders. Broker-dealers or agents may also receive compensation from the purchasers of the shares for whom they act as agents or to whom they sell as principals, or both. Compensation as to a particular broker-dealer might be in excess of customary commissions and will be in amounts to be negotiated in connection with the sale. Broker-dealers or agents and any other participating broker-dealers or the selling stockholders may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, as amended (the "Securities Act"), in connection with sales of the shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the shares purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. Each of the selling stockholders has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock. Because the selling stockholders may be deemed to be an "underwriter" within the meaning of Section 2(11) of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify

for sale in compliance with Rule 144 promulgated under the Securities Act may be sold under Rule 144 rather than under this prospectus.

The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934 (the "Exchange Act"), any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our common stock for a restricted period before the commencement of such distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our common stock by the selling stockholders. We will make copies of this prospectus available to the selling stockholders and has informed them of the need to deliver copies of this prospectus to purchasers at or before the time of any sale of the shares.

We will file a supplement to this prospectus, if required, to comply with Rule 424(b) under the Securities Act, upon being notified by a selling stockholder that any material arrangement have been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer. Such supplement will disclose:

- the name of each such selling stockholder and of the participating broker-dealer(s);
- the number of shares involved;
- the price at which such shares were sold;
- the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable;
- that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and
- other facts material to the transaction.

The selling stockholders may from time to time pledge shares of common stock owned by them to secure margin or other loans made to one or more of the selling stockholders or to entities in which one or more of the selling stockholders have a direct or indirect equity interest. Thus, the person or entity receiving a pledge of any shares of common stock may sell them in a foreclosure sale or otherwise in the same manner as described above to a selling stockholder.

There is no assurance that the selling stockholders will offer or sell any or all of their shares of common stock registered under this prospectus.

In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from the selling stockholders in amounts to be negotiated prior to the sale. Such brokers or dealers and any other participating brokers or dealers may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. We will pay all expenses incident to the offering and sale to the public of shares by the selling stockholders, including all registration, filing, securities exchange listing and NASD fees, all registration, filing, qualification and other fees and expenses of complying with securities or blue sky laws, and the fees and disbursements of a single legal counsel acting for the selling stockholders. We will not pay underwriting commissions or similar charges for the selling stockholders.

We agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until such time as all of the shares are eligible for sale pursuant to Rule 144 in one three month period. In addition, any shares of common stock covered by this prospectus which qualify for sale in compliance with Rule 144 of the Securities Act may be sold under Rule 144 rather than under this prospectus.

We intend to de-register any of the shares not sold by the selling stockholders at the end of such period. At such time, however, any unsold shares may be freely tradable subject to compliance with Rule 144 of the Securities Act.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for PDL by DLA Piper Rudnick Gray Cary US LLP, San Francisco, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, have audited our consolidated financial statements as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004, included in our Annual Report on Form 10-K for the year ended December 31, 2004 as set forth in their report. Ernst & Young LLP have also audited ESP Pharma Holdings and Subsidiary's financial statements as of December 31, 2003 and 2002, for the year ended December 31, 2003 and for the period from April 15, 2002 (inception) through December 31, 2002, included in our Current Report on Form 8-K dated February 7, 2005, as set forth in their report. Our financial statements and ESP Pharma Holdings and Subsidiary's financial statements are incorporated by reference in this prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's reports, given upon the authority of such firm as experts in accounting and auditing.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the various expenses payable by us in connection with the sale and distribution of the securities being registered. All of the amounts shown are estimates except for the Securities and Exchange Commission registration fee and the Nasdaq listing application fee.

| | | To be Paid By the Registrant |
|---|----|---------------------------------|
| Securities and Exchange Commission registration fee | \$ | 21,700 |
| Accounting fees and expenses | \$ | 10,000 |
| Printing expenses | \$ | 10,000 |
| Transfer agent and registrar fees and expenses | \$ | 5,000 |
| Legal fees and expenses | \$ | 15,000 |
| Miscellaneous expenses | \$ | 8,300 |
| Total | \$ | 70,000 |

Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law permits indemnification of officers, directors, and other corporate agents under certain circumstances and subject to certain limitations. Our restated certificate of incorporation and amended and restated bylaws provide that we shall indemnify our directors, officers, employees, and agents to the full extent permitted by Delaware law. The restated certificate of incorporation and amended and restated bylaws further provide that we may indemnify directors, officers, employees, and agents in circumstances in which indemnification is otherwise discretionary under Delaware law. In addition, we entered into separate indemnification agreements with our directors and officers which would require us, among other things, to indemnify them against certain liabilities which may arise by reason of their status or service (other than liabilities arising from willful misconduct of a culpable nature) and to maintain directors' and officer's liability insurance, if available on reasonable terms.

These indemnification provisions and the indemnification agreements that we have entered into with our officers and directors may be sufficiently broad to permit indemnification of our officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act of 1933, as amended (the Securities Act).

We have a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

At present, there is no pending litigation or proceeding involving any of our directors, officers, employees or other agents in which indemnification is being sought. We are not aware of any threatened litigation that may result in a claim for indemnification by any of our directors, officers, employees or other agents.

Item 16. Exhibits

The following exhibits are filed with this Registration Statement:

| Exhibit Number | Exhibit Title |
|----------------|---|
| 2.1 | Agreement and Plan of Merger with and among Protein Design Labs, Inc., Big Dog Bio, Inc., ESP Pharma Holding Company, Inc. and certain individuals, as amended. |
| 5.1 | Legal opinion of DLA Piper Rudnick Gray Cary US LLP, counsel to the Registrant. |
| 23.1 | Consent of independent registered public accounting firm. |
| 23.2 | Consent of independent registered public accounting firm. |
| 23.3 | Consent of DLA Piper Rudnick Gray Cary US LLP (included in Exhibit 5.1 to this Registration Statement). |
| 24.1† | Power of Attorney. |

† Previously filed.

Item 17. Undertakings

Insofar as indemnification by the registrant for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act, and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (1)(i) and (a)(1)(ii) above shall not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of Prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective; and

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of Prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Fremont, State of California, on the 25th day of March, 2005.

PROTEIN DESIGN LABS, INC.

By: /s/ MARK MCDADE

Mark McDade
Chief Executive Officer

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**AMENDED AND RESTATED
AGREEMENT AND PLAN OF MERGER**

dated as of March 22, 2005

by and among

PURCHASER,

BIG DOG BIO, INC.,

ESP PHARMA HOLDING COMPANY, INC.

and

THE CONTRIBUTING STOCKHOLDERS REFERRED TO HEREIN

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This Table of Contents is not part of the Agreement to which it is attached but is inserted for convenience only.

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This AMENDED AND RESTATED AGREEMENT AND PLAN OF MERGER dated as of March 22, 2005 is made and entered into by and among Protein Design Labs, Inc., a Delaware corporation ("*Purchaser*"), Big Dog Bio, Inc., a Delaware corporation ("*Merger Sub*"), ESP Pharma Holding Company, Inc., a Delaware corporation (the "*Company*"), and the Contributing Stockholders (as defined herein). Capitalized terms not otherwise defined herein have the meanings set forth in *Section 12.01*.

WHEREAS, as of the date hereof, there are issued and outstanding (i) 28,200,000 shares of Series A Convertible Preferred Stock, par value \$.0001 per share, of the Company ("*Series A Stock*"), (ii) 12,500,000 shares of Series B Convertible Preferred Stock, par value \$.0001 per share, of the Company ("*Series B Stock*", and, together with the Series A Stock, the "*Company Preferred Stock*"), (iii) 6,592,774 shares (not including 48,901 authorized but unissued shares held in reserve) of common stock, par value \$.0001 per share, of the Company ("*Company Common Stock*" and, together with the Company Preferred Stock, the "*Shares*"), and (iv) options to purchase 3,207,226 shares of Company Common Stock (the "*Company Options*") issued under the Stock Option Plan, all as more fully set forth in *Annex I* hereto;

WHEREAS, the Boards of Directors of Purchaser, Merger Sub and the Company have each determined that it is advisable and in the best interests of their respective stockholders to consummate, and have approved, the business combination transaction provided for herein in which Merger Sub would merge with and into the Company and the Company would become a wholly-owned subsidiary of Purchaser (the "*Merger*");

WHEREAS, Purchaser, Merger Sub, the Company and certain individuals and entities entered into an Agreement and Plan of Merger, dated as of January 24, 2005 (the "*Original Agreement*"), agreeing to and setting forth the terms and conditions of the Merger;

WHEREAS, concurrently with the execution and delivery of the Original Agreement, the Merger was approved by the requisite vote of the holders of Shares and by Purchaser as the sole stockholder of Merger Sub;

WHEREAS, the Contributing Stockholders, who as of the date hereof collectively own approximately 95% of the Shares, have appointed Anthony A. Rascio (such individual, or his successor named in accordance with *Section 13.04*, being referred to herein as the "*Stockholders' Agent*") to act on their behalf with respect to certain matters set forth herein;

WHEREAS, in connection with the Merger, all Company Options which have not been exercised will be cancelled in exchange for a cash payment on the terms and subject to the conditions set forth in this Agreement;

WHEREAS, the parties to the Original Agreement amended the Original Agreement by entering into Amendment No. 1 to the Original Agreement as of January 31, 2005; and

WHEREAS, each of the parties has determined that it is advisable and in its best interests, and each of the parties that is an entity has determined that it is advisable and in the best interests of its respective stockholders or constituent members, as applicable, to amend and restate the Original Agreement, as amended, as set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE I
THE MERGER

1.01 *The Merger.* Upon the terms and subject to the conditions of this Agreement, at the Effective Time, Merger Sub shall be merged with and into the Company in accordance with the General Corporation Law of the State of Delaware (the "*DGCL*"), whereupon the separate existence of Merger Sub shall cease and the Company shall continue as the surviving corporation (the "*Surviving*

Corporation") and a wholly-owned subsidiary of Purchaser. Merger Sub and the Company are sometimes referred to herein as the "Constituent Corporations". As a result of the Merger, the outstanding shares of capital stock of the Constituent Corporations shall be converted or cancelled in the manner provided in Section 1.02. Subject to the foregoing and to the other sections of this Article I, the effects of the Merger shall be as provided in the applicable provisions of the DGCL.

1.02 *Conversion of Capital Stock.* At the Effective Time, by virtue of the Merger and without any action on the part of the holder thereof:

(a) *Capital Stock of Merger Sub.* Each issued and outstanding share of the common stock, par value \$0.001 per share, of Merger Sub ("Merger Sub Common Stock") shall be converted into and become one fully paid and nonassessable share of common stock, par value \$0.001 per share, of the Surviving Corporation ("Surviving Corporation Common Stock"). Each certificate representing outstanding shares of Merger Sub Common Stock shall at the Effective Time represent an equal number of shares of Surviving Corporation Common Stock.

(b) *Capital Stock of the Company.* The consideration payable for each class of the capital stock of the Company (in the case of each such class, the "Applicable Merger Price") shall be as follows:

(i) each issued and outstanding share of Company Common Stock (other than shares to be canceled in accordance with Section 1.02(c) or Section 1.02(d)) shall be converted into the right to receive an amount equal to the Company Common Stock Per Share Purchase Price, payable in cash and/or shares of common stock, par value \$0.01 per share, of Purchaser ("Purchaser Common Stock") as provided in Section 2.01(c);

(ii) each issued and outstanding share of Series A Stock shall be converted into the right to receive an amount equal to the Company Preferred Stock Per Share Purchase Price, payable in cash and shares of Purchaser Common Stock, plus the Preferred Stock Dividend payable in cash, as provided in Section 2.01(c); and

(iii) each issued and outstanding share of Series B Stock shall be converted into the right to receive an amount equal to the Company Preferred Stock Per Share Purchase Price, payable in cash and shares of Purchaser Common Stock, plus the Preferred Stock Dividend payable in cash, as provided in Section 2.01(c).

All Shares converted in accordance with this Section 1.02(b) shall no longer be outstanding and shall automatically be deemed canceled and retired and shall cease to exist as of the Effective Time, and each holder of a certificate representing any such Shares ("Certificates") shall cease to have any rights with respect thereto, except the right to receive the Applicable Merger Price as of the Effective Time, without interest, regardless of whether such holder's Certificates are delivered to the Stockholders' Agent for delivery at Closing as contemplated by Section 2.01(d). The payment of the Applicable Merger Price in accordance with the terms of Section 2.01(c) shall be deemed to have been paid in full satisfaction of all rights pertaining to the Shares. From and after the Effective Time there shall be no further registration of transfers effected on the stock transfer books of the Surviving Corporation of shares of capital stock of the Company which were outstanding immediately prior to the Effective Time.

(c) *Cancellation of Treasury Stock.* Notwithstanding any provision of this Agreement to the contrary, all Shares that are owned by the Company or any of its Subsidiaries as treasury stock shall be canceled and retired and shall cease to exist and no shares of Purchaser Common Stock or other consideration shall be delivered in exchange therefor.

(d) *Dissenting Shares.* (i) Notwithstanding any provision of this Agreement to the contrary, each outstanding Share the holder of which has not voted in favor of the Merger, has perfected

such holder's right to an appraisal of such holder's shares in accordance with the applicable provisions of the DGCL and has not effectively withdrawn or lost such right to appraisal (a "*Dissenting Shares*"), shall not be converted into or represent a right to receive the Applicable Merger Price, but the holder thereof shall be entitled only to such rights as are granted by the applicable provisions of the DGCL; *provided, however*, that any Dissenting Shares held by a person at the Effective Time who shall, after the Effective Time, withdraw the demand for appraisal or lose the right of appraisal, in either case pursuant to the DGCL, shall be deemed to be converted into, as of the Effective Time, the right to receive the Applicable Merger Price.

(ii) The Company shall give Purchaser (x) prompt notice of any written demands for appraisal, withdrawals of demands for appraisal and any other instruments served pursuant to the applicable provisions of the DGCL relating to the appraisal process received by the Company and (y) the opportunity to direct all negotiations and proceedings with respect to demands for appraisal under the DGCL. The Company will not voluntarily make any payment with respect to any demands for appraisal and will not, except with the prior written consent of Purchaser, settle or offer to settle any such demands.

(iii) Each of the Contributing Stockholders hereby acknowledges that such Contributing Stockholder has voted such Contributing Stockholder's Shares in favor of the Merger and will not seek to assert any right to an appraisal of such Contributing Stockholder's Shares under the DGCL.

(e) *Fractional Shares.* Notwithstanding any provision of this Agreement to the contrary, no certificates or scrip representing fractional shares of Purchaser Common Stock will be issued in exchange for Certificates, no dividend or other distributions with respect to Purchaser Common Stock will be payable on or with respect to any fractional share and such fractional share interests will not entitle the owner thereof to any rights of a stockholder of Purchaser. In lieu of such fractional share interests, Purchaser shall deliver to Stockholders' Agent on behalf of each holder of Shares who would otherwise be entitled to receive a fractional share of Purchaser Common Stock, together with the amounts deliverable pursuant to clauses (iii) and (v) of *Section 2.01(c)*, an amount in cash equal to the fractional share interest of Purchaser Common Stock to which such holder (after taking into account all Shares held immediately prior to the Effective Time by such holder) would otherwise be entitled, multiplied by the Value Per Share.

(f) *Change in Purchaser Common Stock.* If between the date of the Original Agreement and the Effective Time the outstanding shares of Purchaser Common Stock shall have been increased, decreased, changed into or exchanged for a different number of shares or a different class, by reason of any stock dividend, subdivision, reclassification, recapitalization, split, combination, exchange of shares, reverse stock split or other similar change in capitalization, the Applicable Merger Price shall be correspondingly adjusted to reflect such stock dividend, subdivision, reclassification, recapitalization, split, combination, exchange of shares, reverse stock split or other similar change in capitalization.

1.03 *Certificate of Incorporation and Bylaws of the Surviving Corporation.* At the Effective Time, (i) the Certificate of Incorporation of Merger Sub as in effect immediately prior to the Effective Time shall be amended to change the name of the Surviving Corporation to "ESP Pharma Holding Company, Inc." and, as so amended, shall become the Certificate of Incorporation of the Surviving Corporation, until the same shall be amended in accordance with its terms and applicable Law, and (ii) the Bylaws of Merger Sub as in effect immediately prior to the Effective Time shall be the Bylaws of the Surviving Corporation until thereafter amended as provided by law, the Certificate of Incorporation of the Surviving Corporation and such Bylaws.

1.04 *Directors and Officers of the Surviving Corporation.* The directors of Merger Sub and the officers of the Company immediately prior to the Effective Time shall, from and after the Effective Time, be the directors and officers, respectively, of the Surviving Corporation until their successors shall have been duly elected or appointed and qualified or until their earlier death, resignation or removal in accordance with the Surviving Corporation's Certificate of Incorporation and Bylaws.

ARTICLE II CLOSING; PAYMENT OF PURCHASE PRICE

2.01 *Closing; Payment of Purchase Price.*

(a) Unless this Agreement shall have been terminated and the transactions herein contemplated shall have been abandoned pursuant to *Section 11.01*, and subject to the satisfaction or waiver (where applicable) of the conditions set forth in *Articles VII* and *VIII*, the closing of the Merger (the "*Closing*") will take place at the offices of Milbank, Tweed, Hadley & McCloy LLP, 1 Chase Manhattan Plaza, New York, New York, at 10:00 a.m., local time, on the Closing Date, or at such other place and time as is agreed to in writing by Purchaser and the Company.

(b) At the Closing, a certificate of merger (the "*Certificate of Merger*") shall be duly prepared and executed by the Surviving Corporation and thereafter delivered to the Secretary of State of the State of Delaware (the "*Secretary of State*") for filing, as provided in Section 251 of the DGCL, as soon as practicable on the Closing Date. The Merger shall become effective at the time of the filing of the Certificate of Merger with the Secretary of State (the date and time of such filing being referred to herein as the "*Effective Time*").

(c) At the Closing, Purchaser will pay the Purchase Price by delivering a combination of (x) cash in an aggregate amount of \$325,000,000 (the "Cash Amount") payable in immediately available United States funds wired to the account of the applicable recipient provided to Purchaser prior to the Closing Date, and (y) 8,868,393 shares of Purchaser Common Stock (if and as adjusted in the manner provided below, the "Closing Shares") by delivery of certificates representing the Closing Shares issued in the names provided to Purchaser by or on behalf of the Stockholders' Agent prior to the Closing Date, to be allocated among the applicable recipients in the following manner:

(i) to the Company, cash in an amount necessary to enable the Company to pay and satisfy the Transaction Expenses and Change of Control Payments in the manner contemplated by *Section 2.05*;

(ii) to the Escrow Agent under the Escrow Agreement substantially in the form of *Exhibit A* hereto to be entered into on the Closing Date by Stockholders' Agent (on behalf of the Contributing Stockholders), Purchaser and the Escrow Agent (the "*Escrow Agreement*"), a number of shares (ignoring fractions) of Purchaser Common Stock having an aggregate Value Per Share equal to ten percent (10%) of the Contributing Stockholder Purchase Price for deposit with the Escrow Agent under the Escrow Agreement (the "*Escrow Shares*");

(iii) to Stockholders' Agent on behalf of each Contributing Stockholder who owns shares of Company Preferred Stock, (A) a cash amount equal to the result obtained by multiplying the Preferred Stock Dividend by the number of shares of Preferred Stock owned by such Contributing Stockholder and (B) an amount equal to the result obtained by multiplying the Company Preferred Stock Per Share Purchase Price by the number of shares of Company Preferred Stock owned by such Contributing Stockholder (the "*Preferred Stock Payment*"), such Preferred Stock Payment to be payable in a combination of (x) a number of shares of Purchaser Common Stock equal to the result obtained by multiplying the total number of Closing Shares by a fraction, the numerator of which is the number of shares of Company

Common Stock issuable upon conversion of all shares of Company Preferred Stock owned by such Contributing Stockholder and the denominator of which is the total number of Outstanding Contributing Stockholder Company Shares, less the number of Escrow Shares (ignoring fractions) allocated to such Contributing Stockholder in *Annex I* hereto, and (y) cash in an amount equal to the amount by which the Preferred Stock Payment exceeds the result obtained by multiplying the number of shares of Purchaser Common Stock calculated in accordance with the preceding clause (x) (before deducting the Escrow Shares allocated to such Contributing Stockholder) by the Closing Value Per Share;

(iv) to Stockholders' Agent on behalf of each holder of Company Options (subject to deduction for any applicable withholding Tax), whether or not then exercisable, a cash amount equal to the result obtained by multiplying the Option Consideration by the number of Company Options held by such optionholder;

(v) to Stockholders' Agent on behalf of each Contributing Stockholder who owns shares of Company Common Stock, an amount equal to the result obtained by multiplying the Company Common Stock Per Share Purchase Price by the number of shares of Company Common Stock owned by such Contributing Stockholder (the "*Common Stock Payment*"), such Common Stock Payment to be payable in a combination of (A) a number of shares of Purchaser Common Stock equal to the result obtained by multiplying the total number of Closing Shares by a fraction, the numerator of which is the number of shares of Company Common Stock owned by such Contributing Stockholder and the denominator of which is the total number of Outstanding Contributing Stockholder Company Shares, less the number of Escrow Shares (ignoring fractions) allocated to such Contributing Stockholder in *Annex I* hereto, and (B) cash in an amount equal to the amount by which the Common Stock Payment exceeds the result obtained by multiplying the number of shares of Purchaser Common Stock calculated in accordance with the preceding clause (A) (before deducting the Escrow Shares allocated to such Contributing Stockholder) by the Closing Value Per Share; and

(vi) to Stockholders' Agent on behalf of (A) each owner of shares of Company Preferred Stock who is not a Contributing Stockholder, (x) a cash amount equal to the result obtained by multiplying the Preferred Stock Dividend by the number of shares of Preferred stock owned by such stockholder and (y) a cash amount equal to the result obtained by multiplying the Company Preferred stock Per Share Purchase Price by the number of shares of Company Preferred Stock owned by such stockholder; and (B) each owner of shares of Company Common Stock who is not a Contributing Stockholder, cash in an amount equal to the result obtained by multiplying the Company Common Stock Per Share Purchase Price by the number of shares of Company Common Stock owned by such stockholder;

provided however, that if, at the time of Closing, the closing of the transactions contemplated by the Retavase® Purchase Agreement shall not have occurred and the Retavase® Purchase Agreement shall not be in full force and effect, or either party shall be in breach thereof (other than breaches (a) caused by Purchaser's failure to provide the financing described in that certain Commitment Letter dated January 31, 2005 from Purchaser to the Company in accordance with its terms or (b) that Purchaser determines in its reasonable discretion (i) can be cured without other than nominal expense to Purchaser and (ii) will not unreasonably prevent or impede the closing of the transaction contemplated by the Retavase® Purchase Agreement), the Cash Amount shall be reduced to \$300,000,000.

Notwithstanding the foregoing, if (I) the Closing Value Per Share is less than \$17.7597, the number of Closing Shares shall be increased to the extent necessary so that the result obtained by multiplying the number of Closing Shares (as so increased) by the Closing Value Per Share is equal to \$157,500,000 (provided that such number shall not be increased to more than a maximum of

9,853,770 shares of Purchaser Common Stock), or (II) the Closing Value Per Share is greater than \$21.7063, the number of Closing Shares shall be decreased to the extent necessary so that the result obtained by multiplying the number of Closing Shares (as so decreased) by the Closing Value Per Share is equal to \$192,500,000 (provided that such number shall not be decreased to less than a minimum of 8,062,175 shares of Purchaser Common Stock).

If Purchaser determines in its discretion not to issue any additional shares that may otherwise be issuable under the foregoing provision, Purchaser may instead increase the total cash compensation payable under this *Section 2.01(c)* by an amount equal to the number of additional shares otherwise issuable under this *Section 2.01* multiplied by the Closing Value Per Share. To effect this provision, Purchaser must give notice to the Stockholders' Agent at least two (2) days prior to the Closing electing to make such change including the amount of the adjusted cash purchase price and the calculation thereof. In such case, appropriate adjustments will be made, if any, by the parties to the provisions of this *Section 2.01*.

Notwithstanding any provisions of this Agreement to the contrary, (x) to the extent that Purchaser is obligated hereunder to deliver any cash to the Company for the payment of any Transaction Expenses or Change in Control Payments, at the Company's election, Purchaser shall deliver such cash payments directly, in the case of Transaction Expenses, to recipients designated on the certificate delivered pursuant to Section 2.05 and, in the case of all or a portion of Change in Control Payments, to one single agent that has been engaged by the Company to distribute such cash payments in accordance with this Agreement; (y) to the extent that Purchaser is obligated to deliver any cash payments to the Stockholders' Agent under Sections 2.01(c)(iii), (iv), (v) or (vi) of this Agreement, at the Stockholders' Agent's election, Purchaser shall deliver all such cash payments to no more than five agents that have been engaged by the Stockholders' Agent to allocate or distribute such cash payments in accordance with this Agreement, and one of which agents must be the same agent as set forth in subsection (x) above if an election is made by the Company under subsection (x) above; and (z) to the extent that Purchaser is obligated to deliver any shares of Purchaser Common Stock to the Stockholders' Agent under Sections 2.01(c)(iii) or (v), at the Stockholders' Agent's election, Purchaser shall deliver such shares directly to the individuals or entities entitled to such shares.

(d) *Delivery of Certificates.* At the Closing, the Stockholders' Agent shall deliver to Purchaser the Certificates representing the Shares owned by the Contributing Stockholders and any other stockholder of the Company who has forwarded certificates representing Shares to the Stockholders' Agent prior to the Closing, duly endorsed in blank for transfer or accompanied by duly executed stock powers assigning the Shares represented thereby in blank. If any Certificate shall have been lost, stolen or destroyed, upon the making of an affidavit of that fact and the providing of an indemnity as reasonably requested by Purchaser by the person claiming such Certificate to be lost, stolen or destroyed, Purchaser shall cause the Surviving Corporation to issue in exchange for such lost, stolen or destroyed Certificate the Applicable Merger Price. Notwithstanding the foregoing, but subject to *Section 5.08*, it shall not be a condition to Purchaser's obligation to pay the Purchase Price in accordance with *Section 2.01(c)* that any stockholder of the Company, other than the Contributing Stockholders, shall have delivered Certificates representing their Shares, and all holders of Shares entitled to receive shares of Purchaser Common Stock in the Merger shall, for all purposes, be deemed to be the record holders of such shares of Purchaser Common Stock as of the Effective Time.

(e) *Withholding of Tax.* The Surviving Corporation shall be entitled to deduct and withhold from any amounts payable in respect of Shares or Company Options such amount, if any, as the Surviving Corporation (or any Affiliate thereof) is required to deduct and withhold with respect to the making of such payment under federal, state, local or foreign Tax Law. To the extent that amounts are so withheld by the Surviving Corporation, such withheld amounts shall be treated for

all purposes of this Agreement as having been paid to the former holder of Shares or Company Options, as the case may be, in respect of which such deduction and withholding was made by the Surviving Corporation.

2.02 Prepayment of Credit Agreement Indebtedness; Termination of Hedging Arrangements. (a) As soon as practicable prior to the Closing Date, the Company and ESP Pharma, Inc., a Delaware corporation wholly owned by the Company ("*Pharma*"), shall provide the minimum notice required under the terms of (i) the Credit Agreement in connection with the prepayment on the Closing Date of all outstanding Indebtedness under the Credit Agreement and (ii) any hedging arrangement entered into by Pharma with respect to the Indebtedness under the Credit Agreement in order to unwind such hedging arrangement on the Closing Date in connection with the repayment of the Indebtedness under the Credit Agreement.

(b) At or prior to the Closing, Purchaser shall pay to (i) the lenders under the Credit Agreement, a cash amount (payable in immediately available United States funds wired to the account of the applicable recipient provided to Purchaser prior to the Closing Date) equal to the outstanding principal of, accrued and unpaid interest on, any prepayment penalties or premiums on, and any other amounts payable with respect to, the Indebtedness of Pharma as of the Closing Date under the terms of the Credit Agreement (the "*Credit Agreement Payments*"), and (ii) any counterparty under the terms of any hedging arrangement entered into with respect to the Indebtedness under the Credit Agreement, a cash amount (payable in immediately available United States funds wired to the account of the applicable recipient provided to Purchaser prior to the Closing Date) equal to all amounts that are required to be made by Pharma to such parties in order to unwind such hedging arrangement as of the Closing Date (the "*Hedge Payments*"); provided that, if the Company has sufficient funds to make any of the payments contemplated by this paragraph, it may do so.

2.03 Company Options. At the Closing, each outstanding Company Option shall automatically be cancelled upon payment of the amounts described in Section 2.01(c)(iv). The surrender of a Company Option to the Company in exchange for the Option Consideration shall be deemed a release of any and all rights the holder had or may have had in respect of such Company Option. Prior to the Closing, the Company shall use its reasonable best efforts to obtain all necessary consents or releases from holders of Company Options under the Stock Option Plan and take all such other lawful action as may be necessary to give effect to the transactions contemplated by this Section.

2.04 Restricted Shares As provided in the Stock Purchase and Stock Restriction Agreements pursuant to which the Company granted to certain employees restricted shares of its Common Stock as indicated in *Annex I* hereto (the "*Restricted Shares*"), as of the Effective Time, each outstanding Restricted Share shall vest and the restrictions thereon shall lapse and such Restricted Share shall represent the right to receive the Applicable Merger Price as set forth in Section 1.02(b)(i).

2.05 Transaction Expenses and Change of Control Payments. At least two (2) Business Days prior to the Closing Date, the Company shall prepare and deliver to Purchaser a certificate setting forth the Company's calculation of the Transaction Expenses and Change of Control Payments. On the Closing Date, Purchaser shall deliver to the Company, from the cash portion of the Purchase Price, the amount of cash in immediately available funds necessary to enable the Company to pay and satisfy the Transaction Expenses and Change of Control Payments on the Closing Date, and the Company shall utilize such amounts to pay and satisfy the Transaction Expenses and Change of Control Payments; *provided, however*, that the Company shall not pay any Change of Control Payment to any individual unless and until such individual has executed and delivered to the Company a release in form and substance reasonably satisfactory to Purchaser; *provided, further*, that Purchaser and the Company hereby agree that an amount of cash equal to the aggregate of all Change of Control Payments that are not paid on or after the Closing Date, if any, shall be retained by the Company until used for the

payment and satisfaction of such unpaid Change in Control Payments; *provided, further*, that Purchaser and the Company hereby agree and covenant that upon the delivery to the Company of such a release after the Closing by any individual entitled to a Change in Control Payment, the Company shall pay such Change in Control Payment to such individual within three (3) Business Days after such receipt by the Company.

2.06 *Additional Contributing Stockholders.* From time to time following the date of the Original Agreement and not later than two (2) Business Days prior to the Closing Date, any owner of shares of Company Common Stock who is not at the time a Contributing Stockholder and who demonstrates to the reasonable satisfaction of Purchaser that such stockholder is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act may, by execution and delivery of an instrument in form and substance reasonably satisfactory to Purchaser and the Company confirming that such a stockholder agrees to become, and to be bound by the terms and provisions of this Agreement applicable to, a Contributing Stockholder, become a Contributing Stockholder for all purposes of this Agreement (including, without limitation, for purposes of making the representation and warranties of a Contributing Stockholder under *Article III* and the appointment of the Stockholders' Agent) as though an original signatory hereto.

2.07 *Further Assurances.* At any time or from time to time after the Closing, each of the parties hereto shall, at the expense of the party making such request, execute and deliver such other documents and instruments, provide such materials and information and take such other actions as may reasonably be necessary, proper or advisable, to the extent permitted by Law, to fulfill its obligations under this Agreement.

ARTICLE III REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company and, only where a specific representation or warranty is made with respect thereto, each Contributing Stockholder, hereby represent and warrant to Purchaser that the statements contained in this *Article III* are correct and complete as of the date of the Original Agreement, except as set forth in the Company Disclosure Schedule.

3.01 *Power and Authority.* The Company has full corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby. Each Contributing Stockholder has full power and authority to execute and deliver this Agreement, to perform such Contributing Stockholder's obligations hereunder and to consummate the transactions contemplated hereby.

3.02 *Execution and Delivery.* (a) The execution and delivery by the Company of this Agreement, and the performance by the Company of its obligations hereunder, have been duly and validly authorized by the Board of Directors and by the requisite vote of the stockholders of the Company and no other corporate action on the part of the Company or any of the stockholders of the Company is necessary. This Agreement has been duly and validly executed and delivered by the Company and constitutes a legal, valid and binding obligation of the Company enforceable against the Company in accordance with its terms.

(b) The execution and delivery by each Contributing Stockholder of this Agreement, and the performance by each Contributing Stockholder of such Contributing Stockholder's obligations hereunder, have been duly and validly authorized by or on behalf of such Contributing Stockholder, no other action on the part of such Contributing Stockholder being necessary except as expressly contemplated hereby. This Agreement has been duly and validly executed and delivered by each Contributing Stockholder and constitutes a legal, valid and binding obligation of such Contributing Stockholder enforceable against such Contributing Stockholder in accordance with its terms.

3.03 *Corporate Existence of the Company.* The Company is a corporation validly existing and in good standing under the Laws of the State of Delaware, and has full corporate power and authority to conduct its business as and to the extent now conducted and to own, use and lease its Assets and Properties. The Company is duly qualified, licensed or admitted to do business and is in good standing in each jurisdiction in which the ownership, use or leasing of its Assets and Properties, or the conduct or nature of its business, makes such qualification, licensing or admission necessary, except for those jurisdictions in which the adverse effects of all such failures by the Company to be qualified, licensed or admitted and in good standing could not in the aggregate reasonably be expected to have a material adverse effect on the Business or Condition of the Company. *Section 3.03* of the Company Disclosure Schedule sets forth a list of each jurisdiction in which the Company or Pharma is qualified or licensed to do business and each assumed name under which either of them conducts business in any jurisdiction. The Company has made available to Purchaser prior to the execution of the Original Agreement complete and correct copies of the organizational documents of the Company and Pharma.

3.04 *Capital Stock; Ownership.* (a) *Annex I* hereto sets forth (i) the name of each owner of Shares and the number and class of Shares owned by each such stockholder (indicating how many of such Shares are Restricted Shares) and (ii) the name of each holder of Company Options and the number of shares of Company Common Stock subject to such Company Options. There are no shares of capital stock of the Company issued and outstanding other than the Shares, and no shares of capital stock of the Company are held by the Company as treasury shares. The Shares have been duly authorized and validly issued, are fully paid and nonassessable, and are owned, beneficially and of record, free and clear of all Liens, by the stockholders listed on *Annex I* hereto. Except for this Agreement and for the Company Options disclosed in *Annex I* hereto, there are no outstanding Options with respect to any shares of capital stock of the Company, and no shares of capital stock of the Company are reserved for issuance except upon exercise of the Company Options. *Annex II* hereto sets forth the issue date, the exercise price and the vesting schedule for all outstanding Company Options. The shares of Company Common Stock issuable upon exercise of the Company Options have been duly authorized and, when issued in accordance with the terms of the Company Options, will be validly issued, fully paid and nonassessable shares of Company Common Stock.

(b) Each Contributing Stockholder represents that such Contributing Stockholder (i) owns the number of Shares set forth next to such Contributing Stockholder's name in *Annex I* hereto; (ii) owns no other securities of the Company other than Company Options as indicated on *Annex I* hereto, (iii) waives any right to an appraisal of such Contributing Stockholder's Shares that may exist under the DGCL; (iv) is acquiring the shares of Purchaser Common Stock to be issued to such Contributing Stockholder in the Merger for Contributing Stockholder's own account for investment, not as a nominee or agent, and not with a view to the resale or distribution of such shares or any part thereof in violation of the Securities Act or any state securities or blue sky law, and has no present intention of selling, granting any participation in, or otherwise distributing the same, except as contemplated by *Section 6.09*; (v) acknowledges that the issuance of the shares of Purchaser Common Stock in the Merger will not be registered under the Securities Act or any state securities or blue sky law, on the grounds that the offering and sale of the shares of Purchaser Common Stock in the Merger are exempt from registration pursuant to exceptions available under such laws, and that Purchaser's reliance upon such exemptions is predicated upon this representation; (vi) acknowledges and understands that the shares of Purchaser Common Stock to be issued to such Contributing Stockholder in the Merger must be retained until they are subsequently registered under the Securities Act and/or applicable state securities or blue sky laws or an exemption from such registration is available; and (vii) is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act.

3.05 *Subsidiaries; Investment Assets.* (a) The Company has no Subsidiaries other than Pharma. Pharma is a corporation validly existing and in good standing under the Laws of Delaware, and has full corporate power and authority to conduct its business as and to the extent now conducted and to own, use and lease its Assets and Properties. Pharma is duly qualified, licensed or admitted to do business and is in good standing in each jurisdiction in which the ownership, use or leasing of Pharma's Assets and Properties, or the conduct or nature of its business, makes such qualification, licensing or admission necessary, except for those jurisdictions in which the adverse effects of all such failures by Pharma to be qualified, licensed or admitted and in good standing could not in the aggregate reasonably be expected to have a material adverse effect on the Business or Condition of the Company. All of the issued and outstanding shares of capital stock of Pharma have been duly authorized and validly issued, are fully paid and nonassessable and are owned, beneficially and of record, by the Company free and clear of all Liens. There are no outstanding Options with respect to any shares of capital stock of Pharma.

(b) *Section 3.05(b)* of the Company Disclosure Schedule lists each Investment Asset held by the Company or Pharma in any Person which is not a Subsidiary of the Company.

3.06 *No Conflicts.* (a) The execution and delivery by the Company of this Agreement do not, and the performance by the Company of its obligations under this Agreement and the consummation of the transactions contemplated hereby will not:

(i) conflict with or result in a violation or breach of any of the terms, conditions or provisions of the organizational documents of the Company or Pharma;

(ii) subject to obtaining the consents, approvals and actions, making the filings and giving the notices disclosed in *Section 3.06* of the Company Disclosure Schedule, conflict with or result in a violation or breach of any term or provision of any material Law or Order applicable to the Company or Pharma or any of their respective Assets and Properties; or

(iii) except as disclosed in *Section 3.06* of the Company Disclosure Schedule, (A) conflict with or result in a violation or breach of, (B) constitute (with or without notice or lapse of time or both) a default under, (C) require the Company or Pharma to obtain any consent, approval or action of, make any filing with or give any notice to any Person as a result or under the terms of, (D) result in or give to any Person any right of termination, cancellation, acceleration or modification in or with respect to, or (E) result in the creation or imposition of any Lien upon the Company or Pharma or any of their respective Assets and Properties under, any Contract or License to which the Company or Pharma is a party or by which any of their respective Assets and Properties is bound, other than Liens in respect of obligations in an aggregate amount not exceeding \$100,000.

(b) The execution and delivery by each Contributing Stockholder of this Agreement do not, and the performance by such Contributing Stockholder of such Contributing Stockholder's obligations under this Agreement and the consummation of the transactions contemplated hereby will not:

(i) conflict with or result in a violation or breach of any of the terms, conditions or provisions of the organizational documents of any such Contributing Stockholder who is not an individual;

(ii) conflict with or result in a violation or breach of any term or provision of any material Law or Order applicable to such Contributing Stockholder or any of such Contributing Stockholder's Assets and Properties; or

(iii) (A) conflict with or result in a violation or breach of, (B) constitute (with or without notice or lapse of time or both) a default under, (C) require such Contributing Stockholder to

obtain any consent, approval or action of, make any filing with or give any notice to any Person as a result or under the terms of, (D) result in or give to any Person any right of termination, cancellation, acceleration or modification in or with respect to, or (E) result in the creation or imposition of any Lien upon such Contributing Stockholder or any of such Contributing Stockholder's Assets and Properties under, any material Contract or License to which such Contributing Stockholder is a party or by which any of such Contributing Stockholder's Assets and Properties is bound.

3.07 Governmental Approvals and Filings. Except as disclosed in *Section 3.07* of the Company Disclosure Schedule, and except for the filing of the Certificate of Merger with the Secretary of State and a premerger notification report by the Company under the HSR Act, no consent, approval or action of, filing with or notice to any Governmental or Regulatory Authority on the part of any Contributing Stockholder, the Company or Pharma is required in connection with the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby.

3.08 Books and Records. The minute books and other similar records of the Company and Pharma as made available to Purchaser prior to the execution of the Original Agreement contain a true and complete record, in all material respects, of all action taken at all meetings and by all written consents in lieu of meetings of the stockholders, the Boards of Directors and committees of the Boards of Directors of the Company and Pharma. The stock transfer ledgers of the Company and Pharma as made available to Purchaser prior to the execution of the Original Agreement accurately reflect all record transfers prior to the execution of the Original Agreement in the capital stock of the Company and Pharma.

3.09 Financial Statements and Condition. (a) Prior to the execution of the Original Agreement, the Company has made available to Purchaser true and complete copies of (i) the audited consolidated balance sheet of the Company as of December 31, 2003, and the related audited consolidated statements of operations, stockholders' equity and cash flows for the fiscal period then ended, together with a true and correct copy of the report on such audited information by Ernst & Young LLP, independent auditors, and (ii) the unaudited consolidated balance sheet of the Company as of December 31, 2004, and the related unaudited consolidated statements of operations, stockholders' equity and cash flows for the portion of the fiscal year then ended (the "Unaudited Financials"). Except as set forth in the notes thereto or as disclosed in *Section 3.09* of the Company Disclosure Schedule, all such financial statements were, and the financial statements to be delivered to Purchaser pursuant to *Section 5.06* will be, prepared in accordance with GAAP applied on a basis consistent throughout the periods indicated and consistent with each other (except as may be indicated in the notes thereto) and fairly present in all material respects the consolidated financial condition and results of operations of the Company as of the respective dates thereof and for the respective periods covered thereby.

(b) Except for the execution and delivery of this Agreement and the transactions to take place pursuant hereto on or prior to the Closing Date or as disclosed in *Section 3.09* of the Company Disclosure Schedule, since December 31, 2004 the business of the Company and Pharma has been operated in all material respects in the ordinary course and there has not been any material adverse change in the Business or Condition of the Company, other than (i) any adverse change, effect, event, occurrence, state of facts or development to the extent attributable to the announcement or pendency of this Agreement or the transactions contemplated hereby, (ii) any adverse change, effect, event, occurrence, state of facts or development after the date of the Original Agreement, attributable to conditions affecting the industry in which the Company and Pharma operate as a whole, or the United States economy or financial markets, (iii) any adverse change, effect, event, occurrence, state of facts or development arising from or relating to compliance with the terms of this Agreement, or action taken, or failed to be taken, to which

Purchaser has consented, (iv) changes in Laws after the date of the Original Agreement, or (v) changes in GAAP or regulatory accounting principles after the date of the Original Agreement; *provided* that with respect to clauses (ii) and (iv), such change, effect, event, circumstance, occurrence or state of facts (A) does not specifically relate to (or have the effect of specifically relating to) the Company and/or Pharma and (B) is not materially more adverse to the Company and/or Pharma than to other companies operating in the industry in which the Company and Pharma operate. Except as set forth in *Section 3.09* of the Company Disclosure Schedule, since September 30, 2004 neither the Company nor Pharma has taken any action or engaged in any transaction which, if taken or engaged in after the date of the Original Agreement, would require the consent of Purchaser pursuant to *Section 5.07* or *5.08*.

(c) Except as reflected in the Financial Statements described in paragraph (a) of this Section or as set forth in *Section 3.09* of the Company Disclosure Schedule, and except for Liabilities incurred in the ordinary course of business consistent with past practice, neither the Company nor Pharma has any Liabilities of any nature (whether accrued, absolute, contingent or otherwise) required by GAAP to be set forth on a consolidated balance sheet of the Company or in the notes thereto.

(d) The Company and Pharma maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements of the Company and to maintain accountability for assets; (iii) access to the Company's assets is permitted only in accordance with management's authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Neither the Company nor Pharma is a party to or otherwise involved in any "off-balance sheet arrangements" (as defined in Item 303 of Regulation S-K promulgated by the SEC).

3.10 Taxes. Except as disclosed in *Section 3.10* of the Company Disclosure Schedule:

(a) Each of the Company and Pharma have timely filed all Tax returns and reports required to be filed by or on behalf of each of them, or requests for extensions to file such returns or reports have been timely filed or granted and have not expired, and all such Tax returns and reports are complete and accurate in all material respects. The Company and Pharma have paid all Taxes shown as due on such Tax returns and reports, copies of which have been made available to Purchaser prior to the execution of the Original Agreement.

(b) The Financial Statements made available to Purchaser pursuant to *Section 3.09(a)* reflect an adequate reserve for all Taxes payable by the Company and Pharma for all taxable periods and portions thereof accrued through the date of such Financial Statements.

(c) No requests for waivers of the time to assess any Taxes against the Company or Pharma have been granted or are pending, except for requests with respect to such Taxes that have been adequately reserved for in all material respects in the Financial Statements made available to Purchaser pursuant to *Section 3.09(a)*.

(d) Neither the Company nor Pharma is a party to, is bound by, or has any obligation under, any agreement relating to the allocation or sharing of Taxes.

(e) Neither the Company nor Pharma has ever been a member of an affiliated group of corporations (within the meaning of Code Section 1504(a)) filing consolidated Tax returns, other than the affiliated group of which the Company is the common parent.

(f) No deficiencies for any Tax have been threatened, claimed, proposed or assessed against the Company or Pharma which have not been settled or paid. No Tax return of the Company or

Pharma is currently being audited or examined by the IRS or any other Governmental or Regulatory Authority and neither the Company nor Pharma has been notified of any request for such an audit or other examination; *provided* that the Company and Pharma are currently contesting in good faith certain state Taxes as disclosed in *Section 3.10(f)* of the Company Disclosure Schedule.

(g) The Company and Pharma have complied with all applicable laws relating to the payment and withholding of Taxes (including withholding of Taxes pursuant to Code Sections 1441, 1442, 1445 and 1446 or similar provisions under any foreign Law), and have, within the time and in the manner prescribed by applicable Laws, withheld from employee wages and paid over to the proper Governmental or Regulatory Authorities all amounts required to be so withheld and paid over under all applicable Laws, and have timely filed all withholding Tax returns.

(h) No claim has ever been made by a Governmental or Regulatory Authority in a jurisdiction where the Company or Pharma does not file Tax returns that the Company or Pharma is or may be subject to taxation by that jurisdiction.

(i) Neither the Company nor Pharma has consummated, has participated in or is currently participating in any transaction which was or is a "Tax shelter" transaction as defined in Section 6662, 6011, 6111 or 6112 of the Code or applicable Treasury Regulations. Neither the Company nor Pharma has entered into any reportable transaction as defined in Treasury Regulation Section 1.6011-4(b).

3.11 *Legal Proceedings.* Except as disclosed in the Company Disclosure Schedule, as of the date of the Original Agreement:

(a) there are no Actions or Proceedings pending or, to the Knowledge of the Company, threatened against, relating to or affecting the Company or Pharma or any of their respective Assets and Properties; and

(b) there are no outstanding Orders to which the Company or Pharma is a party or is subject which, individually or in the aggregate with other such Orders, adversely affect the Business or Condition of the Company.

3.12 *Compliance With Laws and Orders; Regulatory Filings.* Except as disclosed in *Section 3.12* of the Company Disclosure Schedule, neither the Company nor Pharma is in violation of or in default under any material Law or Order applicable to the Company or Pharma or any of their respective Assets and Properties.

3.13 *Benefit Plans; ERISA.* (a) Except as disclosed in *Section 3.13* of the Company Disclosure Schedule (the plans disclosed in the Company Disclosure Schedule, being referred to herein as the "*Company Plans*"), neither the Company nor Pharma has any material "employee benefit plan" (within the meaning of section 3(3) of the Employee Retirement Income Security Act of 1974, as amended, and the rules and regulations promulgated thereunder ("*ERISA*")), severance, change-in-control or employment plan, program or agreement, stock option, bonus plan, or incentive plan or program. Copies of the Company Plans (or descriptions if no plan document exists) have been made available to Purchaser prior to the execution of the Original Agreement.

(b) Each Company Plan has been administered and is in compliance with the terms of such Company Plan and all applicable laws, rules and regulations in all material respects.

(c) Except as disclosed in the Company Disclosure Schedule: (i) each Company Plan intended to be qualified under the Code has received a favorable determination from the IRS and (ii) to the Knowledge of the Company, nothing has occurred since that would adversely affect such qualification.

(d) (i) No "reportable event" (as such term is used in section 4043 of ERISA) (other than those events for which the 30-day notice has been waived pursuant to the regulations) is pending with respect to any Company Plan, and (ii) no "accumulated funding deficiency" (as such term is used in section 412 or 4971 of the Code) has occurred with respect to any Company Plan.

(e) No litigation or administrative or other proceeding involving any Company Plan is pending or, to the Knowledge of the Company, is threatened.

(f) Neither the Company nor Pharma has contributed to any (i) "pension plan" (as defined in Section 3(2) of ERISA) subject to Title IV of ERISA or Section 412 of the Code or (ii) "multiemployer plan" (within the meaning of section 3(37) of ERISA), and neither the Company nor any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of organizations within the meaning of Code sections 414(b), (c), (m) or (o)) has incurred any material withdrawal liability which remains unsatisfied.

(g) No Company Plan or plan sponsored by any member of the Company's Controlled Group has been terminated, where such termination has resulted in material liability to the Company or Pharma under Title IV of ERISA.

(h) Except for the Company Options or as disclosed in the Company Disclosure Schedule, no employer securities, employer real property or other employer property is included in the assets of any Company Plan. All agreements pursuant to which Company Options have been awarded are identical in form, other than for the name of the recipient, the date of the award, the exercise price, the number of shares of Company Common Stock subject to each Company Option and, in the case of recipients who are consultants to the Company or Pharma rather than employees, their Company Options are immediately exercisable rather than subject to vesting over five years in equal annual installments. The Company is not required to obtain the consent of any holder of Company Options in order to consummate the cancellation of Company Options in accordance with *Section 2.03*.

(i) No Company Plan (other than a Company Plan that may be terminated without penalty) promises or provides retiree medical or other retiree welfare benefits to any Person other than as required by applicable Law.

(j) There have been no "prohibited transactions" (other than exempt prohibited transactions), as such term is defined in Section 406 of ERISA or Section 4975 of the Code, with respect to any Company Plan.

3.14 Employee Matters. Each of the Company and Pharma is in material compliance with all currently applicable Laws respecting terms and conditions of employment. There are no proceedings pending or, to the Knowledge of the Company threatened, between the Company threatened between the Company or Pharma, on the one hand, and any or all of its current or former employees, on the other hand, including without limitation any claims for actual or alleged harassment or discrimination based on race, national origin, age, sex, sexual orientation, religion, disability or similar tortious conduct, breach of contract, wrongful termination, defamation, intentional or negligent infliction of emotional distress, interference with contract or interference with actual or prospective economic disadvantage. There are no claims pending or, to the Knowledge of the Company threatened, against the Company or Pharma under any workers' compensation or long-term disability plan or policy. Neither the Company nor Pharma has any material unsatisfied obligations to any employees, former employees or qualified beneficiaries pursuant to COBRA, HIPAA or any state law governing health care coverage extension or continuation. Each of the Company and Pharma has provided all employees with all wages, benefits, relocation benefits, stock options, bonuses and incentives and all other compensation that became due and payable through the date of the Original Agreement.

3.15 *Real Property.*

(a) Neither the Company nor Pharma owns any real property.

(b) The Company or Pharma has a valid and subsisting leasehold estate in and the right to quiet enjoyment of the real properties leased by it as lessee for the full term of the lease thereof. Each such lease is a legal, valid and binding agreement, enforceable in accordance with its terms, of the Company or Pharma and, to the Knowledge of the Company, of each other Person that is a party thereto, and except as set forth in *Section 3.15* of the Company Disclosure Schedule, to the Knowledge of the Company, there is no default (or any condition or event which, after notice or lapse of time or both, would constitute a default) thereunder in any material respect. True and complete copies of each Contract in respect of all leases of real property by the Company or Pharma have been made available to Purchaser prior to the execution of the Original Agreement.

(c) Except as disclosed in *Section 3.15* of the Company Disclosure Schedule, the improvements on the real property leased by the Company or Pharma are in all material respects in good operating condition and in a state of adequate and acceptable maintenance and repair consistent with past custom and practice, ordinary wear and tear excepted, and are adequate and suitable for the purposes for which they are currently being used by the Company or Pharma and, to the Knowledge of the Company, there are no condemnation or appropriation proceedings pending or threatened against any of such real property or the improvements thereon.

3.16 *Tangible Personal Property.* The Company or Pharma are in possession of and have good title to, or have valid leasehold interests in or valid rights under Contract to use, all tangible personal property used in and individually or in the aggregate with other such property material and necessary to the Business or Condition of the Company. All such tangible personal property is free and clear of all Liens, other than Permitted Liens or Liens disclosed in *Section 3.16* of the Company Disclosure Schedule, and is in reasonably good order and condition and adequate and suitable for the purposes for which they are currently being used by the Company or Pharma, ordinary wear and tear excepted.

3.17 *Intellectual Property Rights.* *Section 3.17* of the Company Disclosure Schedule discloses all (i) registered Intellectual Property used by the Company or Pharma in the pharmaceutical business in which the Company or Pharma is engaged and (ii) all Intellectual Property used in and individually or in the aggregate with other such Intellectual Property material to the Business or Condition of the Company (collectively, "*Company Intellectual Property*"), each of which the Company or Pharma either has all right, title and interest in or a valid and binding right under Contract to use. Except as disclosed in *Section 3.17* of the Company Disclosure Schedule, (a) all registrations with and applications to Governmental or Regulatory Authorities in respect of Company Intellectual Property owned by the Company or Pharma are valid and in full force and effect, (b) the execution of this Agreement and the consummation of the transactions contemplated hereby do not trigger any restrictions on the direct or indirect transfer of any Contract, or any interest therein, held by the Company or Pharma in respect of Company Intellectual Property, (c) neither the Company nor Pharma is in default (or with the giving of notice or lapse of time or both, would be in default) under any Contract to use the Company Intellectual Property and (d) to the Knowledge of the Company, the Company Intellectual Property is not being infringed by any other Person. Neither the Company nor Pharma has received notice that either is infringing any Intellectual Property of any other Person, no claim is pending nor to the Knowledge of the Company has been made to such effect that have not been resolved and, to the Knowledge of the Company, neither the Company nor Pharma is infringing any Intellectual Property of any other Person.

3.18 *Contracts.*

(a) *Section 3.18* of the Company Disclosure Schedule contains a true and complete list of each of the following Contracts (true and correct copies of which have been delivered to Purchaser

prior to the execution of the Original Agreement) to which the Company or Pharma is a party or by which any of their respective Assets and Properties is bound:

(i) all Contracts (excluding Benefit Plans) providing for a commitment of employment or consultation services for a specified or unspecified term or otherwise relating to employment or the termination of employment (including without limitation, individual change of control, severance or similar agreements), the name, position and rate of compensation of each party to each such Contract and the expiration date of each such Contract;

(ii) all Contracts containing any provision or covenant prohibiting or materially limiting the ability of the Company or Pharma to engage in any business activity or compete with any Person or prohibiting or limiting the ability of any Person to compete with the Company or Pharma (other than limitations inherent in the scope of any license granted in any agreement between the Company or Pharma and any other Person);

(iii) all partnership, joint venture, shareholders' or other similar Contracts with any Person;

(iv) all Contracts relating to Indebtedness of the Company or Pharma (other than intracompany Indebtedness between the Company and Pharma);

(v) all Contracts with distributors, manufacturers, suppliers of raw materials or active ingredients or sales agencies;

(vi) all Contracts relating to (A) the future disposition or acquisition of any Assets and Properties, other than dispositions or acquisitions in the ordinary course of business, and (B) any merger or other business combination (other than this Agreement);

(vii) all Contracts (other than this Agreement) that (A) limit or contain restrictions on the ability of the Company or Pharma to declare or pay dividends on, to make any other distribution in respect of or to issue or purchase, redeem or otherwise acquire its capital stock, to incur Indebtedness, to incur or allow to exist any Lien, to purchase or sell any Assets and Properties, to change the lines of business in which it participates or engages, to engage in any merger or other business combination or to otherwise not operate in the ordinary course of business, or (B) require the Company or Pharma to maintain specified financial ratios or levels of net worth or other indicia of financial condition;

(viii) all other Contracts (other than Company Plans listed in *Section 3.13* of the Company Disclosure Schedule) that (A) involve a binding payment or obligation, pursuant to the terms of any such Contract, by or to the Company or Pharma of more than \$50,000 annually and (B) cannot be terminated within sixty (60) days after giving notice of termination without resulting in any material cost or penalty to the Company or Pharma; and

(ix) all Contracts pursuant to which Company Intellectual Property is licensed to or from the Company (other than Contracts including implied licenses in distribution and marketing agreements).

(b) Each Contract required to be disclosed in the Company Disclosure Schedule is in full force and effect and constitutes a legal, valid and binding agreement, enforceable in accordance with its terms, of the Company or Pharma and, to the Knowledge of the Company, of each other party thereto; and except as disclosed in *Section 3.18* of the Company Disclosure Schedule, neither the Company, Pharma nor, to the Knowledge of the Company, any other party to such Contract is in violation or breach of or default under any such Contract (or with notice or lapse of time or both, would be in violation or breach of or default under any such Contract) in any material respect.

3.19 *Licenses.* Section 3.19 of the Company Disclosure Schedule contains a true and complete list of all Licenses used in and individually or in the aggregate with other such Licenses significant to the Business or Condition of the Company and all pending applications for any such Licenses ("*Company Licenses*"), setting forth the grantor, the grantee, the function and the expiration and renewal date of each. Except as disclosed in Section 3.19 of the Company Disclosure Schedule:

- (i) the Company or Pharma owns or validly holds all Company Licenses;
- (ii) each Company License is valid, binding and in full force and effect; and
- (iii) to the Knowledge of the Company neither the Company nor Pharma is in default (or with the giving of notice or lapse of time or both, would be in default) under any Company License.

3.20 *Insurance.* Section 3.20 of the Company Disclosure Schedule contains a true and complete list of all material insurance policies currently in effect that insure the business, operations or employees of the Company or Pharma or affect or relate to the ownership, use or operation of any of the Assets and Properties of the Company or Pharma. Each such policy is valid and binding and in full force and effect, no premiums due thereunder have not been paid and neither the Company nor Pharma has received any notice of cancellation or termination in respect of any such policy or is in default thereunder in any material respect.

3.21 *Labor Relations.* Except as disclosed in Section 3.21 of the Company Disclosure Schedule, no employee of the Company or Pharma is currently a member of a collective bargaining unit and, to the Knowledge of the Company, there are no overtly threatened attempts to organize for collective bargaining purposes any employees of the Company or Pharma. There has been no work stoppage, strike or other concerted action by employees of the Company or Pharma which have materially adversely affected the Business or Condition of the Company.

3.22 *Environmental Matters.* Each of the Company and Pharma has obtained all material Licenses which are required under applicable Environmental Laws in connection with the conduct of the business or operations of the Company or Pharma, each of such Licenses is in full force and effect and each of the Company and Pharma is in compliance in all material respects with the terms and conditions of all such Licenses and with any applicable Environmental Law.

3.23 *Regulatory Matters.*

(a) The Company Disclosure Schedule sets forth a complete and accurate list of (i) each investigational new drug application and the dates and type of all subsequent filings made by the Company or Pharma with the U.S. Food and Drug Administration (the "*FDA*") or any non-U.S. equivalents, (ii) each clinical trial protocol submitted by the Company or Pharma to the FDA or any non-U.S. equivalents and (iii) each new drug application and the dates and type of all subsequent filings made by the Company or Pharma pursuant to the Federal Food, Drug and Cosmetic Act, as amended ("*FDCA*"), or any non-U.S. equivalents.

(b) (i) Except as listed in Section 3.23 of the Company Disclosure Schedule, there are no lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, complaints or investigations by the FDA, the Department of Health and Human Services, the Center for Medicare and Medicaid Services, the U.S. Drug Enforcement Agency (the "*DEA*"), the U.S. Department of Justice (the "*DOJ*"), the Federal Trade Commission (the "*FTC*") or any state or non-U.S. regulatory agency pending or, to the Knowledge of the Company, threatened against or relating to the Company or Pharma, or any product marketed by or under clinical investigation conducted by or on behalf of the Company or Pharma, (ii) there have been no product recalls or similar actions by the Company or Pharma, (iii) neither the Company nor Pharma nor any of their respective officers or employees nor, to the Knowledge of the Company, any of their agents has

made an untrue statement of material fact or fraudulent statement to the FDA, the DEA or other regulatory agencies, including but not limited to those identified in *Section 3.23(b)(i)* or failed to disclose a material fact required to be disclosed to any of them, (iv) there are no unresolved reports, warning letters, inspections or other documents received from or issued to the Company or Pharma or, to the Knowledge of the Company, to any other Person by the FDA, the DEA or other regulatory agencies that indicate or suggest lack of compliance with applicable regulatory requirements by the Company, Pharma or, to the Knowledge of the Company, Persons providing services for the benefit of any of them, (v) as to each drug of the Company or Pharma for which a new drug application or abbreviated new drug application has been approved by the FDA or other regulatory agencies, the applicant and all persons performing operations covered by the application are in substantial compliance with 21 U.S.C. Section 355 or 357, 21 C.F.R. Part 314 or 430 *et seq.* (or non-U.S. equivalents), and all terms and conditions of the application, (vi) the Company and Pharma are in substantial compliance with all applicable registration and listing requirements set forth in 21 U.S.C. Section 360 and 21 C.F.R. Part 207 and, to the extent required, the Company or Pharma has obtained all material licenses from the DEA and is in substantial compliance with all such licenses and all applicable regulations promulgated by the DEA, (vii) to the Knowledge of the Company, all manufacturing operations conducted for the benefit of the Company or Pharma have been and are being conducted in substantial compliance with applicable current good manufacturing practice regulations, including those set forth in 21 C.F.R. Parts 210 and 211, (viii) neither the Company nor Pharma has received any written notice that the FDA, the DEA or other regulatory agencies have commenced, or threatened to initiate, any action to withdraw its approval or request the recall of any product of the Company or Pharma or withdrawn advertising or sales promotion materials or commenced, or threatened to initiate, any action to enjoin production at any facility at which any product of the Company or Pharma is manufactured, (ix) as to each article of drug or consumer product currently manufactured and/or distributed by or on behalf of the Company or Pharma, such article is not adulterated or misbranded within the meaning of the FDCA, 21 U.S.C. Section 301 *et seq.*, and all advertising and sales promotional materials of the Company or Pharma are otherwise in conformance with applicable regulations and FDA policies and guidelines, and (x) neither the Company nor Pharma nor, to the Knowledge of the Company, any of their respective officers, employees, agents, Affiliates, consultants or contractors has been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Section 335(a) or authorized by 21 U.S.C. Section 335a(b). To the Knowledge of the Company, the Company's and Pharma's contractors are in substantial compliance with all applicable laws and regulations and have secured all material licenses, renewals and quotas from the FDA and the DEA necessary to their operations.

(c) The Company has made available to Purchaser prior to the execution of the Original Agreement copies of all written communications to or from the FDA and the DEA, minutes of meetings and records of telephone and email contact relating specifically to the Company or Pharma or any of their products.

(d) To the Knowledge of the Company, the Merger and the transactions contemplated thereby will not limit in any significant manner any of the Company's or Pharma's regulatory rights or approvals.

3.24 Products.

(a) Each of the products sold by the Company or Pharma: (i) is, and at all times up to and including the date of the Original Agreement has been, in compliance in all material respects with all applicable federal, state and local Laws; (ii) is, and at all relevant times has been, fit for the ordinary purposes for which it is intended to be used and conforms to any promises, representations, claims or affirmations of fact made on the container or label, made in promotional materials or contained on a website for such product or, to the Knowledge of the

Company, otherwise in connection with its sale; and (iii) contains no material design or manufacturing defect.

(b) Neither the Company nor Pharma is aware of any facts which could reasonably be expected to cause (i) the withdrawal or recall of any product sold or intended to be sold by the Company or Pharma, (ii) a change in the marketing classification, labeling or promotional materials of any such product, (iii) a termination or suspension of marketing of any such product or (iv) any adverse events or safety concerns not already disclosed that could have an impact on the ability to market any such product. There are no claims pending nor, to the Knowledge of the Company, threatened against the Company or Pharma with respect to the quality of or absence of defects in such products, nor to the Knowledge of the Company are there any facts relating to the quality of or absence of defects in such products which, if known by a potential claimant or Governmental or Regulatory Authority, could reasonably be expected to give rise to a claim or proceeding. To the Knowledge of the Company, no supplier of a raw material or active ingredient required for the manufacture of a product of the Company or Pharma for which there is not a permissible replacement obtainable under commercially reasonable terms, including timing of such replacement to ensure uninterrupted supply of finished product, has indicated that it will not continue to supply such raw material on terms consistent with those on the date of the Original Agreement.

(c) To the Knowledge of the Company, its foreign marketing partners for Busulfex, Pierre Fabre in Europe and Kirin Pharmaceuticals in Japan, have secured all permits, approvals or licenses to market such products in the territories in which each currently markets such products, and are in compliance with all applicable laws, regulations and requirements with respect to the marketing of the product.

(d) For the period commencing on the Closing Date and ending on the first anniversary of the Closing Date (the "*Return Target Period*"), the aggregate actual (i) returns under the Company Returns Policy in effect as of the date of the Original Agreement, (ii) rebates, (iii) Medicaid reimbursements or refunds, and (iv) federal medicare reimbursements or refunds (collectively, the "*Returns*") with respect to products sold by the Company or Pharma prior to the Closing Date ("*Total Returns*") will not exceed nine percent (9%) (the "*Return Target*") of gross sales generated by the Company and Pharma during the one year period prior to the Closing Date ("*Gross Sales*"). For purposes of calculating Total Returns, Purchaser will apply the same policies as the Company's policies with respect to Returns and will apply such policies (for this purpose) in good faith and in a manner consistent with the manner in which the Company administered such policies immediately prior to the Closing, including without limitation, by not encouraging, or by taking actions that could reasonably be expected to encourage, Returns. Gross Sales shall not include any sales of Retavase, if such product is acquired prior to the Closing Date. Total Returns shall not include any returns of Retavase, if such product is acquired prior to the Closing Date.

(e) Section 3.24 of the Company Disclosure Schedule sets forth (i) a summary dated January 4, 2005 of inventory levels for the top four (4) wholesalers of the Company and Pharma, as previously furnished to Purchaser and (ii) a summary of the physical inventory conducted as of January 14, 2005 of the Company's inventory at ICS.

3.25 *Marketing Practices.* The Company's operations and commercial products and those of Pharma have at all times conformed in all material respects to the Code of Marketing Practices of the Pharmaceutical Research and Manufacturing Association (PhRMA).

3.26 *Affiliate Transactions.* Except as disclosed in Section 3.26 of the Company Disclosure Schedule, (a) there is no Indebtedness between the Company or Pharma, on the one hand, and any stockholder of the Company or any Affiliate thereof (other than the Company or Pharma), on the other, (b) none of such stockholders or Affiliates provides or causes to be provided any assets, services or facilities to the Company or Pharma pursuant to any Contract which are individually or in the aggregate material to the Business or Condition of the Company, and (c) neither the Company nor Pharma provides or causes to be provided any assets, services or facilities to any such stockholders or Affiliates which are individually or in the aggregate material to the Business or Condition of the Company. Except as disclosed Section 3.26 of in the Company Disclosure Schedule, each of the Liabilities and transactions listed in the Company Disclosure Schedule in respect of this Section was incurred or engaged in, as the case may be, on an arm's-length basis. Section 3.26 of the Company Disclosure Schedule lists all transactions that would be required to be disclosed under paragraphs (a),(b) or (c) of Item 404 of Regulation S-K promulgated by the SEC if the Company were required to comply with such disclosure requirement.

3.27 *Brokers.* Except for SG Cowen Securities Corporation and Citigroup Global Markets, Inc., whose fees, commissions and expenses are the sole responsibility of the Company, all negotiations relative to this Agreement and the transactions contemplated hereby have been carried out by or on behalf of the Company and the Contributing Stockholders directly with Purchaser without the intervention of any Person in such manner as to give rise to any valid claim by any Person against Purchaser, the Company or Pharma for a finder's fee, brokerage commission or similar payment as a result of actions taken by or on behalf of the Company or any Contributing Stockholder.

3.28 *Retavase® Acquisition.* The Company and Pharma has provided to Purchaser any material information in their possession regarding their proposed acquisition of the Retavase® Assets.

3.29 *Net Debt.* As of the Closing Date, the aggregate amount of the Credit Agreement Payments less the amount of cash on the balance sheet of the Company ("Closing Net Debt") shall not exceed \$14,000,000.

3.30 *Government Contracts.*

(a) The Company has not, in obtaining or performing any Contract with any Governmental or Regulatory Authority, violated (i) the Truth in Negotiations Act of 1962, as amended, (ii) the Service Contract Act of 1963, as amended, (iii) the Contract Disputes Act of 1978, as amended, (iv) the Office of Federal Procurement Policy Act, as amended, (v) the Federal Acquisition Regulations or any applicable agency supplement thereto, (vi) the Cost Accounting Standards, (vii) the Defense Industrial Security Manual (DOD 5220.22-M), or (viii) the Defense Industrial Security Regulation (DOD 5220.22-R) or any related security regulations.

(b) Neither the Company nor any of its employees (during their employment with the Company) has been debarred or suspended from doing business with any Governmental or Regulatory Authority, and, to the Knowledge of the Company, no circumstances exist that could reasonably be expected to warrant the debarment or suspension of the Company or any such employee of the Company.

(c) To the Knowledge of the Company, there are not and have not been any irregularities, misstatements or omissions relating to any Contract with any Governmental or Regulatory Authority or bid to obtain business with any Governmental or Regulatory Authority that have led to or could reasonably be expected to lead to (i) a finding of defective pricing, or (ii) the disallowance of any costs submitted for payment by the Company.

(d) The Company has not undergone any audit, and to the Knowledge of the Company, there is no basis for any impending audit, arising under or relating to any Contract with any

Governmental or Regulatory Authority (other than normal routine audits conducted in the ordinary course of business).

ARTICLE IV REPRESENTATIONS AND WARRANTIES OF PURCHASER AND MERGER SUB

Purchaser and Merger Sub hereby represent and warrant to the Company and the Contributing Stockholder as follows:

4.01 *Corporate Existence.* Purchaser is a corporation validly existing and in good standing under the Laws of the State of Delaware and Merger Sub is a corporation validly existing and in good standing under the Laws of the State of Delaware. Purchaser and Merger Sub each has full corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby.

4.02 *Authority.* The execution and delivery by Purchaser and Merger Sub of this Agreement, and the performance by each of its obligations hereunder, have been duly and validly authorized by the Board of Directors of Purchaser and Merger Sub and by Purchase as the sole stockholder of Merger Sub, no other corporate action on the part of Purchaser or Merger Sub or their respective stockholders being necessary. This Agreement has been duly and validly executed and delivered by Purchaser and Merger Sub and constitutes a legal, valid and binding obligation of Purchaser and Merger Sub enforceable against Purchaser and Merger Sub in accordance with its terms.

4.03 *No Conflicts.* The execution and delivery by Purchaser and Merger Sub of this Agreement do not, and the performance by Purchaser and Merger Sub of their obligations under this Agreement and the consummation of the transactions contemplated hereby will not:

(a) conflict with or result in a violation or breach of any of the terms, conditions or provisions of the corporate organizational documents of Purchaser or Merger Sub;

(b) conflict with or result in a violation or breach of any term or provision of any Law or Order applicable to Purchaser or Merger Sub or any of their respective Assets and Properties; or

(c) (i) conflict with or result in a violation or breach of, (ii) constitute (with or without notice or lapse of time or both) a default under, (iii) require Purchaser or Merger Sub to obtain any consent, approval or action of, make any filing with or give any notice to any Person as a result or under the terms of, (iv) result in or give to any Person any right of termination, cancellation, acceleration or modification in or with respect to, or (v) result in the creation or imposition of any Lien upon Purchaser or Merger Sub or any of their respective Assets or Properties under, any Contract or License to which Purchaser or Merger Sub is a party or by which any of their respective Assets and Properties is bound.

4.04 *Governmental Approvals and Filings.* Except for the filing of the Certificate of Merger with the Secretary of State and a premerger notification report by Purchaser under the HSR Act, no consent, approval or action of, filing with or notice to any Governmental or Regulatory Authority on the part of Purchaser or Merger Sub is required in connection with the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby.

4.05 *Legal Proceedings.* There are no Actions or Proceedings pending or, to the knowledge of Purchaser, threatened against, relating to or affecting Purchaser or any of its subsidiaries or any of their respective Assets and Properties as of the date of the Original Agreement which, individually or in the aggregate, could reasonably be expected to (a) result in the issuance of an Order restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement or (b) have a material adverse effect on Purchaser and its subsidiaries taken as a whole.

4.06 *Capital Stock.* The authorized capital stock of Purchaser consists solely of 260,000,000 shares of Purchaser Common Stock and 10,000,000 shares of preferred stock, par value \$0.01 per share ("*Purchaser Preferred Stock*"). As of January 18, 2005, 95,935,314 shares of Purchaser Common Stock were issued and outstanding and no shares were held in the treasury of Purchaser. As of the date of the Original Agreement, no shares of Purchaser Preferred Stock are issued and outstanding. All of the issued and outstanding shares of Purchaser Common Stock are, and the shares of Purchaser Common Stock issuable in the Merger will be, upon issuance in accordance with the terms specified in this Agreement, duly authorized, validly issued, fully paid and nonassessable. As of January 18, 2005, there were outstanding Options obligating Purchaser to issue 27,774,536 shares of Purchaser Common Stock, excluding shares issuable under the Company's 1993 Employee Stock Purchase Plan, as amended, under which 814,806 shares were reserved and available for issuance as of January 18, 2005.

4.07 *SEC Reports and Financial Statements.* Each form, report, schedule, registration statement, definitive proxy statement and other document (together with all amendments thereof and supplements thereto) filed by Purchaser or any of its subsidiaries with the SEC since December 31, 2001 (as such documents have since the time of their filing been amended or supplemented, the "*Purchaser SEC Reports*"), which are all the documents (other than preliminary material) that Purchaser and its subsidiaries were required to file with the SEC since such date, (i) complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as the case may be, and (ii) did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The audited consolidated financial statements and unaudited interim consolidated financial statements (including, in each case, the notes, if any, thereto) included in the Purchaser SEC Reports (the "*Purchaser Financial Statements*") complied as to form in all material respects with the published rules and regulations of the SEC with respect thereto, were prepared in accordance with GAAP applied on a consistent basis during the periods involved (except as may be indicated therein or in the notes thereto and except with respect to unaudited statements as permitted by Form 10-Q of the SEC) and fairly present (subject, in the case of the unaudited interim financial statements, to normal, recurring year-end audit adjustments (which are not expected to be, individually or in the aggregate, materially adverse to Purchaser and its subsidiaries taken as a whole)) in all material respects the consolidated financial position of Purchaser and its consolidated subsidiaries as at the respective dates thereof and the consolidated results of their operations and cash flows for the respective periods then ended.

4.08 *Absence of Certain Changes or Events.* Except as disclosed in the Purchaser SEC Reports filed prior to the date of the Original Agreement, since September 30, 2004 there has not been any change, event or development having, or that could be reasonably expected to have, individually or in the aggregate, a material adverse effect on Purchaser and its subsidiaries taken as a whole.

4.09 *Absence of Undisclosed Liabilities.* Except for matters reflected or reserved against in the balance sheet for the period ended September 30, 2004 included in the Purchaser Financial Statements, neither Purchaser nor any of its subsidiaries had at such date, or has incurred since that date, any Liabilities or obligations (whether absolute, accrued, contingent, fixed or otherwise, or whether due or to become due) of any nature that would be required by GAAP to be reflected on a consolidated balance sheet of Purchaser and its consolidated subsidiaries (including the notes thereto), except Liabilities or obligations (i) which were incurred in the ordinary course of business consistent with past practice or (ii) which have not been, and could not be reasonably expected to be, individually or in the aggregate, materially adverse to Purchaser and its subsidiaries taken as a whole.

4.10 *Internal Controls.* Purchaser and its subsidiaries have designed and maintain a system of internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) sufficient to provide reasonable assurances regarding the reliability of Purchaser's financial reporting. Purchaser (a) has, based on its most recent evaluation of such disclosure controls and

procedures prior to the date of the Original Agreement, designed and maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) to ensure that material information required to be disclosed by Purchaser in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to Purchaser's management as appropriate to allow timely decisions regarding required disclosure and (b) has disclosed to Purchaser's auditors and the audit committee of Purchaser's board of directors (i) any significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting that are reasonably likely to adversely affect in any material respect Purchaser's ability to record, process, summarize and report financial information and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in Purchaser's internal controls over financial reporting.

4.11 *State Takeover Laws.* Purchaser's board of directors has approved this Agreement and the transactions contemplated hereby as required to render inapplicable to this Agreement and such transactions any "takeover" or "interested stockholder" law applicable to the transactions contemplated by this Agreement.

4.12 *Acquisition for Investment; Receipt of Information.* The Shares are being acquired in the Merger for the account of Purchaser and Merger Sub for the purpose of investment and without a view to the sale or distribution thereof in violation of the Securities Act or applicable state securities or blue sky Laws. Each of Purchaser and Merger Sub is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act.

4.13 *Financing.* Purchaser has sufficient cash and/or available credit facilities to make all cash payments contemplated by *Section 2.01(c)* and *Section 2.02(b)* and to make all other necessary payments of fees and expenses in connection with the transactions contemplated by this Agreement.

4.14 *Merger Sub.* Merger Sub has not conducted any activities other than in connection with its organization, the negotiation and execution of this Agreement and the consummation of the transactions contemplated hereby. Merger Sub does not have any subsidiaries.

4.15 *Brokers.* Except for Lazard Frères & Co., LLC, whose fees, commissions and expenses are the sole responsibility of Purchaser, all negotiations relative to this Agreement and the transactions contemplated hereby have been carried out by or on behalf of Purchaser and Merger Sub directly with the Company and the Contributing Stockholders without the intervention of any Person in such manner as to give rise to any valid claim by any Person against any of the Contributing Stockholders, the Company or Pharma for a finder's fee, brokerage commission or similar payment as a result of any action taken by or on behalf of Purchaser or Merger Sub.

ARTICLE V COVENANTS OF THE COMPANY

The Company covenants and agrees with Purchaser that, at all times from and after the date of the Original Agreement until the Closing, the Company will comply with all covenants and provisions of this *Article V*, except to the extent Purchaser may otherwise consent in writing, which consent shall not be unreasonably withheld or delayed.

5.01 *Regulatory and Other Approvals.* The Company will as promptly as practicable (a) take all commercially reasonable steps necessary or desirable to obtain all consents, approvals or actions of, make all filings with and give all notices to Governmental or Regulatory Authorities or any other Person required of the Company or Pharma to consummate the transactions contemplated hereby, including without limitation those described in the Company Disclosure Schedule, (b) provide such other information and communications to such Governmental or Regulatory Authorities or other

Persons as such Governmental or Regulatory Authorities or other Persons may reasonably request in connection therewith and (c) provide reasonable cooperation to Purchaser in connection with the performance of its obligations under *Sections 6.01* and *6.02*. The Company will provide prompt notification to Purchaser when any such consent, approval, action, filing or notice referred to in clause (a) above is obtained, taken, made or given, as applicable, and will advise Purchaser of any communications (and, unless precluded by Law, provide copies of any such communications that are in writing) with any Governmental or Regulatory Authority or other Person regarding any of the transactions contemplated by this Agreement.

5.02 HSR Filings. In addition to and not in limitation of the Company's covenants contained in *Section 5.01*, the Company will (a) take promptly all actions necessary to make the filings required of the Company under the HSR Act, (b) comply at the earliest practicable date with any request for additional information received by the Company or its Affiliates from the Federal Trade Commission or the Antitrust Division of the DOJ pursuant to the HSR Act and (c) cooperate with Purchaser in connection with Purchaser's filing under the HSR Act and in connection with resolving any investigation or other inquiry concerning the transactions contemplated by this Agreement commenced by either the FTC or the Antitrust Division of the DOJ or state attorneys general.

5.03 Investigation by Purchaser. The Company will (a) provide Purchaser and its officers, employees and Representatives with full access, upon reasonable prior notice and during normal business hours, to all officers, employees, agents and accountants of the Company and Pharma and their Assets and Properties and Books and Records, but only to the extent that such access does not unreasonably interfere with the business and operations of the Company and Pharma, and (b) furnish Purchaser with all such information and data (including without limitation copies of Contracts, Benefit Plans and other Books and Records) concerning the business and operations of the Company and Pharma as Purchaser reasonably may request in connection with such investigation, except to the extent that furnishing any such information or data would violate any Law, Order, Contract or License applicable to the Company or Pharma or by which any of their respective Assets and Properties is bound. No information or knowledge obtained in any investigation pursuant to this *Section 5.03* or otherwise shall affect or be deemed to modify any representation or warranty contained herein or the conditions to the obligations of the parties to consummate the Merger.

5.04 No Solicitations. The Company will not take, nor permit any of its Affiliates (or authorize or permit any Representative) to take, directly or indirectly, any action to solicit, encourage, receive, negotiate, assist or otherwise facilitate (including by furnishing confidential information with respect to the Company or Pharma or permitting access to the Assets and Properties and Books and Records of the Company or Pharma) any offer or inquiry from any Person concerning an Acquisition Proposal.

5.05 Conduct of Business. The Company and Pharma will conduct business only in the ordinary course. Without limiting the generality of the foregoing, the Company and Pharma will use commercially reasonable efforts, to the extent the officers of the Company believe such action to be in best interests of the Company and Pharma, to (a) preserve intact the present business organization and reputation of the Company and Pharma in all material respects, (b) keep available (subject to dismissals and retirements in the ordinary course of business) the services of the key officers and employees of the Company and Pharma, (c) maintain the Assets and Properties of the Company and Pharma in working order and condition consistent with past custom and practice, ordinary wear and tear excepted, and (d) maintain the good will of key customers, suppliers and lenders and other Persons with whom the Company or Pharma otherwise has significant business relationships.

5.06 Financial Statements and Reports. (a) As promptly as practicable after the date of the Original Agreement, the Company will deliver to Purchaser true and complete copies of the audited consolidated balance sheet, and the related audited consolidated statements of operations, stockholders' equity and cash flows, of the Company and its consolidated Subsidiaries as of and for the year ended

(b) As promptly as practicable, the Company will deliver to Purchaser true and complete copies of such other regularly-prepared financial statements as may be prepared by the Company or Pharma consistent with prior custom and practice.

5.07 *Certain Restrictions.* The Company and Pharma will refrain from:

(a) amending their organizational documents or taking any action with respect to any such amendment or any recapitalization, reorganization, liquidation or dissolution of any such corporation;

(b) authorizing, issuing, selling or otherwise disposing of any shares of capital stock of, or any Option with respect to, the Company or Pharma (other than the issuance of shares upon the exercise of Company Options outstanding as of the date of the Original Agreement, or as otherwise approved by Purchaser, such consent not to be unreasonably withheld or delayed), or modifying or amending any right of any holder of outstanding shares of capital stock of, or any Option with respect to, the Company or Pharma;

(c) (i) declaring, setting aside or paying any dividend or other distribution in respect of, the capital stock of the Company or Pharma (other than the accrual of dividends in respect of the Series A Stock and the Series B Stock in accordance with their terms) or (ii) directly or indirectly redeeming, purchasing or otherwise acquiring any capital stock of, or any Option with respect to, the Company or Pharma, except as may be required pursuant to the terms of any Contract with any employee of the Company or Pharma;

(d) acquiring or disposing of, or incurring any Lien (other than a Permitted Lien) on, any Assets and Properties individually or in the aggregate material to the Business or Condition of the Company;

(e) entering into, amending, modifying, terminating (partially or completely), granting any waiver under or giving any consent with respect to any Contract or License material to the Business or Condition of the Company;

(f) (i) voluntarily incurring Indebtedness (other than pursuant to the Credit Agreement as in effect on the date of the Original Agreement) in an aggregate principal amount exceeding \$10,000 (net of any amounts of Indebtedness discharged during such period), or (ii) purchasing, canceling, prepaying or otherwise providing for a complete or partial discharge in advance of a scheduled payment date with respect to, or waiving any right under, any Indebtedness other than repayments (including by reason of mandatory prepayments) of amounts borrowed under the revolving credit facility provided under the Credit Agreement (in either case other than intracompany Indebtedness between the Company and Pharma);

(g) engaging with any Person in any merger or other business combination;

(h) making capital expenditures or commitments for additions to property, plant or equipment constituting capital assets in an aggregate amount exceeding \$10,000, except as may be required by Law;

(i) except to the extent required by applicable Law, GAAP or reasonably and in good faith believed by the officers of the Company to be in the best interests of the Company and Pharma, making any material change in (A) any investment, accounting, financial reporting, inventory, credit, allowance or Tax practice or policy, or (B) any method of calculating any bad debt, contingency or other reserve for accounting, financial reporting or Tax purposes;

(j) making any change in its fiscal year;

(k) agreeing or consenting to any material agreements or modifications of material existing agreements with any Government or Regulatory Authority in respect of the operation of the business of the Company or Pharma, except where following discussion with the relevant authority such agreements or modifications are imposed upon the Company or Pharma;

(l) making any further sale or distribution of Declomycin without the prior approval of Purchaser, which approval shall not be unreasonably withheld or delayed; or

(m) entering into any Contract, including without limitation, the Retavase® Purchase Agreement, to do or engage in any of the foregoing.

5.08 *Employee Matters.* Except as may be required by Law, the Company and Pharma will refrain from:

(a) making any increase in the salary, wages or other compensation of any officer or employee of the Company or Pharma; *provided* that nothing contained herein shall prohibit the Company or Pharma from granting such increases to employees who are not officers of the Company or Pharma which are consistent with the prior practice and policy of the Company and Pharma;

(b) adopting, entering into or becoming bound by any Benefit Plan, employment-related Contract or collective bargaining agreement, or amending, modifying or terminating (partially or completely) any Company Plan, employment-related Contract or collective bargaining agreement; or

(c) establishing or modifying any (i) targets, goals, pools or similar provisions in respect of any fiscal year under any Company Plan, employment-related Contract or other employee compensation arrangement or (ii) salary ranges, increase guidelines or similar provisions in respect of any Company Plan, employment-related Contract or other employee compensation arrangement, except for published salary information.

The Company and Pharma will administer each Company Plan, or cause the same to be so administered, in all material respects in accordance with the applicable provisions of the Code, ERISA and all other applicable Laws. The Company will promptly notify Purchaser in writing of any receipt by the Company or Pharma (and furnish Purchaser with copies) of any notice of investigation or administrative proceeding by the IRS, Department of Labor, PBGC or other Person involving any Company Plan.

5.09 *Delivery of Certificates.* Prior to the Closing, the Company shall use its reasonable best efforts to cause owners of Shares who are not Contributing Stockholders to deliver Certificates representing such Shares to the Stockholders' Agent for delivery at the Closing as contemplated by *Section 2.01(d)*.

5.10 *Supplemental Disclosure.* The Company shall have the right from time to time prior to the Closing to supplement or amend the Company Disclosure Schedule with respect to any matter hereafter arising or discovered which, if existing or known at the date of the Original Agreement, would have been required to be set forth or described in the Company Disclosure Schedule; *provided* that no such supplemental or amended disclosure shall be deemed to cure any breach of any representation or warranty made in this Agreement for purposes of determining whether or not the condition set forth in *Section 7.01* has been satisfied.

5.11 *Stockholder Approval.* As soon as practicable following the date of the Original Agreement, the Company will use its commercially reasonable efforts to subject a sufficient amount of compensation payments tentatively payable to "disqualified individuals" (as defined in Code Section 280G (c)) to a stockholder vote, in accordance with and subject to Code Section 280G(b)(5)(A)(ii) and (B) and the regulations promulgated thereunder, such that, after such

vote is conducted, no compensation payment received by any "disqualified individual" (as defined in Code Section 280G(c)) under any Contracts to which the Company or Pharma is a party, separately or in the aggregate, will be treated as a "parachute payment" (as defined in Code Section 280G(b)(2)(A)) as a result of the consummation of the transactions contemplated hereby (the "280G Approvals").

5.12 *Fulfillment of Conditions.* The Company will take all commercially reasonable steps necessary or desirable and proceed diligently and in good faith to satisfy each condition to the obligations of Purchaser contained in this Agreement and will not take or fail to take any action that could reasonably be expected to result in the nonfulfillment of any such condition.

5.13 *Covenant Regarding Retavase® Purchase Agreement.* The Company and Pharma will use their reasonable good faith efforts necessary to consummate the transactions contemplated by the Retavase® Purchase Agreement; *provided* that any changes or modifications to the Retavase® Purchase Agreement must be approved in advance by Purchaser, such approval not to be unreasonably withheld or delayed.

ARTICLE VI COVENANTS OF PURCHASER

6.01 *Regulatory and Other Approvals.* Purchaser will as promptly as practicable (a) take all commercially reasonable steps necessary or desirable to obtain all consents, approvals or actions of, make all filings with and give all notices to Governmental or Regulatory Authorities or any other Person required of Purchaser to consummate the transactions contemplated hereby, (b) provide such other information and communications to such Governmental or Regulatory Authorities or other Persons as such Governmental or Regulatory Authorities or other Persons may reasonably request in connection therewith and (c) provide reasonable cooperation to the Company and Pharma in connection with the performance of their obligations under Sections 5.01 and 5.02. Purchaser will provide prompt notification to the Company when any such consent, approval, action, filing or notice referred to in clause (a) above is obtained, taken, made or given, as applicable, and will advise the Company of any communications (and, unless precluded by Law, provide copies of any such communications that are in writing) with any Governmental or Regulatory Authority or other Person regarding any of the transactions contemplated by this Agreement.

6.02 *HSR Filings.* In addition to and without limiting Purchaser's covenants contained in Section 6.01, Purchaser will (a) take promptly all actions necessary to make the filings required of Purchaser or its Affiliates under the HSR Act, (b) comply at the earliest practicable date with any request for additional information received by Purchaser or its Affiliates from the Federal Trade Commission or the Antitrust Division of the DOJ pursuant to the HSR Act and (c) cooperate with the Company in connection with the Company's filing under the HSR Act and in connection with resolving any investigation or other inquiry concerning the transactions contemplated by this Agreement commenced by either the FTC or the Antitrust Division of the DOJ or state attorneys general.

6.03 *Employee Matters.*

(a) During the period from the Closing Date until the end of the first anniversary of the Closing Date, the aggregate target cash compensation of each of each of the individuals referenced in Section 7.10 who accepts an offer of employment from Purchaser shall be at least equal to such individual's targeted cash compensation on the date of the Original Agreement (for this purpose, target compensation payable by Purchaser includes salary and all targeted bonuses including retention bonuses and existing target compensation at the Company means 2005 salary and actual 2004 performance bonus paid), *provided* that with respect to all individuals who receive incentive sales based compensation: (i) base compensation shall be at least equal to base compensation as of the date of the Original Agreement, and (ii) the Company's 2005 sales incentive compensation program will be maintained (with such modifications as may be made to include additional

products within such sales incentive structure). In addition, all individuals who accept an offer of employment with Purchaser will be eligible to participate in Purchaser's retention program as summarized in the side letter referenced in *Section 7.10*.

(b) This Section is not intended to be a benefit enforceable by any one individual employee, and, subject to the terms of any Contracts with employees or former employees disclosed in the Company Disclosure Schedule or entered into pursuant to the terms of this Agreement, individual salaries may be increased or decreased and no covenant is hereby made with respect to continued employment for any period. After the Closing Date, except as otherwise expressly provided in this Agreement or in a Contract to which such employee or former employee of the Company or Pharma is a party, all the former employees of the Company and Pharma who become employees of Purchaser or any of its Affiliates shall participate in the employee pension, health and welfare plans sponsored by Purchaser to the same extent as similarly situated Purchaser employees participate.

(c) Purchaser agrees to accept rollovers from participants in the Company's 401(k) Plan in the form of promissory notes.

6.04 *Severance Policy and Other Agreements.*

(a) Purchaser shall maintain or cause to be maintained in effect the severance policy of the Company and Pharma as disclosed to Purchaser for a period of six (6) months from the Effective Time with respect to employees of the Company or Pharma who become employees of Purchaser and its Affiliates immediately following the Effective Time.

(b) Following the Closing, Purchaser shall honor or cause its Affiliates to honor all severance agreements and employment Contracts with the directors, officers and employees of the Company and Pharma as disclosed in the Company Disclosure Schedule and as in effect immediately prior to the Closing Date.

6.05 *Prior Service.* Following the Closing, Purchaser will, and it will cause its Affiliates to, (a) waive all limitations as to preexisting conditions, exclusions and waiting periods with respect to participation and coverage requirements applicable to the individuals who at the Closing Date were employed by the Company or Pharma and who continue to be employed by Purchaser or any of its Affiliates after the Closing, under any pension, health or welfare plan of Purchaser or any of its Affiliates in which such employees are eligible to participate after the Closing, (b) provide each such employee with credit for any co-payments and deductibles paid prior to the Closing in satisfying any applicable deductible or out-of-pocket requirements under any pension, health or welfare plans of Purchaser or any of its Affiliates in which such employee is eligible to participate after the Closing to the extent such deductible or out-of-pocket requirements were incurred in the calendar year or plan year in which such employee becomes eligible to participate in the pension, health or welfare plans maintained by Purchaser or any of its Affiliates, and (c) provide each such employee with credit for all service with the Company and Pharma under each pension, health or welfare plan of Purchaser and its Affiliates in which such employee is eligible to participate after the Closing for vesting, eligibility and benefit and contribution calculation purposes; *provided, however*, that in no event shall such employees be entitled to any credit to the extent that it would result in a duplication of benefits with respect to the same period of service.

6.06 *Directors' and Officers' Indemnification and Insurance.*

(a) From and after the Closing and until the sixth anniversary thereof and for so long thereafter as any claim for indemnification asserted on or prior to such date has not been fully adjudicated, Purchaser shall, and shall cause the Company and Pharma to, indemnify, defend and hold harmless each Person who is now, or has been at any time prior to the date of the Original Agreement or who becomes prior to the Closing, a director or officer of the Company or Pharma

(the "*Indemnified Agents*") against (i) all losses, claims, damages, costs and expenses (including reasonable attorneys' fees), Liabilities, judgments and settlement amounts that are paid or incurred in connection with any claim, action, suit, proceeding or investigation (whether civil, criminal, administrative or investigative and whether asserted or claimed prior to or after the Closing) that is based on, or arises out of, the fact that such Indemnified Agent is or was a director or officer of the Company or Pharma and relates to or arises out of any action or omission occurring at or prior to the Closing ("*Indemnified Liabilities*"), and (ii) all Indemnified Liabilities based on, or arising out of, or pertaining to this Agreement or the transactions contemplated hereby, in each case to the full extent a corporation is permitted under the DGCL to indemnify its own directors or officers, as the case may be; *provided* that the Purchaser shall not be liable for any settlement of any claim effected without its written consent; and *provided, further*, that the Purchaser shall not be liable for any Indemnified Liabilities which occur as a result of the gross negligence or willful misconduct of any Indemnified Agent. Any Indemnified Agent wishing to claim indemnification under this Section, upon learning of any such claim, action, suit, proceeding or investigation, shall notify the Purchaser, but the failure so to notify the Purchaser shall not relieve the Purchaser from any liability which it may have under this paragraph except to the extent such failure prejudices the Purchaser. The Indemnified Agents as a group may retain only one law firm to represent them with respect to each such matter unless there is, under applicable standards of professional conduct, a conflict on any significant issue between the positions of any two or more Indemnified Agents, in which case the Indemnified Agents may retain more than one law firm.

(b) Except to the extent required by Law, until the sixth anniversary of the Closing, Purchaser will not take any action so as to amend, modify or repeal the provisions for indemnification of directors, officers or employees contained in the organizational documents of the Company or Pharma (which as of the Closing shall be no more favorable to such individuals than those maintained by the Company and Pharma on the date of the Original Agreement) in such a manner as would adversely affect the rights of any individual who shall have served as a director, officer or employee of the Company or Pharma prior to the Closing to be indemnified by such corporations in respect of their serving in such capacities at or prior to the Closing.

(c) Purchaser shall, until the sixth anniversary of the Closing and for so long thereafter as any claim for insurance coverage asserted on or prior to such date has not been fully adjudicated, cause to be maintained in effect, to the extent available, the policies of directors' and officers' liability insurance maintained by the Company and Pharma as of the Closing, or policies of at least the same coverage and amounts containing terms that are no less advantageous to the insured parties, with respect to claims arising from facts or events that occurred on or prior to the Closing; *provided* that in no event shall Purchaser be obligated to expend in order to maintain or procure insurance coverage pursuant to this paragraph any amount per annum in excess of two hundred percent (200%) of the aggregate premiums payable by the Company and Pharma in the current policy year (on an annualized basis) allocable to the directors' and officers' liability insurance portion of such policies for such purpose, but in such case the Purchaser shall purchase as much coverage as reasonably practicable for such maximum amount.

(d) The provisions of this *Section 6.06* are intended to be for the benefit of, and shall be enforceable by, each Indemnified Agent, his or her heirs and his or her legal representatives and are in addition to any other rights to indemnification that such Person may have by Contract or otherwise.

6.07 Company 401(k) Plan. Unless Purchaser and the Company agree otherwise in writing, the board of directors of the Company shall adopt resolutions terminating, effective at least two (2) days prior to the Closing Date, any Benefit Plan which is intended to meet the requirements of Section 401(k) of the Code (each such Benefit Plan, a "401(k) Plan"). At the Closing, the Company shall provide Purchaser (i) executed resolutions of the board of directors of the Company authorizing

such termination and (ii) if required, an executed amendment to each such 401(k) Plan intended to assure compliance with all applicable requirements of the Code and regulations thereunder.

6.08 *Listing of Stock.* Purchaser shall cause all shares of Purchaser Common Stock issuable in the Merger (including the Escrow Shares) to be listed prior to such issuance, subject only to official notice of issuance, on the principal national securities exchange on which such shares of Purchaser Common Stock are listed or traded.

6.09 *Registration of Shares.*

(a) Purchaser shall use its reasonable commercial efforts to cause the Registrable Securities to be registered under the Securities Act so as to permit the resale thereof under any available method (other than an underwritten offering), and in connection therewith shall use its commercially reasonable efforts to prepare and file a registration statement (the "*Registration Statement*") with the SEC with respect to the Registrable Securities as soon as practicable, and in any event within thirty (30) days after the date of the Original Agreement, and shall use its commercially reasonable efforts to cause the Registration Statement to become effective prior to the Effective Time, or if it is impracticable to do so using commercially reasonable efforts, then Purchaser shall continue to use such commercially reasonable efforts after the Effective Time until the Registration Statement is declared effective by the SEC; *provided, however*, that each Contributing Stockholder who will receive shares of Purchaser Common Stock in the Merger (each a "*Holder*" and, collectively, the "*Holders*") shall provide all such information and materials to Purchaser and take all such action as may be required in order to permit Purchaser to comply with all applicable requirements of the SEC and to obtain any desired acceleration of the effective date of such Registration Statement. Such provision of information and materials is a condition precedent to the obligations of Purchaser pursuant to this *Section 6.09*. In the event the Registration Statement is not declared effective on or before March 31, 2005, Purchaser shall pay to the Contributing Stockholders the amount of \$25,000.00, as liquidated damages and not as a penalty, for each Trading Day after March 31, 2005 that the Registration Statement is not declared effective by the SEC through and including the date on which the Registration Statement is declared effective by the SEC. The liquidated damages payable pursuant to the preceding sentence will become due and payable on the Business Day immediately following the date on which the Registration Statement is declared effective by the SEC and shall be payable by wire transfer of immediately available funds to the account designated by the Stockholders' Agent for the benefit of the Contributing Stockholders. Purchaser shall not be required to effect more than one (1) registration under this *Section 6.09*.

(b) Purchaser shall: (i) prepare and file with the SEC the Registration Statement in accordance with *Section 6.09(a)* with respect to the Registrable Securities (which one legal counsel acting for the Holders shall be given a reasonable opportunity to review and comment on (which comments shall be considered in good faith) prior to its filing) and shall use all commercially reasonable efforts to cause the Registration Statement to remain effective for a period ending on the date all of the Registrable Securities may be sold under Rule 144 in one three-month period (assuming compliance by the Holders with the provisions thereof); (ii) prepare and file with the SEC such amendments and supplements to the Registration Statement and the prospectus used in connection therewith as may be necessary, and comply with the provisions of the Securities Act with respect to the sale or other disposition of all Registrable Securities until the termination of effectiveness of the Registration Statement; (iii) for so long as Purchaser is required to cause the Registration Statement to remain effective, furnish to each Holder such number of copies of any prospectus (including any preliminary prospectus and any amended or supplemented prospectus) as required by the Securities Act, and such other documents as each Holder may reasonably request in order to effect the offering and sale of the Registrable Securities to be offered and sold; (iv) promptly notify Stockholders' Agent: when the Registration Statement or any prospectus used

in connection therewith, or any amendment or supplement thereto, has been filed and, with respect to the Registration Statement or any post-effective amendment thereto, when the same has become effective, of any written request by the SEC for amendments or supplements to the Registration Statement or prospectus, and of the notification to Purchaser by the SEC of its initiation of any proceeding with respect to the issuance, or of the issuance, by the SEC of any stop order suspending the effectiveness of the Registration Statement; (v) use its commercially reasonable efforts to register or qualify all Registrable Securities under such other securities or blue sky laws of such jurisdictions as Stockholders' Agent shall reasonably request, to keep such registration or qualification in effect for so long as the Registration Statement remain in effect, and take any other action which may be reasonably necessary or advisable to enable the Holders to consummate the disposition in such jurisdictions of their Registrable Securities, except that Purchaser shall not for any such purpose be required (x) to qualify generally to do business as a foreign corporation in any jurisdiction wherein it would not but for the requirements of this clause (v) be obligated to be so qualified, (y) to subject itself to taxation in any such jurisdiction or (z) to consent to general service of process in any such jurisdiction; (vi) notify Stockholders' Agent at any time when a prospectus relating to the Registration Statement is required to be delivered under the Securities Act, of the happening of any event as a result of which any prospectus included in the Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, and at the request of Stockholders' Agent promptly prepare and furnish to Stockholders' Agent a reasonable number of copies of a supplement to or an amendment of such prospectus as may be necessary so that, as thereafter delivered to the purchasers of such securities, such prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; and (vii) otherwise use its commercially reasonable efforts to comply with all applicable rules and regulations of the SEC.

(c) Notwithstanding any other provision of this *Section 6.09*, Purchaser shall have the right at any time to require that all Holders suspend open market offers and sales of Registrable Securities pursuant to the Registration Statement whenever, and for so long as, in the reasonable, good-faith judgment of Purchaser after consultation with counsel, there is in existence material undisclosed information or events with respect to Purchaser the disclosure of which at such time would be materially detrimental to Purchaser (the "*Suspension Right*"). In the event Purchaser exercises the Suspension Right, such suspension will continue for the period of time reasonably necessary for disclosure to occur at a time that is not materially detrimental to Purchaser or until such time as the information or event is no longer material, whichever is the first to occur, each as reasonably determined in good faith by Purchaser after consultation with counsel. Notwithstanding the foregoing, the periods during which Purchaser may exercise its Suspension Right shall be limited in the following manner: (i) Purchaser shall not exercise the Suspension Right during the forty-five (45) calendar days immediately following the date on which the Registration Statement is declared effective by the SEC, (ii) Purchaser shall not exercise a Suspension Right less than sixty (60) calendar days after termination of its most recent exercise of a Suspension Right and (iii) Purchaser shall not exercise its Suspension Right more than a total of four (4) times, two (2) times for a period not to exceed thirty (30) calendar days each and two (2) times for a period not to exceed fifteen (15) calendar days each. Purchaser will promptly give the Stockholders' Agent notice, in a writing signed by an executive officer of Purchaser, of any such suspension (the "*Suspension Notice*"). Purchaser shall notify the Stockholders' Agent promptly upon termination of the suspension (the "*Resumption Notice*"). Upon receipt of either a Suspension Notice or Resumption Notice, the Stockholders' Agent shall immediately notify each Holder concerning the status of the Registration Statement.

(d) Purchaser shall promptly pay (including upon presentation of invoices therefore submitted by or on behalf of any Holder) all Registration Expenses incurred in connection with any registration and sale of Registrable Securities pursuant to this *Section 6.09*.

(e) To the fullest extent permitted by Law, Purchaser will indemnify, defend, protect and hold harmless each selling Holder, each underwriter of Registrable Securities being sold pursuant to this *Section 6.09*, each Person, if any, who controls any such Holder or underwriter within the meaning of the Securities Act or the Exchange Act and their respective Affiliates, officers, directors, partners, successors and assigns (each a "*Holder Indemnitee*"), against all actions, claims, losses, damages, liabilities and expenses to which they or any of them become subject under the Securities Act, the Exchange Act or under any other statute or at common law or otherwise and, except as hereinafter provided, will promptly reimburse each Holder Indemnitee for any legal or other expenses reasonably incurred in connection with investigating or defending any actions, whether or not resulting in any liability, insofar as such actions, claims, losses, damages, liabilities and expenses arise out of or are based upon any untrue statement or alleged untrue statement of material fact in the Registration Statement and any related prospectus, or any post-effective amendment thereto or arise out of or are based upon any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, or any violation by Purchaser of any rule or regulation promulgated under the Securities Act, the Exchange Act or any Law applicable to Purchaser and relating to action or inaction required of Purchaser in connection with such registration; *provided, however*, that Purchaser shall not be liable to any such Holder Indemnitee in respect of any actions, claims, losses, damages, liabilities and expenses resulting from any untrue statement or alleged untrue statement, or omission or alleged omission, made in reliance upon and in conformity with information furnished in writing to Purchaser by such Holder Indemnitee specifically for use in connection with the Registration Statement and prospectus or post-effective amendment.

(f) To the fullest extent permitted by Law, each selling Holder of Registrable Securities will indemnify Purchaser, each Person, if any, who controls Purchaser within the meaning of the Securities Act or the Exchange Act, each underwriter of Registrable Securities and their respective Affiliates, officers, directors, partners, successors and assigns (each a "*Purchaser Indemnitee*") against any actions, claims, losses, damages, liabilities and expenses to which they or any of them may become subject under the Securities Act, the Exchange Act or under any other statute or at common law or otherwise, and, except as hereinafter provided, will promptly reimburse each Purchaser Indemnitee for any legal or other expenses reasonably incurred in connection with investigating or defending any actions, whether or not resulting in any liability, insofar as such actions, claims, losses, damages, liabilities and expenses arise out of or are based upon any untrue statement or alleged untrue statement of a material fact in the Registration Statement and any related prospectus or any post-effective amendment thereto, or any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, which untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with information furnished in writing to Purchaser by such Holder or underwriter specifically for use in connection with the Registration Statement, prospectus or post-effective amendment; *provided, however*, that the obligations of each such selling Holder hereunder shall be limited to an amount equal to the net proceeds to such Holder from the sale of such Holder's Registrable Securities.

(g) Each person entitled to indemnification under this *Section 6.09* (an "*Indemnified Person*") shall give notice to the party required to provide indemnification (the "*Indemnifying Person*") promptly after such Indemnified Person has actual knowledge of any claim as to which indemnity may be sought and shall permit the Indemnifying Person to assume the defense of any such claim and any litigation resulting therefrom; *provided, however*, that counsel for the Indemnifying Person

who conducts the defense of such claim or any litigation resulting therefrom shall be approved by the Indemnified Person (whose approval shall not unreasonably be withheld or delayed), and the Indemnified Person may participate in such defense at such party's expense (unless the Indemnified Person has reasonably concluded that there may be a conflict of interest between the Indemnifying Person and the Indemnified Person in such action, in which case the fees and expenses of counsel for the Indemnified Person shall be at the expense of the Indemnifying Person); and provided, further, that the failure of any Indemnified Person to give notice as provided herein shall not relieve the Indemnifying Person of its obligations under this *Section 6.09* except to the extent that the Indemnifying Person is materially prejudiced thereby. No Indemnifying Person, in the defense of any such claim or litigation, shall (except with the consent of each Indemnified Person) consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Person of a release from all liability in respect to such claim or litigation. Each Indemnified Person shall furnish such information regarding itself or the claim in question as an Indemnifying Person may reasonably request in writing and as shall be reasonably required in connection with the defense of such claim and litigation resulting therefrom.

(h) In order to provide for just and equitable contribution to joint liability under the Securities Act in any case in which indemnification pursuant to this *Section 6.09* is unavailable or insufficient to hold harmless an Indemnified Person in respect of obligations otherwise indemnifiable under this *Section 6.09*, Purchaser and such Holder shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of Purchaser on the one hand and the Holder on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations or, if the allocation provided herein is not permitted by applicable Law, in such proportion as shall be permitted by applicable Law to reflect as nearly as possible the allocation provided herein. The relative fault of Purchaser on the one hand and of any Holder on the other shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by Purchaser on the one hand or by such Holder on the other, and each party's relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; *provided, however*, that in any such case (i) no Holder will be required to contribute any amount in excess of the net proceeds received by such Holder from the sale of Registrable Securities pursuant to the Registration Statement; and (ii) no Person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

(i) In the event that the Registration Statement is for any reason not in effect during the period specified in *Section 6.09(b)*, Purchaser will file reports in compliance with the Exchange Act, will comply with all rules and regulations of the SEC applicable in connection with the use of Rule 144 and will take such other actions and furnish the Holders with such other information as legal counsel to the Holders may reasonably request to the extent necessary to permit the Holders to sell the Registrable Securities pursuant to Rule 144.

(j) Purchaser represents and warrants to the Holders that there is not in effect on the date of the Original Agreement any agreement by Purchaser pursuant to which any holders of securities of Purchaser have a right to cause Purchaser to register or qualify their securities under the Securities Act or any securities or blue sky laws of any jurisdiction that would conflict or be materially inconsistent with any provision of this *Section 6.09*. Purchaser shall not hereafter enter into any agreement with the holders of any securities issued or to be issued by Purchaser to register or qualify their securities under the Securities Act or any securities or blue sky laws of any

jurisdiction in a manner that would conflict or be inconsistent with any provision of this *Section 6.09*.

6.10 *Fulfillment of Conditions.* Purchaser will take all commercially reasonable steps necessary or desirable and proceed diligently and in good faith to satisfy each condition to the obligations of the Company contained in this Agreement and will not take or fail to take any action that could reasonably be expected to result in the nonfulfillment of any such condition.

ARTICLE VII CONDITIONS TO OBLIGATIONS OF PURCHASER AND MERGER SUB

The obligations of Purchaser and Merger Sub to consummate the transactions contemplated by this Agreement are subject to the fulfillment, at or before the Closing, of each of the following conditions (all or any of which may be waived in whole or in part by Purchaser in its sole discretion):

7.01 *Representations and Warranties.* The representations and warranties made by the Company and the Contributing Stockholders in this Agreement, taken as a whole, shall be true and correct on and as of the Closing Date as though made on and as of the Closing Date (or, in the case of representations and warranties made as of a specified date earlier than the Closing Date, on and as of such earlier date), except for any such breaches which, individually or in the aggregate, could not reasonably be expected to be materially adverse to the Business or Condition of the Company or to the Company's ability to consummate the transactions contemplated hereby.

7.02 *Performance.* The Company shall have performed and complied with, in all material respects, the agreements, covenants and obligations required by this Agreement to be so performed or complied with by the Company at or before the Closing.

7.03 *Bring-Down Certificate.* The Company shall have delivered to Purchaser a certificate, dated the Closing Date and executed in the name and on behalf of the Company by a duly authorized officer of the Company, in a form reasonably acceptable to Purchaser and to the effect of *Sections 7.01* and *7.02*.

7.04 *Orders and Laws.* There shall not be in effect on the Closing Date any Order or Law restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement.

7.05 *Regulatory Consents and Approvals.* All consents, approvals and actions of, filings with and notices to any Governmental or Regulatory Authority necessary to permit Purchaser and the Company to perform their obligations under this Agreement and to consummate the transactions contemplated hereby shall have been duly obtained, made or given and shall be in full force and effect, and all terminations or expirations of waiting periods imposed by any Governmental or Regulatory Authority necessary for the consummation of the transactions contemplated by this Agreement, including under the HSR Act, shall have occurred.

7.06 *Third Party Consents.* The consents (or in lieu thereof waivers) listed in *Section 7.06* of the Company Disclosure Schedule shall have been obtained and shall be in full force and effect.

7.07 *Resignations of Directors.* The members of the Boards of Directors of the Company and Pharma shall have tendered, effective at the Closing, their resignations as such directors.

7.08 *Escrow Agreement.* The Stockholders' Agent (on behalf of the Contributing Stockholders) and the Escrow Agent shall have executed and delivered the Escrow Agreement.

7.09 *Voting Agreement.* The Voting Agreement and all other agreements between the Company or Pharma and their stockholders granting information, registration or other rights to such stockholders in their capacities as such shall have been terminated by the requisite vote of the parties thereto.

7.10 *Retention of Employees.* At least 80% of the Company's sales representatives, 80% of its Regional Business Managers and each of the individuals referenced in the side letter dated as of the date of the Original Agreement (which letter shall also include the titles, areas of responsibility and locations of employment for such individuals) shall have accepted offers of employment from Purchaser as set forth in offer letters substantially in the form for particular levels of employees provided to the Company by Purchaser prior to the date of the Original Agreement.

7.11 *Financial Statements.* Purchaser shall have received the audited financial statements required to be delivered pursuant to *Section 5.06*, and such audited financial statements shall not reflect any material adverse change in the financial condition or results of operations of the Company and its consolidated Subsidiaries from that reflected in the Unaudited Financials; *provided* that no material adverse change shall be deemed to have occurred for purposes of this condition by reason of the occurrence of any of the events referred to in the proviso to *Section 7.12*.

7.12 *No Material Adverse Event.* No change, event, occurrence or circumstance that is materially adverse to the business, financial condition or results of operations of the Company and Pharma taken as a whole shall have occurred since the date of the Original Agreement; *provided* that neither (a) the execution and delivery (subject to compliance with the terms of this Agreement) of the Retavase® Purchase Agreement nor the completion of the purchase of the Retavase® Assets pursuant thereto, (b) the failure of the Company or Pharma to enter into the Retavase® Purchase Agreement or to complete the purchase of the Retavase® Assets, (c) a requirement that the Company recognize increased compensation expense with respect to outstanding Company Options under GAAP nor (d) any of the following shall constitute such a material adverse event for purposes of this condition: changes, effects, events, occurrences and circumstances that the Company demonstrates are caused primarily and directly by (i) changes in the U.S. economy or the pharmaceutical industry as a whole (to the extent that such changes do not have a disproportionately adverse effect on the Company), (ii) changes that result from the announcement or pendency of this Agreement or the transactions contemplated hereby, (iii) changes that result from changes in Laws after the date of the Original Agreement (other than changes specifically or disproportionately related in fact or in effect to the Company) or (iv) changes in GAAP or regulatory accounting principles after the date of the Original Agreement.

7.13 *Employee Loans.* All loans extended by the Company or Pharma to any of their employees remaining outstanding on the Closing Date shall have been repaid in full.

7.14 *280G Approvals.* The Company shall have obtained the 280G Approvals as contemplated by Section 5.11.

ARTICLE VIII CONDITIONS TO OBLIGATIONS OF THE COMPANY

The obligation of the Company to consummate the transactions contemplated by this Agreement is subject to the fulfillment, at or before the Closing, of each of the following conditions (all or any of which may be waived in whole or in part by the Company in its sole discretion):

8.01 *Representations and Warranties.* The representations and warranties made by Purchaser in this Agreement, taken as a whole, shall be true and correct in all material respects on and as of the Closing Date as though made on and as of the Closing Date.

8.02 *Performance.* Purchaser shall have performed and complied with, in all material respects, the agreements, covenants and obligations required by this Agreement to be so performed or complied with by Purchaser at or before the Closing.

8.03 *Bring-Down Certificate.* Purchaser shall have delivered to the Company a certificate, dated the Closing Date and executed in the name and on behalf of Purchaser by a duly authorized officer of Purchaser, in a form reasonably acceptable to the Company and to the effect of *Sections 8.01* and *8.02*.

8.04 *Orders and Laws.* There shall not be in effect on the Closing Date any Order or Law restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement.

8.05 *Regulatory Consents and Approvals.* All consents, approvals and actions of, filings with and notices to any Governmental or Regulatory Authority necessary to permit the Company and Purchaser to perform their obligations under this Agreement and to consummate the transactions contemplated hereby shall have been duly obtained, made or given and shall be in full force and effect, and all terminations or expirations of waiting periods imposed by any Governmental or Regulatory Authority necessary for the consummation of the transactions contemplated by this Agreement, including under the HSR Act, shall have occurred.

8.06 *Third Party Consents.* The consents (or in lieu thereof waivers) listed in *Section 7.06* of the Company Disclosure Schedule shall have been obtained and shall be in full force and effect.

8.07 *Escrow Agreement.* Purchaser and the Escrow Agent shall each have executed and delivered the Escrow Agreement.

8.08 *Listing of Stock.* The shares of Purchaser Common Stock issuable in the Merger shall have been approved for listing on the principal national securities exchange on which shares of Purchaser Common Stock are listed or traded, subject only to official notice of issuance.

ARTICLE IX SURVIVAL; NO OTHER REPRESENTATIONS

9.01 *Survival of Representations, Warranties, Covenants and Agreements.* Subject to the following sentence, the representations, warranties, covenants and agreements of the Company, the Contributing Stockholders and Purchaser made in or pursuant to this Agreement will survive the Closing. The representations, warranties, covenants and agreements of the Company and the Contributing Stockholders contained in *Articles III* and *V* of this Agreement (including pursuant to the certificates delivered pursuant to *Sections 2.05* and *7.03*) will survive only until the first anniversary of the Closing and shall thereupon expire together with any right to indemnification for breach thereof, except that any representation, warranty, covenant or agreement that would otherwise terminate in accordance with this sentence will continue to survive if a Claim Notice or Indemnity Notice (as applicable) shall have been timely given in good faith based on facts reasonably expected to establish a valid claim under *Article X* on or prior to such termination date, until the related claim for indemnification has been satisfied or otherwise resolved as provided in *Article X*. The representations, warranties, covenants and agreements of Purchaser contained in *Articles IV* and *VI* of this Agreement will survive only until the first anniversary of the Closing and shall thereupon expire together with any right to indemnification for breach thereof, except that any representation, warranty, covenant or agreement that would otherwise terminate in accordance with this sentence will continue to survive until satisfied if a Claim Notice or Indemnity Notice (as applicable) shall have been timely given in good faith based on facts reasonably expected to establish a valid claim under *Article X* on or prior to such termination date, until the related claim for indemnification has been satisfied or otherwise resolved as provided in *Article X*.

9.02 *No Other Representations.* Notwithstanding anything to the contrary contained in this Agreement, it is the explicit intent of each party hereto that neither the Company nor any Contributing Stockholder is making any representation or warranty whatsoever, express or implied, at Law or in equity, whether under Contract, tort or other applicable Law, in respect of the Company or Pharma or

any of their respective Assets and Properties, Liabilities or operations, including without limitation the Business or Condition of the Company, except those representations and warranties contained in *Article III*, in the Company Disclosure Schedule and in the certificates delivered pursuant to *Sections 2.05* and *7.03*. Purchaser acknowledges that to the extent the transactions contemplated herein are construed as the transfer of Assets and Properties of the Company and Pharma, such transfer is made "AS IS WHERE IS", with no warranty whatsoever, whether express or implied, other than as expressed in *Article III*, in the Company Disclosure Schedule or in the certificates delivered pursuant to *Sections 2.05* and *7.03*, and Purchaser expressly waives all other warranties as to such Assets and Properties, including those pertaining to habitability, merchantability or fitness for a particular purpose, as well as any warranty against apparent or latent defects of any type. In addition, neither the Company nor any Contributing Stockholder makes any representation or warranty to Purchaser with respect to any financial projection or forecast relating to the Business or Condition of the Company provided by or on behalf of the Company or any of its Affiliates to Purchaser or any of its Affiliates or Representatives, including without limitation, the Confidential Private Placement Memorandum. With respect to any projection or forecast delivered by or on behalf of the Company or any of its Affiliates to Purchaser or any of its Affiliates or Representatives, Purchaser acknowledges that (a) there are uncertainties inherent in attempting to make such projections and forecasts, (b) it is familiar with such uncertainties, (c) it is taking full responsibility for making its own evaluation of the adequacy and accuracy of all such projections and forecasts furnished to it and (d) it shall have no claim against the Company or any of its Affiliates or Representatives with respect thereto; *provided* that the foregoing is (subject to the last sentence of *Section 10.01(c)*) not intended to limit the representation contained in *Section 3.24(d)*.

ARTICLE X INDEMNIFICATION

10.01 *Indemnification.*

(a) Following the Closing, subject to paragraph (c) of this Section and to *Section 10.04* and the other Sections of this *Article X*, the Contributing Stockholders shall, severally in accordance with the applicable percentage of the Escrow Shares allocated to each Contributing Stockholder in *Annex I* hereto, and not jointly, indemnify Purchaser in respect of, and hold it harmless from and against, any and all Losses suffered, incurred or sustained by it or to which it becomes subject resulting from, arising out of or relating to any breach of representation or warranty or nonfulfillment of or failure to perform any covenant or agreement on the part of the Company made in or pursuant to this Agreement.

(b) Following the Closing, subject to *Section 10.04* and the other Sections of this *Article X*, Purchaser shall indemnify each of the Contributing Stockholders in respect of, and hold each of them harmless from and against, any and all Losses suffered, incurred or sustained by any of them or to which any of them becomes subject, resulting from, arising out of or relating to any breach of representation or warranty or nonfulfillment of or failure to perform any covenant or agreement on the part of Purchaser made in or pursuant to this Agreement.

(c) Notwithstanding anything to the contrary contained in this Agreement, no amounts of indemnity shall be payable by any Contributing Stockholder as a result of any claim in respect of a Loss arising under paragraph (a) of this *Section 10.01*:

(i) unless and until Purchaser has suffered, incurred, sustained or become subject to any such Losses in the aggregate in excess of one percent (1%) of the Contributing Stockholder Purchase Price, in which event Purchaser shall be entitled to claim indemnity for the full amount of such Losses that exceed \$1,000,000; *provided, however*, that such limitations shall not apply to any Losses suffered, incurred or sustained by Purchaser or to which Purchaser becomes subject resulting from, arising out of or relating to any breach of representation or

warranty on the part of the Company made in or pursuant to the certificate to be delivered pursuant to *Section 2.05* to Purchaser with respect to Transaction Expenses payable to any brokers, accountants, legal advisors or agents engaged by the Company for the allocation or distribution of any amounts under *Article II* of this Agreement to or among the recipients thereof; *provided, further*, that no Losses shall be included in determining whether such amounts have been reached unless a valid Claim Notice or Indemnity Notice (as applicable) in respect of such Losses has been given by Purchaser to Stockholders' Agent in accordance with *Section 10.02*;

(ii) unless Purchaser has given the Stockholders' Agent a Claim Notice or Indemnity Notice, as applicable, with respect to such claim, setting forth in reasonable detail the specific facts and circumstances pertaining thereto, (A) as soon as practical following the time at which the Indemnified Party discovered or reasonably should have discovered such claim; *provided* that any failure to provide such timely notice shall not affect the rights of the parties if the Indemnifying Party is not prejudiced by any delay in the delivery of such notice, and (B) in any event prior to the applicable Cut-off Date;

(iii) except to the extent that Purchaser had a reasonable opportunity, but failed in good faith, to mitigate such Loss, including but not limited to recovery under a policy of insurance or under a contractual right of set-off or indemnity; or

(iv) to the extent it arises from or was caused by actions taken or failed to be taken by Purchaser or any of its Affiliates, including without limitation, by reason of Purchaser operating the business of the Company and Pharma in the same manner as such business was operated at any time prior to the Closing;

provided, however, that the provisions of *Section 10.01(c)(i)*, *(iii)* and *(iv)* shall not apply to claims with respect to breach of the representations and warranties contained in *Section 3.04* or *Sections 3.24(d)* or *(e)* or *Section 3.29*. Notwithstanding the foregoing, Purchaser's sole remedy for a breach of the representation and warranty contained in (I) *Section 3.24(d)* shall be (x) a claim under the Escrow Agreement for damages equal to the amount, if any, by which Total Returns exceed the Return Target during the 12 months following the Closing and (y) subject to Purchaser's compliance with its covenant contained in *Section 3.24(d)*, and (II) *Section 3.29* shall be a claim under the Escrow Agreement for damages equal to the amount, if any, by which the Closing Net Debt exceeds the amount set forth in *Section 3.29*.

10.02 Method of Asserting Claims. All claims for indemnification by any Indemnified Party under *Section 10.01* must be asserted and resolved as follows:

(a) In the event any claim or demand in respect of which an Indemnified Party might seek indemnity under *Section 10.01* is asserted against or sought to be collected from such Indemnified Party by a Person other than any of the Contributing Stockholders or Purchaser or any of their respective Affiliates (a "*Third Party Claim*"), the Indemnified Party shall deliver a Claim Notice with reasonable promptness to the Indemnifying Party. The Indemnifying Party will notify the Indemnified Party as soon as practicable within the Dispute Period whether the Indemnifying Party disputes its liability to the Indemnified Party under *Section 10.01* and whether the Indemnifying Party desires, at its sole cost and expense, to defend the Indemnified Party against such Third Party Claim.

(i) If, in the case of a Third Party Claim that involves a claim solely for money damages and does not involve a dispute with respect to any Company Intellectual Property, a product liability claim or claim with respect to the safety of a product sold by the Company or Pharma or a dispute with a Person having a material business relationship with the Company or Pharma, the Indemnifying Party notifies the Indemnified Party within the Dispute Period that

the Indemnifying Party desires to defend the Indemnified Party with respect to such Third Party Claim pursuant to this *Section 10.02(a)*, then the Indemnifying Party will have the right to defend, at the sole cost and expense of the Indemnifying Party, such Third Party Claim by all appropriate proceedings, which proceedings will be vigorously and diligently prosecuted by the Indemnifying Party to a final conclusion or will be settled at the discretion of the Indemnifying Party (but only with the consent of the Indemnified Party, which consent will not be unreasonably withheld or delayed in the case of any settlement that provides for any relief other than the payment of monetary damages as to which the Indemnified Party will be indemnified in full). The Indemnifying Party will have full control of such defense and proceedings, including (except as provided in the immediately preceding sentence) any settlement thereof; *provided, however*, that the Indemnified Party may, at the sole cost and expense of the Indemnified Party, at any time prior to the Indemnifying Party's delivery of the notice referred to in the first sentence of this clause (i), file any motion, answer or other pleadings or take any other action that the Indemnified Party reasonably believes to be necessary or appropriate to protect its interests and not prejudicial to the Indemnifying Party (it being understood and agreed that, except as provided in clause (ii) below, if an Indemnified Party takes any such action that is prejudicial and causes a final adjudication that is adverse to the Indemnifying Party, the Indemnifying Party will be relieved of its obligations hereunder with respect to the portion of such Third Party Claim prejudiced by the Indemnified Party's action); and *provided further*, that if requested by the Indemnifying Party, the Indemnified Party will, at the sole cost and expense of the Indemnifying Party, cooperate with the Indemnifying Party and its counsel in contesting any Third Party Claim that the Indemnifying Party elects to contest, or, if appropriate and related to the Third Party Claim in question, in making any counterclaim against the Person asserting the Third Party Claim, or any cross-complaint against any Person (other than the Indemnified Party or any of its Affiliates). The Indemnified Party may retain separate counsel to represent it in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnifying Party pursuant to this clause (i), and the Indemnified Party will bear its own costs and expenses with respect to such separate counsel except as provided in the preceding sentence. Notwithstanding the foregoing, the Indemnified Party may retain or take over the control of the defense or settlement of any Third Party Claim the defense of which the Indemnifying Party has elected to control if the Indemnified Party irrevocably waives its right to indemnity under *Section 10.01* with respect to such Third Party Claim.

(ii) If the Indemnifying Party fails to notify the Indemnified Party within the Dispute Period that the Indemnifying Party desires to defend a Third Party Claim which the Indemnifying Party has the right to defend pursuant to *Section 10.02(a)(i)*, or in connection with any Third Party Claim which the Indemnifying Party does not have the right to defend pursuant to *Section 10.02(a)(i)*, then the Indemnified Party will have the right to defend, at the sole cost and expense of the Indemnifying Party, such Third Party Claim by all appropriate proceedings, which proceedings will be vigorously and diligently prosecuted by the Indemnified Party to a final conclusion or will be settled at the discretion of the Indemnified Party (with the consent of the Indemnifying Party, which consent will not be unreasonably withheld or delayed). The Indemnified Party will have full control of such defense and proceedings, including (except as provided in the immediately preceding sentence) any settlement thereof; *provided, however*, that if requested by the Indemnified Party, the Indemnifying Party will, at the sole cost and expense of the Indemnifying Party, cooperate with the Indemnified Party and its counsel in contesting any Third Party Claim which the Indemnified Party is contesting, or, if appropriate and related to the Third Party Claim in question, in making any counterclaim against the Person asserting the Third Party Claim, or any cross-complaint against any Person (other than the Indemnifying Party or any of its Affiliates). Notwithstanding the foregoing

provisions of this clause (ii), if the Indemnifying Party has notified the Indemnified Party within the Dispute Period that the Indemnifying Party disputes its liability hereunder to the Indemnified Party with respect to such Third Party Claim and if such dispute is resolved in favor of the Indemnifying Party in the manner provided in clause (iii) below, the Indemnifying Party will not be required to bear the costs and expenses of the Indemnified Party's defense pursuant to this clause (ii) or of the Indemnifying Party's participation therein at the Indemnified Party's request, and the Indemnified Party will reimburse the Indemnifying Party in full for all reasonable costs and expenses incurred by the Indemnifying Party in connection with such litigation. The Indemnifying Party may retain separate counsel to represent it in, but not control, any defense or settlement controlled by the Indemnified Party pursuant to this clause (ii), and the Indemnifying Party will bear its own costs and expenses with respect to such participation.

(iii) If the Indemnifying Party notifies the Indemnified Party that it does not dispute its liability to the Indemnified Party with respect to the Third Party Claim under *Section 10.01* or fails to notify the Indemnified Party within the Dispute Period whether the Indemnifying Party disputes its liability to the Indemnified Party with respect to such Third Party Claim, the Loss arising from such Third Party Claim will, subject to the provisions of *Section 10.01(c)*, be conclusively deemed a liability of the Indemnifying Party under *Section 10.01* and the Indemnifying Party shall, subject to the provisions of *Section 10.01(c)*, pay the amount of such Loss to the Indemnified Party on demand following the final determination thereof. If the Indemnifying Party has timely disputed its liability with respect to such claim, the Indemnifying Party and the Indemnified Party will proceed in good faith to negotiate a resolution of such dispute and, if not resolved through negotiations, either party may seek a resolution of such dispute by litigation in a court of competent jurisdiction.

(b) In the event a claim by any Indemnified Party under *Section 10.01* against any Indemnifying Party that does not involve a Third Party Claim, the Indemnified Party shall deliver an Indemnity Notice with reasonable promptness to the Indemnifying Party. If the Indemnifying Party notifies the Indemnified Party that it does not dispute the claim described in such Indemnity Notice or fails to notify the Indemnified Party within the Dispute Period whether the Indemnifying Party disputes the claim described in such Indemnity Notice, the Loss arising from the claim specified in such Indemnity Notice will, subject to the provisions of *Section 10.01(c)*, be conclusively deemed a liability of the Indemnifying Party under *Section 10.01* and the Indemnifying Party shall, subject to the provisions of *Section 10.01(c)*, pay the amount of such Loss to the Indemnified Party on demand following the final determination thereof. If the Indemnifying Party has timely disputed its liability with respect to such claim, the Indemnifying Party and the Indemnified Party will proceed in good faith to negotiate a resolution of such dispute, and if not resolved through negotiations, either party may, by written notice to the other, demand arbitration of the matter, in accordance with *Section 10.02(c)*, unless the amount of the Losses is at issue in pending litigation with a third party, in which event arbitration shall not be commenced until such amount is ascertained or both parties agree to arbitration.

(c) Any dispute, claim or controversy arising out of or relating to *Article X* or the breach, termination, enforcement, interpretation or validity thereof, including the determination of the scope or applicability of *Article X* to arbitrate, shall be determined by arbitration in the State of Delaware before one (1) arbitrator selected by the mutual agreement of the Indemnified Party and Indemnifying Party; *provided, however*, that if such parties cannot agree on an arbitrator, either party may request that Judicial Arbitration and Mediation Services ("*JAMS*") select the arbitrator. The arbitration shall be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures. Judgment on the arbitration award may be entered in any court having jurisdiction. This paragraph shall not preclude the parties from seeking provisional remedies in aid

of arbitration from a court of appropriate jurisdiction. The arbitrator may, in the arbitration award, allocate all or part of the costs of the arbitration, including fees of the arbitrator and the reasonable attorneys' fees of the prevailing party.

(d) In the event of any claim for indemnity under *Section 10.01(a)*, Purchaser agrees to give each Contributing Stockholder and their respective Representatives reasonable access to the Books and Records and employees of the Company and Pharma in connection with the matters for which indemnification is sought to the extent such Contributing Stockholder and their Representatives reasonably deem necessary in connection with their rights and obligations under this *Article X*.

(e) Concurrently with the delivery of a Claim Notice or an Indemnity Notice by Purchaser to Stockholders' Agent pursuant to this *Article X*, Purchaser will deliver to the Escrow Agent a Certificate of Instruction (as defined in the Escrow Agreement). No Certificate of Instruction may be delivered by Purchaser after the close of business on the Business Day immediately preceding the first anniversary of the Closing Date.

10.03 Method of Calculating Losses. The amount of any payment to an Indemnified Party shall be reduced by the amount of any corresponding federal, state or local income Tax benefit derived or to be derived by the Indemnified Party from payment of the liability upon which the claim for indemnity is based. All indemnification payments under this *Article X* shall be deemed adjustments to the portion of the Purchase Price payable for the Shares.

10.04 Exclusivity. After the Closing, the indemnities set forth in this *Article X* shall be the sole and exclusive remedies of Purchaser and the Contributing Stockholders and their respective officers, directors, employees, agents and Affiliates for any breach of representation or warranty or nonfulfillment or failure to be performed of any covenant or agreement made in or pursuant to this Agreement, and the parties shall not be entitled to a rescission of this Agreement or to any further indemnification rights or claims of any nature whatsoever in respect thereof, all of which the parties hereto hereby waive. Notwithstanding anything to the contrary in this Agreement, after the Closing, any liability of the Contributing Stockholders to indemnify Purchaser pursuant to *Section 10.01(a)* shall be limited to the Escrow Shares and any and all indemnification claims thereunder shall be paid therefrom. The maximum indemnity obligation of each Contributing Stockholder under this Agreement and the Escrow Agreement shall not exceed the applicable percentage of the Escrow Shares allocated to such Contributing Stockholder in *Annex I* hereto. No Person who was an officer, director, stockholder or holder of any Option to purchase shares of capital stock of the Company or Pharma prior to the Closing shall have any liability to make any payment in respect of any breach of any representation or warranty or non-performance of any covenant or agreement made in or pursuant this *Article X*, except for the Contributing Stockholders' indemnification obligations under this *Article X*.

10.05 No Consequential Damages. Anything herein to the contrary notwithstanding, no party shall be liable under this Agreement or with respect to the transactions contemplated hereby for any consequential, exemplary, punitive, special, indirect or incidental damages, or any multiple of damages or diminution of value, including without limitation, loss of profits or revenue.

ARTICLE XI TERMINATION

11.01 Termination. This Agreement may be terminated, and the transactions contemplated hereby may be abandoned:

(a) at any time before the Closing, by mutual written agreement of the Company and Purchaser;

(b) at any time before the Closing, by the Company or Purchaser, in the event that any Law or any final, nonappealable Order becomes effective restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement, upon notification of the non-terminating party by the terminating party;

(c) at any time after sixty (60) days following the date of the Original Agreement (the "*Outside Date*") by the Company or Purchaser, upon notification of the non-terminating party by the terminating party, if the Closing shall not have occurred on or before such date and such failure to consummate is not caused by a breach of this Agreement by the terminating party; *provided* that the Outside Date shall be extended to the date ninety (90) days following the date of the Original Agreement to resolve any pending litigation seeking to enjoin the Merger if the sole reason that the Closing shall not have occurred on or prior to the Outside Date is a failure of any condition to Closing contained in *Section 7.05* (by virtue of the failure of any material regulatory requirement to be satisfied, including termination or expiration of the waiting period under the HSR Act), *Section 7.11*, but only so if all other conditions to the Closing shall have been satisfied or are reasonably capable of being satisfied; or

(d) at any time before the Closing, by the Company or Purchaser, in the event (i) of a material breach hereof by the non-terminating party if such non-terminating party fails to cure such breach within twenty (20) Business Days following notification thereof by the terminating party; *provided* that for purposes of this paragraph only, a material breach on the part of the Company shall not be deemed material unless it results or could be expected to result in a material adverse change in the Business or Condition of the Company.

11.02 *Effect of Termination.* If this Agreement is validly terminated pursuant to *Section 11.01*, this Agreement will forthwith become null and void, and there will be no liability or obligation on the part of the Company or Purchaser (or any of their respective officers, directors, employees or other Representatives or Affiliates) under this Agreement or in connection with the transactions contemplated hereby, *provided* that the provision with respect to expenses in *Section 13.03* will continue to apply following any such termination. Notwithstanding any other provision in this Agreement to the contrary, upon termination of this Agreement pursuant to *Section 11.01(b), (c) or (d)*, the Company will remain liable to Purchaser for any willful breach of *Section 5.12* by the Company existing at the time of such termination, and Purchaser will remain liable to the Company for any willful breach of *Section 6.10* by Purchaser existing at the time of such termination, and the Company or Purchaser may seek such remedies, including damages and reasonable fees of attorneys, against the other with respect to any such breach as are provided in this Agreement or as are otherwise available at Law or in equity.

ARTICLE XII
DEFINITIONS

12.01 *Definitions.*

(a) *Defined Terms.* As used in this Agreement, the following defined terms have the meanings indicated below:

"*Acquisition Proposal*" means any proposal for a merger or other business combination to which the Company or Pharma is a party or the direct or indirect acquisition of any equity interest in, or fifty percent (50%) of the assets of, the Company or Pharma, other than (i) the transactions contemplated by this Agreement and (ii) any merger or other business combination or sale of equity interests or assets to which Purchaser or any of its Affiliates is a party and which indirectly involves the Company or Pharma.

"*Actions or Proceedings*" means any action, suit, proceeding, arbitration or Governmental or Regulatory Authority investigation.

"*Affiliate*" means any Person that directly, or indirectly through one of more intermediaries, controls or is controlled by or is under common control with the Person specified. For purposes of this definition, control of a Person means the power, direct or indirect, to direct or cause the direction of the management and policies of such Person whether by Contract or otherwise.

"*Agreement*" means the Original Agreement as amended and restated by this Amended and Restated Agreement and Plan of Merger and the Exhibits, the Company Disclosure Schedule and the Annexes hereto and the certificates delivered in accordance with *Sections 2.05, 7.03 and 8.03*, as the same shall be amended from time to time.

"*Applicable Merger Price*" has the meaning ascribed to it in *Section 1.02(b)*.

"*Assets and Properties*" of any Person means all assets and properties of every kind, nature, character and description (whether real, personal or mixed, whether tangible or intangible, and wherever situated), including the goodwill related thereto, operated, owned or leased by such Person.

"*Benefit Plan*" means any Plan established by the Company or Pharma, or any predecessor or Affiliate of any of the foregoing, existing at the Closing Date or at any time prior thereto, to which the Company or Pharma contributes or has contributed, or under which any employee, former employee or director of the Company or Pharma or any beneficiary thereof is covered, is eligible for coverage or has benefit rights.

"*Books and Records*" means all files, documents, instruments, papers, books and records relating to the Business or Condition of the Company, including without limitation financial statements, Tax returns and related work papers and letters from accountants, budgets, pricing guidelines, ledgers, journals, deeds, title policies, minute books, stock certificates and books, stock transfer ledgers, Contracts, Licenses, operating data and plans.

"*Business Day*" means a day other than Saturday, Sunday or any day on which banks located in the State of California, the State of New Jersey or the State of New York are authorized or obligated to close.

"*Business or Condition of the Company*" means the business, financial condition or results of operations of the Company and Pharma taken as a whole.

"*Certificate of Merger*" has the meaning ascribed to it in *Section 2.01(b)*.

"*Certificates*" has the meaning ascribed to it in *Section 1.02(b)*.

"*Change of Control Payments*" means any amounts which become payable by the Company or Pharma to any of their respective employees or former employees on or prior to the Closing Date as a result of the execution and delivery of this Agreement or the consummation of the transactions contemplated hereby, whether pursuant to the Company's severance policy or individual employment, severance or change-of-control Contract or otherwise.

"*Claim Notice*" means written notification pursuant to *Section 10.02(a)* of a Third Party Claim as to which indemnity under *Section 10.01* is sought by an Indemnified Party, enclosing a copy of all papers served, if any, and specifying the nature of and basis for such Third Party Claim and for the Indemnified Party's claim against the Indemnifying Party under *Section 10.01*, together with the amount or, if not then reasonably determinable, the estimated amount, determined in good faith, of the Loss arising from such Third Party Claim.

"*Closing*" has the meaning ascribed to it in *Section 2.01(a)*.

"*Closing Date*" means (i) the second Business Day after the later of (x) the day on which the waiting period under the HSR Act with respect to the transactions contemplated by this Agreement has been terminated or expired and (y) the day on which the other conditions set forth in *Articles VII* and *VIII* have been satisfied (excluding conditions that, by their terms, are to be satisfied at the Effective Time, but subject to the satisfaction or waiver of such conditions), or (ii) such other date as Purchaser and the Company mutually agree upon in writing.

"*Closing Shares*" has the meaning ascribed to it in *Section 2.01(c)*.

"*Closing Value Per Share*" means the arithmetic average of the closing sales prices of a share of Purchaser Common Stock, as reported on the principal national securities exchange on which shares of Purchaser Common Stock are listed or traded, on each of the ten (10) Trading Days ending on and including the third Trading Day immediately preceding the Closing Date.

"*Code*" means the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder.

"*Common Stock Payment*" has the meaning ascribed to it in *Section 2.01(c)(v)*.

"*Company*" has the meaning ascribed to it in the forepart of this Agreement.

"*Company Common Stock*" has the meaning ascribed to it in the forepart of this Agreement.

"*Company Common Stock Per Share Purchase Price*" means the amount by which the sum of (I) the Purchase Price plus (II) the aggregate exercise price of all outstanding Company Options exceeds the sum of (III) the aggregate amount of Preferred Stock Dividends in respect of all outstanding shares of Company Preferred Stock plus (IV) the aggregate amount of Transaction Expenses and Change of Control Payments, divided by the total number of Outstanding Company Shares.

"*Company Disclosure Schedule*" means the record delivered to Purchaser pursuant to the terms of this Agreement on behalf of the Company with the Original Agreement and dated as of the date of the Original Agreement, containing all lists, exceptions and other information and materials as may be provided pursuant to this Agreement.

"*Company Intellectual Property*" has the meaning ascribed to it in *Section 3.17*.

"*Company Licenses*" has the meaning ascribed to it in *Section 3.19*.

"*Company Options*" has the meaning ascribed to it in the forepart of this Agreement.

"*Company Plans*" has the meaning ascribed to it in *Section 3.13(a)*.

"*Company Preferred Stock*" has the meaning ascribed to it in the forepart of this Agreement.

"*Company Preferred Stock Per Share Purchase Price*" means, with respect to each share of Company Preferred Stock, the result obtained by multiplying the Company Common Stock Per Share Purchase Price by the number of shares of Company Common Stock issuable upon the conversion of such share of Company Preferred Stock.

"*Confidentiality Agreement*" has the meaning ascribed to it in *Section 13.02*.

"*Constituent Corporations*" has the meaning ascribed to it in *Section 1.01*.

"*Contract*" means any agreement, lease, license, evidence of Indebtedness, mortgage, indenture, security agreement or other contract.

"*Contributing Stockholder*" means each individual stockholder of the Company who is a signatory to the Original Agreement on the date of the Original Agreement and each other owner of shares of Company Common Stock or Company Preferred Stock who becomes a party to this Agreement in accordance with the procedures set forth in *Section 2.06*.

"*Contributing Stockholder Purchase Price*" means the result obtained by dividing (a) the sum of (i) the product of (x) the total number of Closing Shares multiplied by (y) the Value Per Share plus (ii) the Cash Amount by (b) the total number of Outstanding Company Shares and multiplying the result by (c) the total number of Outstanding Contributing Stockholder Company Shares.

"*Credit Agreement*" means the Credit Agreement, dated as of October 3, 2003, as amended, among Pharma, the other Credit Parties signatory thereto, the persons designated as Lenders thereunder, Fleet National Bank, as Syndication Agent, and GECC, as Administrative Agent.

"*Credit Agreement Payments*" has the meaning ascribed to it in *Section 2.02(b)(i)*.

"*Cut-off Date*" means, with respect to any representation, warranty, covenant or agreement contained in this Agreement, the date on which such representation, warranty, covenant or agreement ceases to survive as provided in *Section 9.01*.

"*DEA*" has the meaning ascribed to it in *Section 3.23(b)*.

"*DGCL*" has the meaning ascribed to it in *Section 1.01*.

"*Dispute Period*" means the period ending sixty (60) days following receipt by an Indemnifying Party of either a Claim Notice or an Indemnity Notice.

"*Dissenting Shares*" has the meaning ascribed to it in *Section 1.02(d)*.

"*DOJ*" has the meaning ascribed to it in *Section 3.23(b)*.

"*Effective Time*" has the meaning ascribed to it in *Section 2.01(b)*.

"*Environmental Law*" means any Law or Order relating to the regulation or protection of the environment or to emissions, discharges, releases or threatened releases of pollutants, contaminants, chemicals or industrial, toxic or hazardous substances or wastes into the environment (including, without limitation, ambient air, soil, surface water, ground water, wetlands, land or subsurface strata), or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of pollutants, contaminants, chemicals or industrial, toxic or hazardous substances or wastes.

"*ERISA*" has the meaning ascribed to it in *Section 3.13(a)*.

"*Escrow Agent*" shall mean an escrow agent mutually acceptable to the Company and Purchaser and who enters into the Escrow Agreement.

"*Escrow Agreement*" and "*Escrow Shares*" have the respective meanings ascribed to them in *Section 2.01(c)(i)*.

"*Exchange Act*" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"*FDA*" has the meaning ascribed to it in *Section 3.23(a)*.

"*FDCA*" has the meaning ascribed to it in *Section 3.23(a)*.

"*Financial Statements*" means the consolidated financial statements of the Company delivered to Purchaser pursuant to *Sections 3.09* and *5.06*.

"*FTC*" has the meaning ascribed to it in *Section 3.23(b)*.

"*GAAP*" means generally accepted accounting principles in the United States, consistently applied throughout the specified period and in the immediately prior comparable period.

"*GECC*" means General Electric Capital Corporation.

"*Governmental or Regulatory Authority*" means any court, tribunal, arbitrator, authority, agency, commission, official or other instrumentality of the United States or any state, county, city or other political subdivision.

"*Gross Sales*" has the meaning ascribed to it in *Section 3.24(d)*.

"*Hedge Payments*" has the meaning ascribed to it in *Section 2.02(b)(ii)*.

"*Holder*" has the meaning ascribed to it in *Section 6.09(a)*.

"*Holder Indemnitee*" has the meaning ascribed to it in *Section 6.09(e)*.

"*HSR Act*" means Section 7A of the Clayton Act (Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended) and the rules and regulations promulgated thereunder.

"*Indebtedness*" of any Person means all obligations of such Person (i) for borrowed money, (ii) evidenced by notes, bonds, debentures or similar instruments, (iii) under capital leases and (iv) in the nature of guarantees of the obligations described in clauses (i) through (iii) above of any other Person.

"*Indemnified Agents*" has the meaning ascribed to it in *Section 6.06(a)*.

"*Indemnified Liabilities*" has the meaning ascribed to it in *Section 6.06(a)*.

"*Indemnified Party*" means any Person claiming indemnification under any provision of *Article X*.

"*Indemnified Person*" has the meaning ascribed to it in *Section 6.09(g)*.

"*Indemnifying Party*" means any Person against whom a claim for indemnification is being asserted under any provision of *Article X*.

"*Indemnifying Person*" has the meaning ascribed to it in *Section 6.09(g)*.

"*Indemnity Notice*" means written notification pursuant to *Section 10.02(b)* of a claim for indemnity under *Article X*, specifying the nature of and basis for such claim, together with the amount or, if not then reasonably determinable, the estimated amount, determined in good faith, of the Loss arising from such claim.

"*Intellectual Property*" of any Person means all patents and patent rights, trademarks and trademark rights, trade names and trade name rights, service marks and service mark rights, service names and service name rights, brand names, inventions, copyrights and copyright rights, know-how and all pending applications for and registrations of patents, trademarks, service marks and copyrights of such Person.

"*Investment Assets*" of any Person means all debentures, notes and other evidences of Indebtedness, stocks, securities (including rights to purchase and securities convertible into or exchangeable for other securities), interests in joint ventures and general and limited partnerships, mortgage loans and other investment or portfolio assets owned of record or beneficially by such Person (other than trade receivables generated in the ordinary course of business of such Person).

"*IRS*" means the United States Internal Revenue Service.

"*JAMS*" has the meaning ascribed to it in *Section 10.02(c)*.

"*Knowledge of the Company*" means the actual knowledge of the individuals listed on *Section 12.01(a)* of the Company Disclosure Schedule.

"*Laws*" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of the United States or any state, county, city or other political subdivision or of any Governmental or Regulatory Authority.

"*Liabilities*" means all Indebtedness, obligations and other liabilities of a Person (whether absolute, accrued, contingent, fixed or otherwise, or whether due or to become due).

"*Licenses*" means all licenses, permits, certificates of authority, authorizations, approvals, registrations, franchises and similar consents granted or issued by any Governmental or Regulatory Authority.

"*Liens*" means any mortgage, pledge, assessment, security interest, lease, lien, adverse claim, levy, charge or other encumbrance of any kind, or any conditional sale Contract, title retention Contract or other Contract to give any of the foregoing.

"*Loss*" means any and all damages, fines, penalties, deficiencies, losses and expenses (including without limitation interest, court costs, fees of attorneys, accountants and other experts or other

expenses of litigation or other proceedings or of any claim, default or assessment), but not including internal management, administrative or overhead costs.

"*Merger*" has the meaning ascribed to it in the forepart of this Agreement.

"*Merger Sub*" has the meaning ascribed to it in the forepart of this Agreement.

"*Merger Sub Common Stock*" has the meaning ascribed to it in *Section 1.02(a)*.

"*NASD*" means the National Association of Securities Dealers.

"*Option*" with respect to any Person means any security, right, subscription, warrant, option, "phantom" stock right or other Contract that gives the right to (i) purchase or otherwise receive or be issued any shares of capital stock of such Person or any security of any kind convertible into or exchangeable or exercisable for any shares of capital stock of such Person or (ii) receive or exercise any benefits or rights similar to any rights enjoyed by or accruing to the holder of shares of capital stock of such Person, including any rights to participate in the equity or income of such Person or to participate in or direct the election of any directors or officers of such Person or the manner in which any shares of capital stock of such Person are voted.

"*Option Consideration*" means, with respect to any Company Option, the amount equal to (a) the number of shares of Company Common Stock issuable upon exercise of such Company Option multiplied by (b) the amount, if any, by which (i) the Company Common Stock Per Share Purchase Price exceeds (ii) the per share exercise price of such Company Option.

"*Order*" means any writ, judgment, decree, injunction or similar order of any Governmental or Regulatory Authority (in each such case whether preliminary or final).

"*Original Agreement*" has the meaning ascribed to it in the forepart of this Agreement.

"*Outside Date*" has the meaning ascribed to it *Section 11.01(c)*.

"*Outstanding Company Shares*" means the sum of: (x) the number of shares of Company Common Stock outstanding as of the Closing Date, (y) the number of shares of Company Common Stock issuable upon the exercise of all Company Options outstanding as of the Closing Date and (z) the number of shares of Company Common Stock issuable upon the conversion of all shares of Company Preferred Stock outstanding as of the Closing Date.

"*Outstanding Contributing Stockholder Company Shares*" means the sum of (x) the number of shares of Company Common Stock owned by Contributing Stockholders outstanding on the Closing Date and (y) the number of shares of Company Common Stock issuable upon conversion of all shares of Company Preferred Stock owned by all Contributing Stockholders outstanding as of the Closing Date.

"*PBGC*" means the Pension Benefit Guaranty Corporation established under ERISA.

"*Permitted Lien*" means (i) statutory Liens for current Taxes not yet due and payable, (ii) mechanics', carriers', workers', repairers' and other similar Liens imposed by Law arising or incurred in the ordinary course of business for obligations not yet due, (iii) in the case of leases of vehicles and other personal property, Liens which do not, individually or in the aggregate, materially impair the use of such leased equipment or other personal property, (iv) other Liens incidental to the operation of the business of the Company or Pharma or the ownership of their Assets and Properties which were not incurred in connection with the borrowing of money or the advance of credit and which do not materially detract from the value of the assets encumbered thereby or materially interfere with the use thereof, (v) in the case of Licenses or other rights to use Company Intellectual Property, Liens or other restrictions arising from the terms thereof, and (vi) Liens on leases of real property arising from the provisions of such leases, including, in relation to leased real property, any agreements and/or

conditions imposed on the issuance of land use permits, zoning, business licenses, use permits or other entitlements of various types issued by any Governmental or Regulatory Authority, necessary or beneficial to the continued use and occupancy of the Assets and Properties of the Company and Pharma.

"*Person*" means any natural person, corporation, limited liability company, general partnership, limited partnership, proprietorship, other business organization, trust, union, association or Governmental or Regulatory Authority.

"*Pharma*" has the meaning ascribed to it in *Section 2.02(a)*.

"*Preferred Stock Dividend*" means, with respect to each share of Company Preferred Stock, the amount of accrued and unpaid dividends in respect of such share immediately prior to the Closing Date.

"*Preferred Stock Payment*" has the meaning ascribed to it in *Section 2.01(c)(iii)*.

"*Purchase Price*" means the sum of (a) the Cash Amount and (b) the result obtained by multiplying the number of Closing Shares by the Closing Value Per Share.

"*Purchaser*" has the meaning ascribed to it in the forepart of this Agreement.

"*Purchaser Common Stock*" has the meaning ascribed to it in *Section 1.02(b)(i)*.

"*Purchaser Financial Statements*" has the meaning ascribed to it in *Section 5.07*.

"*Purchaser Indemnatee*" has the meaning ascribed to it in *Section 6.09(f)*.

"*Purchaser Preferred Stock*" has the meaning ascribed to it in *Section 4.06*.

"*Purchaser SEC Reports*" has the meaning ascribed to it in *Section 4.07*.

"*Registrable Securities*" means (i) the shares of Purchaser Common Stock issued in the Merger (including Escrow Shares), and (ii) any additional shares of Purchaser Common Stock issued or distributed by way of a dividend, stock split or other distribution in respect of such shares, or acquired by way of any rights offering or similar offering made in respect of such shares. As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (x) the Registration Statement shall have become effective under the Securities Act and such securities shall have been disposed of as contemplated thereby, (y) they shall have been sold in a transaction pursuant to Rule 144 or (z) they shall have ceased to be outstanding (including by reason of the fact that they are delivered to Purchaser pursuant to the terms of the Escrow Agreement).

"*Registration Expenses*" means all expenses incident to Purchaser's performance of or compliance with its obligations under *Section 6.09* to effect the registration of Registrable Securities for sale pursuant to the Registration Statement, including, without limitation, all registration, filing, securities exchange listing and NASD fees, all registration, filing, qualification and other fees and expenses of complying with securities or blue sky laws, all word processing, duplicating and printing expenses, messenger and delivery expenses, the fees and disbursements of legal counsel retained by Purchaser to act for Purchaser and of Purchaser's independent public accountants, including the expenses of any special audits or "cold comfort" letters required by or incident to such performance and compliance, and the fees and disbursements of a single legal counsel acting for the Holders.

"*Registration Statement*" has the meaning ascribed to it in *Section 6.09(a)*.

"*Representatives*" means, with respect to any Person, such Person's counsel, accountants, financial advisors, consultants and other representatives.

"*Restricted Shares*" has the meaning ascribed to it in *Section 2.04*.

"*Resumption Notice*" has the meaning ascribed to it in *Section 6.09(c)*.

"*Retavase® Assets*" mean the assets to be acquired by the Company or Pharma pursuant to the Retavase® Purchase Agreement if such agreement is entered into.

"*Retavase® Purchase Agreement*" means the Avalon-Espirit Asset Purchase Agreement between the Company or Pharma and Centocor (or possibly both Centocor and Scios), the most recent draft of which is attached in *Section 12.01(b)* of the Company Disclosure Schedule.

"*Return Target*" has the meaning ascribed to it in *Section 3.24(d)*.

"*Return Target Period*" has the meaning ascribed to it in *Section 3.24(d)*.

"*Returns*" has the meaning ascribed to it in *Section 3.24(d)*.

"*Rule 144*" means Rule 144 promulgated by the SEC under the Securities Act, and any successor provision thereto.

"*SEC*" means the Securities and Exchange Commission.

"*Secretary of State*" has the meaning ascribed to it in *Section 2.01(b)*.

"*Securities Act*" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"*Series A Stock*" has the meaning ascribed to it in the forepart of this Agreement.

"*Series B Stock*" has the meaning ascribed to it in the forepart of this Agreement.

"*Shares*" has the meaning ascribed to it in the forepart of this Agreement.

"*Stock Option Plan*" means the ESP Pharma, Inc. 2003 Stock Option Plan of the Company, as amended from time to time.

"*Stockholders' Agent*" has the meaning ascribed to it in the forepart of this Agreement.

"*Subsidiary*" means any Person in which the Company, directly or indirectly through its Subsidiary or otherwise, beneficially owns more than fifty percent (50%) of either the equity interests in, or the voting control of, such Person.

"*Surviving Corporation*" has the meaning ascribed to it in *Section 1.01*.

"*Surviving Corporation Common Stock*" has the meaning ascribed to it in *Section 1.02(a)*.

"*Suspension Notice*" has the meaning ascribed to it in *Section 6.09(c)*.

"*Suspension Right*" has the meaning ascribed to it in *Section 6.09(c)*.

"*Taxes*" means any federal, state, local or foreign taxes, charges, fees, levies, other assessments, or withholding taxes or charges imposed by any governmental entity, and includes any interest and penalties on or additions to any such taxes and any expenses incurred in connection with the determination, settlement or litigation of any Tax liability.

"*Third Party Claim*" has the meaning ascribed to it in *Section 10.02(a)*.

"*Total Returns*" has the meaning ascribed to it in *Section 3.24(d)*.

"*Trading Day*" means any day for which quotations are available on the principal national securities exchange on which shares of Purchaser Common Stock are listed or traded.

"*Transaction Expenses*" means all fees and expenses, whether billed or unbilled on or before the Closing, payable by the Company or Pharma to any Person in connection with the negotiation, execution and delivery of this Agreement and the consummation of the transactions contemplated

hereby, including without limitation any amounts payable to the brokers named in *Section 3.27*, accountants or legal advisors.

"*Unaudited Financials*" has the meaning ascribed to it in *Section 3.09*.

"*Value Per Share*" means \$19.7330, calculated as the arithmetic average of the closing sales prices of a share of Purchaser Common Stock, as reported on the principal national securities exchange on which shares of Purchaser Common Stock are listed or traded, on each of the ten (10) Trading Days ending on and including the Trading Day immediately preceding the date of the Original Agreement.

"*Voting Agreement*" means the Amended and Restated Voting Agreement dated as of the 15th day of April 2003 by and among the Company and the stockholders of the Company who are parties thereto, as the same may have been amended.

(b) *Construction of Certain Terms and Phrases.* Unless the context of this Agreement otherwise requires, (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (iv) the terms "Article" or "Section" refer to the specified Article or Section of this Agreement; and (v) the phrase "ordinary course of business" refers to the business of the Company or Pharma consistent with past custom and practice. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. All accounting terms used herein and not expressly defined herein shall have the meanings given to them under GAAP. Any representation or warranty contained herein as to the enforceability of a Contract (including this Agreement) shall be subject to the effect of any bankruptcy, insolvency, reorganization, moratorium or other similar Law affecting the enforcement of creditors' rights generally and to general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at Law).

ARTICLE XIII MISCELLANEOUS

13.01 *Notices.* All notices, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if delivered personally or by facsimile transmission or mailed (first class postage prepaid) to the parties at the following addresses or facsimile numbers:

If to Purchaser or Merger Sub, to:

Protein Design Labs, Inc.
34801 Campus Drive
Fremont, CA 94555
Facsimile No.: 510-574-1500
Attn: Chief Executive Officer and General Counsel

with a copy to:

DLA Piper Rudnick Gray Cary US LLP
153 Townsend Street, Suite 800
San Francisco, CA 94107
Facsimile No.: 415-836-2501
Attn: Howard Clowes

If to any of the Contributing Stockholders, to:

Anthony A. Rascio
c/o Milbank, Tweed, Hadley & McCloy LLP
One Chase Manhattan Plaza

New York, NY 10005
Facsimile No.: 212-530-5219
Attn: Robert S. Reder, Esq.

If to the Company, to:

ESP Pharma Holding Company, Inc.
2035 Lincoln Highway, Suite 2150
Edison, NJ 08817
Facsimile No.: 732-650-1387
Attn: General Counsel

with a copy to:

Milbank, Tweed, Hadley & McCloy LLP
One Chase Manhattan Plaza
New York, NY 10005
Facsimile No.: 212-530-5219
Attn: Robert S. Reder, Esq.

All such notices, requests and other communications will (a) if delivered personally to the address as provided in this Section, be deemed given upon delivery, (b) if delivered by facsimile transmission to the facsimile number as provided in this Section, be deemed given upon receipt, and (c) if delivered by mail in the manner described above to the address as provided in this Section, be deemed given upon receipt (in each case regardless of whether such notice, request or other communication is received by any other Person to whom a copy of such notice, request or other communication is to be delivered pursuant to this Section). Any party from time to time may change its address, facsimile number or other information for the purpose of notices to that party by giving notice specifying such change to the other party hereto.

13.02 Entire Agreement. This Agreement (including the Exhibits, Schedules, Annexes, certificates to be delivered pursuant to the terms hereof and the Escrow Agreement) supersede all prior discussions and agreements between the parties with respect to the subject matter hereof and thereof contains the sole and entire agreement between the parties hereto with respect to the subject matter hereof and thereof, other than that certain confidentiality agreement between the parties dated December 7, 2004 (the "*Confidentiality Agreement*"), which shall survive the execution and delivery of this Agreement in accordance with its terms and shall terminate at the Closing. All information and materials delivered by or on behalf of the Company to Purchaser or its Representatives or Affiliates pursuant to the terms of this Agreement will be subject to the terms and provisions of the Confidentiality Agreement.

13.03 Expenses. Except as otherwise expressly provided in this Agreement (including without limitation as provided in *Section 6.09(d)* and *Section 11.02*), whether or not the transactions contemplated hereby are consummated, each party will pay its own costs and expenses incurred in connection with the negotiation, execution and closing of this Agreement and the Escrow Agreement and the transactions contemplated hereby and thereby.

13.04 Appointment of Stockholders' Agent.

(a) Each Contributing Stockholder hereby appoints Stockholders' Agent to act as such Contributing Stockholder's true and lawful attorney-in-fact, agent and proxy under this Agreement and the Escrow Agreement, with full power and authority, including power of substitution, acting in the name of and for and on behalf of such Contributing Stockholders (i) to amend or waive any provision of this Agreement or the Escrow Agreement, (ii) to terminate this Agreement pursuant to the provisions of *Article XI*, (iii) to execute and deliver stock powers and stock certificates on

behalf of any Contributing Stockholder and (iv) to do all other things and to take all other action under or related to this Agreement that Stockholders' Agent may consider necessary or proper to effectuate the transactions contemplated hereby and to resolve any dispute with Purchaser over any aspect of this Agreement and, on behalf of such Contributing Stockholders, to enter into any agreement to effectuate any of the foregoing which shall have the effect of binding such Contributing Stockholders as if such Contributing Stockholders had personally entered into such an agreement; *provided*, that (x) all actions taken or decisions made by Stockholders' Agent on behalf of the Contributing Stockholders shall be taken or made in a reasonable manner and (y) no action may be taken by Stockholders' Agent under this appointment which would have the effect of prejudicing the relative rights of any Contributing Stockholder under this Agreement in relation to any other Contributing Stockholder. This appointment and power of attorney shall be deemed as coupled with an interest and all authority conferred hereby shall be irrevocable and shall not be subject to termination by operation of law, whether by the death or incapacity or liquidation or dissolution of any Contributing Stockholder or the occurrence of any other event or events and Stockholders' Agent may not terminate this power of attorney with respect to any Contributing Stockholder or such Contributing Stockholder's successors or assigns without the prior written consent of the Contributing Stockholders.

(b) Neither the Stockholders' Agent nor any agent employed by it shall incur any liability to any Contributing Stockholder relating to the performance of its duties or exercise of its rights hereunder, except for actual fraud or bad faith acts by the Stockholders' Agent or pursuant to the commission by the Stockholders' Agent on a continuing basis of acts or omissions determined to be willful or grossly negligent. The Stockholders' Agent shall likewise incur no liability by reason of any error of Law or for any act or omission related thereto. Each of the Contributing Stockholders hereby severally agrees to indemnify and hold harmless the Stockholders' Agent and any agent employed by it against any loss, liability or expense incurred (i) without fraud or bad faith on the part of the Stockholders' Agent or (ii) other than pursuant to the commission by the Stockholders' Agent on a continuing basis of acts or omissions determined to be willful or grossly negligent arising out of or in connection with its performance or exercise of obligations and rights under this Agreement. All expenses, fees and costs reasonably incurred by the Stockholders' Agent in its capacity as such, whether incurred prior to or following the Closing, shall be paid by the Company.

(c) Each Contributing Stockholder agrees that Stockholders' Agent may consult with counsel chosen by Stockholders' Agent and shall have full and complete authorization in good faith to act or refrain from acting in accordance with the opinion of such counsel. Stockholders' Agent may rely and shall be protected in acting, or refraining from acting, upon any written notice, instruction or request furnished to Stockholders' Agent hereunder and reasonably believed by Stockholders' Agent to be genuine and to have been signed or presented by the proper party or parties.

(d) Stockholders' Agent shall have the full power to execute and deliver the Escrow Agreement and shall have all of the rights and shall perform all of the obligations of Stockholders' Agent as set forth in the Escrow Agreement and Stockholders' Agent shall have the exclusive right, power and authority, on behalf of all the Contributing Stockholders, to pursue, defend, and settle any indemnification claims pursuant to *Article X* hereof and to do all things and to take all other actions Stockholders' Agent may consider necessary or proper to resolve any indemnification claims after the Closing Date.

(e) Purchaser may rely and shall be protected in acting, or refraining from acting, upon any written notice, instruction or request furnished to it hereunder and reasonably believed by it to be genuine and to have been signed or presented by Stockholders' Agent as if such written notice, instruction or request had been furnished to it by all the Contributing Stockholders.

(f) The Contributing Stockholders shall be entitled to change Stockholders' Agent by delivery of a written notice to such effect to Purchaser at any time, and the Contributing Stockholders covenant and agree to designate a replacement Stockholders' Agent as soon as practicable following the resignation or inability to serve of the then current Stockholders' Agent.

13.05 *Public Announcements.* At all times at or before the Closing, neither the Company nor Purchaser will issue or make any reports, statements or releases to the public with respect to this Agreement or the transactions contemplated hereby without the consent of the other, which consent shall not be unreasonably withheld or delayed. If either party is unable to obtain the approval of its public report, statement or release from the other party and such report, statement or release is, in the opinion of legal counsel to such party, required by Law in order to discharge such party's disclosure obligations, then such party may make or issue the legally required report, statement or release and promptly furnish the other party with a copy thereof. Stockholders' Agent and Purchaser will also obtain the other party's prior approval of any press release to be issued immediately following the Closing announcing the consummation of the transactions contemplated by this Agreement.

13.06 *Waiver.* Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. All remedies, either under this Agreement or by Law or otherwise afforded, will be cumulative and not alternative.

13.07 *Amendment.* This Agreement may be amended, supplemented or modified only by a written instrument duly executed by or on behalf of each party hereto.

13.08 *No Third Party Beneficiary.* Except as provided in *Section 6.06(d)*, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective successors or permitted assigns, and it is not the intention of the parties to confer third-party beneficiary rights upon any other Person.

13.09 *No Assignment; Binding Effect.* Neither this Agreement nor any right, interest or obligation hereunder may be assigned by any party hereto without the prior written consent of the other party hereto and any attempt to do so will be void, except (a) for assignments and transfers by operation of Law and (b) that Purchaser may assign any or all of its rights, interests and obligations hereunder to a wholly-owned Affiliate, *provided* that any such Affiliate agrees in writing to be bound by all of the terms, conditions and provisions contained herein, but no such assignment referred to in clause (b) shall relieve Purchaser of its obligations hereunder. Subject to the preceding sentence, this Agreement is binding upon, inures to the benefit of and is enforceable by the parties hereto and their respective successors and assigns.

13.10 *Enforcement of Agreement.* The parties hereto agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy would occur in the event that any of the provisions of this Agreement (including the failure by any party to take such actions as are required of it hereunder to consummate the transactions contemplated by this Agreement) was not performed in accordance with its specified terms or was otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of competent jurisdiction, this being in addition to any other remedy to which they are entitled at Law or in equity.

13.11 *Headings.* The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

13.12 *Governing Law; Consent to Jurisdiction.*

(a) This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to applicable principles of conflicts of law.

(b) Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of the State and Federal courts situated in Delaware in any action or proceeding arising out of or relating to this Agreement or the agreements delivered in connection herewith or the transactions contemplated hereby or thereby or for recognition or enforcement of any judgment relating thereto, and each of the parties hereby irrevocably and unconditionally (i) agrees not to commence any such action or proceeding except in such State or Federal court and (ii) waives, to the fullest extent such party may legally and effectively do so, any objection which such party may now or hereafter have to the laying of venue of any such action or proceeding in such State or Federal court. Each of the parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law. Each party to this Agreement irrevocably consents to service of process in the manner provided for notices in *Section 13.01*. Nothing in this Agreement will affect the right of any party to this Agreement to serve process in any other manner permitted by Law.

13.13 *Invalid Provisions.* If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of any party hereto under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom.

13.14 *Counterparts.* This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, this Amended and Restated Agreement and Plan of Merger has been duly executed and delivered by or on behalf of each party hereto as of the date first above written.

PURCHASER
Protein Design Labs, Inc.

Address:

By: /s/ DOUGLAS O. EBERSOLE
Name: Douglas O. Ebersole
Title: Senior Vice President,
Legal and Corporate Development

34801 Campus Drive
Fremont, CA 94555

MERGER SUB
Big Dog Bio, Inc.

Address:

By: /s/ DOUGLAS O. EBERSOLE
Name: Douglas O. Ebersole
Title: Treasurer and Secretary

34801 Campus Drive
Fremont, CA 94555

COMPANY
ESP Pharma Holding Company, Inc.

Address:

By: /s/ HOWARD J. WEISMAN
Name: Howard J. Weisman
Title: President and Chief Operating Officer

2035 Lincoln Highway, Suite 2150
Edison, New Jersey 08817

CONTRIBUTING STOCKHOLDERS

Address:

By: /s/ ANTHONY A. RASCIO
Name: Anthony A. Rascio
Title: Stockholders' Agent

2035 Lincoln Highway, Suite 2150
Edison, New Jersey 08817

Ownership of Shares and Company Options

Issue Date, Exercise Price and Vesting Schedule of Company Options

Escrow Agreement

QuickLinks

[AMENDED AND RESTATED AGREEMENT AND PLAN OF MERGER dated as of March 22, 2005 by and among PURCHASER, BIG DOG BIO, INC., ESP PHARMA HOLDING COMPANY, INC. and THE CONTRIBUTING STOCKHOLDERS REFERRED TO HEREIN](#)

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[Escrow Agreement](#)

OPINION OF DLA PIPER RUDNICK GRAY CARY US LLP

March 25, 2005
Securities and Exchange Commission
Judiciary Plaza
450 Fifth Street, N.W.
Washington, D.C. 20549

Re: Protein Design Labs, Inc. Registration Statement on Form S-3

Ladies and Gentlemen:

As counsel to Protein Design Labs, Inc., a Delaware corporation (the "Company"), we are rendering this opinion in connection with the preparation and filing of a registration statement on Form S-3 (the "Registration Statement") relating to the registration under the Securities Act of 1933, as amended, of up to 9,583,770 shares of common stock to be sold by the selling stockholders named in the Registration Statement (the "Shares").

We have examined all instruments, documents and records which we deemed relevant and necessary for the basis of our opinion hereinafter expressed. In such examination, we have assumed the genuineness of all signatures and the authenticity of all documents submitted to us as originals and the conformity to the originals of all documents submitted to us as copies.

Based on such examination, we are of the opinion that the Shares have been duly authorized and validly issued and are fully paid and nonassessable.

We hereby consent to the filing of this opinion as an exhibit to the above-referenced Registration Statement and to the use of our name wherever it appears in said Registration Statement, including the Prospectus constituting a part thereof, as originally filed or as subsequently amended.

Very truly yours,

/s/ DLA PIPER RUDNICK GRAY CARY US LLP

DLA Piper Rudnick Gray Cary US LLP

QuickLinks

[Exhibit 5.1](#)

[OPINION OF DLA PIPER RUDNICK GRAY CARY US LLP](#)

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" in Amendment No. 1 to the Registration Statement (Form S-3 No. 333-122760) and related Prospectus of Protein Design Labs, Inc. for the registration of 9,853,770 shares of its common stock and to the incorporation by reference therein of our reports dated March 11, 2005, with respect to the consolidated financial statements of Protein Design Labs, Inc., Protein Design Labs, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Protein Design Labs, Inc., included in its Annual Report (Form 10-K) for the year ended December 31, 2004, filed with the Securities and Exchange Commission.

/s/ ERNST & YOUNG LLP
Palo Alto, California
March 21, 2005

QuickLinks

[Exhibit 23.1](#)

[CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM](#)

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" in Amendment No. 1 to the Registration Statement (Form S-3 No. 333-122760) and related Prospectus of Protein Design Labs, Inc. for the registration of 9,853,770 shares of its common stock and to the incorporation by reference therein of our report dated March 12, 2004, with respect to the consolidated financial statements of ESP Pharma Holdings and Subsidiary, included in its Current Report (Form 8-K) dated February 7, 2005, filed with the Securities and Exchange Commission.

/s/ ERNST & YOUNG LLP
MetroPark, New Jersey
March 21, 2005

QuickLinks

[Exhibit 23.2](#)

[CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM](#)

DLA Piper Rudnick Gray Cary US LLP
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East Palo Alto, California 94303-2248
T 650.833.2271
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March 25, 2005

Via EDGAR and Facsimile

Division of Corporate Finance
U.S. Securities Exchange Commission
450 Fifth Street, N.W.
Washington, D.C. 20549
Attn: Mr. Jeffrey P. Riedler and Mr. Albert C. Lee

Re: Protein Design Labs, Inc.
Registration Statement on Form S-3
Filed February 11, 2005
File Number 333-122760

Ladies and Gentlemen:

We are writing on behalf of our client, Protein Design Labs, Inc. (the "Company"), in connection with the filing of Amendment No. 1 to the Company's Registration Statement on Form S-3, File No. 333-122760 (the "Registration Statement").

The Company wishes to advise the Securities and Exchange Commission (the "Commission") that, as provided for in the Instruction to Item 9.01 of Form 8-K, the financial statements required by Rule 3-05 of Regulation S-X will be timely filed.

Further comments or requests for information may be addressed to the undersigned at (650) 833-2271.

Very truly yours,

DLA Piper Rudnick Gray Cary US LLP

/s/ Elizabeth M. O'Callahan
elizabeth.ocallahan@dlapiper.com

cc: Glen Sato, Protein Design Labs, Inc.
J. Howard Clowes, DLA Piper Rudnick Gray Cary US LLP
