SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Quarterly Period Ended June 30, 2005

OR

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number: 0-19756

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3023969**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

34801 Campus Drive
Fremont, CA 94555
(Address of principal executive offices)

Telephone Number **(510) 574-1400**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and, (2) has been subject to such filing requirements for the past 90 days:

Yes ☒ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of Act). Yes ☒ No o

As of July 31, 2005 there were 107,104,133 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Revenues:				
Product Sales	$ 35,345	$ —	$ 36,293	$ —
Royalties	37,528	24,731	70,692	46,741
License and other	4,888	1,052	9,591	6,670
Total revenues	77,761	25,783	116,576	53,411
Costs and expenses:				
Cost of product sales	20,135	—	21,272	—
Research and development	40,339	32,009	75,600	65,038
Selling, general and administrative	19,806	7,450	27,472	15,518
Acquired in-process research and development	—	—	79,417	—
Total costs and expenses	80,280	39,459	203,761	80,556
Operating loss	(2,519)	(13,676)	(87,185)	(27,145)
Interest and other income, net	1,873	2,583	4,808	4,867
Interest expense	(2,709)	(1,351)	(4,851)	(2,736)
Loss before income taxes	(3,355)	(12,444)	(87,228)	(25,014)
Provision for income taxes	65	8	87	56
Net loss	$ (3,420)	$ (12,452)	$ (87,315)	$ (25,070)
Net loss per basic and diluted share	$ (0.03)	$ (0.13)	$ (0.87)	$ (0.27)
Shares used in computation of net loss per basic and diluted share:	103,705	94,587	100,230	94,294

See accompanying notes.

PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS
(unaudited)
(In thousands, except per share data)

	June 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,667	$ 91,395

Marketable securities, including $6.8 million and $6.9 million of restricted investments at June 30, 2005 and December 31, 2004, respectively	150,942	298,969
Accounts receivable, net of allowances of $5.1 million	16,941	—
Inventories	18,142	—
Other current assets	10,647	9,750
Total current assets	233,339	400,114
Land, property and equipment, net	256,443	238,077
Goodwill	67,359	—
Other intangible assets, net	449,896	31,309
Restricted investments	3,369	6,716
Other assets	14,490	7,516
Convertible note receivable	30,000	30,000
Total assets	**$ 1,054,896**	**$ 713,732**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,949	$ 4,921
Accrued compensation	12,158	6,977
Accrued clinical trial costs	2,285	1,324
Accrued interest	4,468	2,593
Royalties payable	3,012	—
Income taxes payable	2,345	—
Other accrued liabilities	21,455	9,327
Deferred revenue	16,332	17,389
Current portion of long-term obligations	752	923
Total current liabilities	69,756	43,454
Convertible subordinated notes	499,998	249,998
Notes payable	7,123	7,469
Other long-term debt	426	301
Total liabilities	577,303	301,222
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value $0.01 per share, 250,000 shares authorized; 106,806 and 95,857 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively	1,068	959
Additional paid-in capital	839,048	686,302
Accumulated deficit	(360,847)	(273,532)
Accumulated other comprehensive loss	(1,676)	(1,219)
Total stockholders' equity	477,593	412,510
Total liabilities and stockholders' equity	**$ 1,054,896**	**$ 713,732**

See accompanying notes.

PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(In thousands)

	Six Months Ended June 30,	
	2005	2004
Cash flows from operating activities:		
Net loss	$ (87,315)	$ (25,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	79,417	—
Depreciation and amortization	7,207	5,528
Amortization of convertible notes offering costs	1,032	605
Stock-based compensation expense	322	560
Amortization of intangible assets	14,113	1,176
Loss on disposal of fixed assets	—	514
Changes in assets and liabilities:		
Inventories	1,570	—
Accounts receivable, net	(19,451)	—
Interest receivable	322	407
Other current assets	1,007	5,448
Other assets	163	(88)
Accounts payable	192	2,422
Accrued liabilities	54	(6,852)
Deferred revenue	(1,057)	(161)
Total adjustments	84,891	9,559
Net cash used in operating activities	(2,424)	(15,511)
Cash flows from investing activities:		
Purchases of marketable securities	—	(235,353)

Maturities of marketable securities	147,060	90,000
Maturities of restricted investments	3,438	3,913
Cash paid for ESP acquisition	(325,000)	—
Cash obtained from ESP	2,442	—
Cash paid for Retavase acquisition	(110,000)	—
Purchases of land, property and equipment	(23,270)	(58,877)
Net cash used in investing activities	(305,330)	(200,317)
Cash flows from financing activities:		
Proceeds from issuance of capital stock	11,587	11,900
Proceeds from issuance of convertible notes	241,831	—
Payments on other long-term obligations	(392)	(753)
Net cash provided by financing activities	253,026	11,147
Net decrease in cash and cash equivalents	(54,728)	(204,681)
Cash and cash equivalents at beginning of period	91,395	341,768
Cash and cash equivalents at end of period	$ 36,667	$ 137,087

See accompanying notes.

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
June 30, 2005
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. (we, us, our, PDL or the Company) is a biopharmaceutical company focused on the research, development and commercialization novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several biopharmaceutical products in the United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products.

On June 8, 2005, our stockholders approved a change in the name of the Company to PDL BioPharma, Inc., but this name change is not yet effective.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The accompanying consolidated condensed financial statements are unaudited, but include all adjustments (consisting only of normal recurring adjustments), which we consider necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in our financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission for quarterly reporting.

The information included in this quarterly report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2004. The Consolidated Condensed Balance Sheet as of December 31, 2004 is derived from our audited consolidated financial statements.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim consolidated condensed financial statements may not be indicative of results for any other interim period or for the entire year. For example, we receive a substantial portion of our royalty revenues on sales of the product *Synagis*® marketed by MedImmune. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters. In addition, as a result of the closing of our acquisition of ESP Pharma Holding Company, Inc. (ESP) on March 23, 2005, the results of operations of ESP from March 24, 2005 through June 30, 2005 are included in the six months of 2005 and the full second quarter of 2005 in our consolidated condensed financial statements (see Note 6).

Principles of Consolidation

The consolidated condensed financial statements include the accounts of the Company and its wholly owned subsidiaries after elimination of inter-company accounts and transactions.

Reclassifications

Certain reclassifications of prior-year amounts have been made to conform to the current-year presentation.

Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in, first-out method. If the inventory costs exceed the market value, reserves are recorded currently for the difference between the cost and the market value. These reserves are determined based on management's estimates. Inventories consist of finished goods and

raw materials (including active pharmaceutical ingredients). As a result of the ESP and *Retavase*® acquisitions (see Notes 6 and 7), we acquired and recorded certain inventories at fair market value, which approximated the original cost of the inventory purchased from third-party manufacturers.

Revenue Recognition

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

If we determine that separate elements exist in a revenue arrangement under Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

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

Product Sales

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

Accounts Receivable, Sales Allowances and Rebate Accruals

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

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

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

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

Royalties

Under most of our patent license agreements, we receive royalty payments based upon our licensees' net sales of products. Generally, under these agreements we receive royalty reports from our licensees approximately one quarter in arrears; that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. We also receive royalties on a generic product that we have licensed for sale. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably

assured. Accordingly, we recognize royalty revenue in the quarter reported to us by our licensees (i.e., generally royalty revenue is recognized one quarter following the quarter in which sales by our licensees occurred).

License and Other

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

Upfront License and License Maintenance Fees

We generally recognize revenue from upfront fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Revenues recognized from upfront fees typically relate to patent license and patent rights agreements. Generally there are three types of collaboration arrangements PDL enters into under which we provide access to our proprietary patent portfolio covering the humanization of antibodies.

- Under Patent License Agreements, the licensee typically obtains a non-exclusive license to one or more of our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements. Consideration that we receive for patent license agreements is recognized upon execution and delivery of the patent license agreement and when payment is reasonably assured. Nonrefundable upfront licensing fees, including certain guaranteed, time-based payments that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue either (a) ratably over the development period if development risk is significant, or (b) ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.

- Under Patent Rights Agreements, the licensee purchases a research patent license in exchange for an upfront fee. In addition, the licensee has the right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. The licensee performs all of the research, and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses; therefore, upon delivery of the patent rights agreement, the earnings process is complete. When a licensee exercises its right to obtain patent licenses to certain designated drug targets for commercial purposes, we recognize the related consideration as revenue upon the licensee's exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.

- Under Humanization Agreements, the licensee typically pays an upfront fee for us to humanize an antibody. These upfront fees are recognized as the humanization work is performed, which is typically over three to six months.

Under Patent License Agreements and Humanization Agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

Milestones

We enter into patent license and humanization agreements that may contain milestones related to reaching particular stages in product development. We recognize revenues from milestones when we have no further obligation with respect to the activities under the agreement and when we have confirmed that the milestone has been achieved. Where we have continuing involvement obligations in the form of development, manufacturing or other commercialization efforts, we recognize revenues from milestones either (a) ratably over the development period if development risk is significant, or (b) ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated. Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization Agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones generally include delivery of a humanized antibody meeting a certain binding affinity and, at the customer's election, delivery of a cell line meeting certain criteria described in the original agreement.

- Patent License Agreements and Humanization Agreements sometimes require our licensees to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the licensee's product.

- We may also receive certain milestone payments in connection with licensing technology to or from our licensees, such as product licenses. Under these agreements, our licensees may make milestone payments to us when they or we achieve certain levels of

development with respect to the licensed technology.

Reimbursement of Development Costs

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

Advertising and Promotion

The Company engages in promotional activities, which typically take the form of industry publications, journal ads, hospital grants, exhibits, speaker programs, and other forms of media. In accordance with procedures defined under Statement of Position 93-7, "Reporting on Advertising Costs," advertising and promotion expenditures are expensed as incurred. Total advertising costs incurred during the three and six months ended June 30, 2005 were $10.2 million and $10.4 million, respectively, and no such costs were incurred in 2004.

Stock-Based Compensation

As of June 30, 2005, we had six stock-based employee compensation plans. We account for our plans under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations. During the quarters ended June 30, 2005 and 2004, we recognized approximately $144,000 and $363,000 respectively, in stock-based compensation expense related to the modification of certain employee stock option awards. The tables below illustrate the effect on net loss and net loss per share if we had applied the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), as amended by FASB Statement No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure," to our stock-based employee compensation plans.

	Three Months Ended	Six Months Ended

(In thousands, except per share data)	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Net loss, as reported	$ (3,420)	$ (12,452)	$ (87,315)	$ (25,070)
Add: Stock-based employee compensation expense included in reported net loss, net of taxes	144	363	144	363
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards, net of taxes	(4,867)	(4,216)	(8,792)	(9,504)
Pro forma net loss	$ (8,143)	$ (16,305)	$ (95,963)	$ (34,211)
Basic and diluted net loss per share:				
As reported	$ (0.03)	$ (0.13)	$ (0.87)	$ (0.27)
Pro forma	$ (0.08)	$ (0.17)	$ (0.96)	$ (0.36)

For the periods presented in the table below, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Expected life, in years	2.9	2.7	2.8	2.7
Risk-free interest rate	3.7%	3.0%	3.6%	2.4%
Volatility	61%	67%	64%	70%
Dividend yield	0	0	0	0

In December 2004, the FASB issued Statement No. 123R “Share Based Payment,” (SFAS 123R) which revises SFAS No. 123 and requires all equity-based awards to employees to be recognized in the statement of operations based on their fair values. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for

compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are evaluating the requirements of SFAS 123R and we expect that the adoption of SFAS 123R will have a material impact on our consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting SFAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Under the current regulations, as amended in April 2005, we will be required to adopt the final standard no later than January 1, 2006.

We account for stock options granted to non-employees at fair value using the Black-Scholes option-pricing model in accordance with EITF 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with, Selling, Goods or Services.” Stock options granted to non-employees are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense over the service period in which the non-employee provides services to the Company. We recognized stock-based compensation expense related to stock options issued to non-employees of approximately $178,000 and $169,000 for the six months ended June 30, 2005 and 2004, respectively, and $30,000 and $124,000 for the three months ended June 30, 2005 and 2004, respectively.

Segment and Concentrations Disclosure

In accordance with FASB Statement No. 131, “Disclosure About Segments of an Enterprise and Related Information” we are required to report operating segments and related disclosures about our products, services, geographic areas and major customers. We have only one segment with facilities located primarily within the United States. The majority of our revenues are earned in the United States.

Sales of *Cardene* IV and *Retavase* accounted for 79% of total product sales in the second quarter of 2005, and 78% of total product sales in the first half of 2005.

Royalty, license and other revenues from Genentech in the second quarters of 2005 and 2004 accounted for 25% and 38% of total revenues, respectively, and revenues from Genentech in the first half of 2005 and 2004 accounted for 31% and 33% of total revenues, respectively. Royalty, license and other revenues from MedImmune in the second quarters of 2005 and 2004 accounted for 19% and 52% of total revenues, respectively, and revenues from MedImmune in the first half of 2005 and 2004 accounted for 23% and 47% of total revenues, respectively. No other revenue from any other source exceeded 10% of total revenues for any periods presented.

Goodwill, Other Intangible Assets and Other Long-Lived Assets

Intangible assets consist of purchased core technology, a reversion right to purchase certain technology from Roche, product rights obtained through the acquisition of ESP and licensed research technology. In accordance with FASB Statement No. 142, “Goodwill and Other Intangible Assets” (SFAS 142), we are amortizing our intangible assets with definite lives over their estimated useful lives and review them for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We are amortizing the core technology, product rights and licensed research technology assets on a straight-line basis over their estimated useful lives, 10, 4 to 12, and 5 years, respectively. We will reclassify the reversion right asset into core technology at that time when the rights to the technology revert back to us. Upon reclassifying the reversion right asset to core technology, we will amortize the asset over the remaining term of the patents underlying the acquired technology. Amortization of intangible assets is included primarily in research and development expenses and costs of product sales in the Consolidated Statement of Operations.

On March 23, 2005, we recorded goodwill in connection with our acquisition of ESP (see Note 6). In accordance with SFAS 142, we do not amortize goodwill. We will test goodwill for impairment using a two-step process on an annual basis, and between annual tests under certain circumstances. Factors that are considered important when evaluating whether impairment might exist include a significant adverse change in the business climate, unanticipated competition, loss of key personnel, significant continued under-performance compared to peers, or other factors specific to each asset or reporting unit being evaluated. Any changes in key assumptions about the business and its prospects, or changes in market conditions or other externalities, could result in an impairment charge and such a charge could have a material effect on our consolidated results of operations.

In accordance with FASB Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," we identify and record impairment losses, as circumstances dictate, on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the discounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. No such impairments have been identified with respect to our long-lived assets, which consist primarily of property and equipment and the intangible assets discussed above.

2. Net Loss Per Share

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

The total weighted-average number of shares excluded from the calculations of diluted net loss per share for outstanding convertible notes was 22,968,418 and 12,415,450 for the three months ended June 30, 2005 and 2004, respectively, and 20,403,010 and 12,415,450 for the six months ended June 30, 2005 and 2004, respectively. The total weighted-average number of shares excluded from the calculation of diluted net loss per share for stock options was 11,111,923 and 8,185,037 for the three months ended June 30, 2005 and 2004, respectively, and 11,299,958 and 8,148,452 for the six months ended June 30, 2005 and 2004, respectively.

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and the change in unrealized gains and losses on our available-for-sale securities. The following table presents the calculation of our comprehensive loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2005	2004	2005	2004
Net loss	$ (3,420)	$ (12,452)	$ (87,315)	$ (25,070)
Other comprehensive loss:				
Change in unrealized gains and losses on marketable securities	815	(2,122)	(457)	(2,267)
Total comprehensive loss	$ (2,605)	$ (14,574)	$ (87,772)	$ (27,337)

4. Inventory

Inventories consisted of the following:

(In thousands)	June 30, 2005	December 31, 2004
Raw materials	$ 2,500	$ —
Work-in-process	12,486	—
Finished goods	3,156	—
	$ 18,142	$ —

5. Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(In thousands)	June 30, 2005	December 31, 2004
Construction-in-process	$ 1,584	$ 3,810
Consulting and services	6,873	5,229
Sales rebates	10,055	—
Other	2,943	288
	$ 21,455	$ 9,327

6. ESP Pharma Acquisition

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

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP. The aggregate preliminary purchase price was approximately $471.3 million, including the cash paid to ESP stockholders of $325.0 million, the fair value of 9,853,770 shares of PDL's common stock issued to ESP stockholders totaling approximately $140.9 million, and estimated direct transaction costs of approximately $5.4 million. The value assigned to our common stock issued to ESP stockholders was based on the average closing market price of our common stock a few days before and after the "measurement date." In accordance with EITF Issue No. 99-12, "Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination," the measurement date was the date on which the number of shares issuable to ESP became fixed at 9,835,770 (March 4, 2005). The ESP acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The results of operations of ESP from March 24, 2005 have been included in our three and six months ended June 30, 2005 condensed consolidated financial statements.

Of the 9,853,770 shares of PDL common stock issued to ESP stockholders, 2,523,588 shares will remain in an escrow account for a period of between six months and one year from the date of the close of the acquisition, pursuant to the terms of the Amended and Restated Agreement and Plan of Merger. We currently expect to issue substantially all of the shares to the former ESP stockholders at the end of this contingency period, and as such, we have included the value for all shares issued in the purchase price of ESP.

As part of the purchase and included in the $325.0 million paid to ESP stockholders, ESP had established a workforce reduction plan and as of the acquisition date, approximately $7.4 million of employee termination costs had been recorded as a severance liability to be paid out over a period of approximately 1 year. ESP stockholders were obligated to pay such termination costs from the cash acquisition proceeds of $325 million. At June 30, 2005, approximately $0.5 million of these ESP termination costs remained as a liability.

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

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

Based in part upon an independent third-party valuation of the intangible assets acquired, we have allocated the total purchase price on March 23, 2005 as follows (in thousands):

Net liabilities	$	(14,640)
Goodwill		67,359
Intangible assets		339,200
Acquired in-process research and development		79,417
	$	471,336

The $339.2 million value assigned to the intangible assets relates to product rights for the six products sold by ESP, and this value will be amortized over periods between 4 and 12 years, or a weighted-average period of approximately 10 years, the estimated useful lives of these assets.

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

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

The nature of the remaining efforts for completion of ESP's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist which could prevent completion of development, including the uncertainty and timing of patient enrollment and uncertainties related to the results of the clinical trials, and obtaining FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that these potential products will be approved in the United States or the European Union or whether marketing

approvals will have significant limitations on their use. The acquired products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals and the fact that the cost of sales to produce these products in a commercial setting has not been determined. As a result, we may make a strategic decision to discontinue development of a given product if we do not believe successful commercialization is possible. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 14%. This discount rate is a significant assumption and is based on our estimated weighted-average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets. In determining the value of the in-process research and development, the assumed commercialization dates for these potential products begins in 2007.

The unaudited pro forma results of operations for the three and six months ended June 30, 2005 and 2004L are set forth below (in thousands, except per share amounts). This presentation assumes that the ESP acquisition had been consummated as of the beginning of each period presented. The net loss includes, on a pre-tax basis, $79.4 million for the write-off of acquired in-process research and development costs and $12.9 million and $22.1 million for the amortization of intangible assets for the three and six months ended June 30, 2005, respectively, and $8.9 million and $18.0 million for the three and six months ended June 30, 2004, respectively.

Pro Forma Results

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2005**	**2004**	**2005**	**2004**
Revenue	$ 77,761	$ 48,281	$ 136,864	$ 102,442
Net loss	(3,420)	(17,512)	(102,293)	(111,398)
Basic and diluted net loss per share	$ (0.03)	$ (0.17)	$ (1.02)	$ (1.10)

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

7. *Retavase*® Acquisition

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

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

Tangible assets	$ 16,500
Intangible assets	93,500
Transaction costs	500
	$ 110,500

The $93.5 million value assigned to the intangible assets is amortized over periods between 3 and 8 years, or a weighted-average period of 7.9 years, the estimated useful lives of these assets.

8. Convertible Debt

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

9. Restructuring Charges

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials in June 2004, management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company’s total workforce, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, we incurred a charge of approximately $305,000, including an adjustment in the fourth quarter of 2004 related to the extension of a sublease of the facilities, $288,000 of which was included in research and development expenses in the Statement of Operations in the quarter ended June 30, 2004. The restructuring charge included approximately $164,000 of severance-related amounts, $97,000 of which was included in the quarter ended June 30, 2004, $119,000 of committed costs for our New Jersey leased facility (net with expected proceeds from a short-term sublease entered into in October 2004), $169,000 of which was included in the quarter ended June 30, 2004, primarily related to lease expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned at the facility. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005, partially offset by expected proceeds from a short-term sublease entered into in October 2004. The balance of the severance costs was paid during the third quarter of 2004, and we expect to pay the facility-related costs through October 2005. The actual

future cash requirements were adjusted downward from the accrual at June 30, 2004 due to subleasing the facility. We expect to pay the balance of the accrued facility related costs of approximately $16,000 at June 30, 2005 through October 2005.

Also in the second quarter of 2004, we completed the first phase of a physical inventory of substantially all of our laboratory equipment at our Fremont facilities. As a result, we recorded a charge to research and development expenses of $300,000, which represented the estimated amount of net book value of assets that are no longer in use. The physical inventory of these assets was completed in the fourth quarter of 2004 and resulted in an actual charge of approximately $277,000.

10. Postretirement Benefit Plan

In June 2003, we established a postretirement health care plan, which covers medical, dental and vision coverage for certain of our former officers and their dependents. During the three months ended June 30, 2005 and 2004, we recognized net periodic benefit cost of approximately $90,000 and $62,000, respectively, and during the six months ended June 30, 2005 and 2004 we recognized net periodic benefit costs of approximately $162,000 and $124,000, respectively. This expense includes service cost, interest cost, and amortization of prior service cost.

11. Subsequent Event

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

Under terms of the agreement, PDL will receive an upfront payment of $40 million, and Biogen Idec will purchase $100 million of common stock from PDL. The closing of the transaction, including the stock purchase, is subject to antitrust review and approval, and other standard closing conditions. The purchase of the stock will be at fair market value.

We and Biogen Idec will share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies will jointly oversee development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise.

PDL will be eligible for development an commercialization milestones based on the further successful development of these molecules, if achieved. Each party will have co-promotion rights in the United States and Europe. Outside the United States and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to PDL on sales of collaboration products.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "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 in this report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

OVERVIEW

We are a biopharmaceutical company focused on the research, development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several biopharmaceutical products in the United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products. On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma Holding Company, Inc. (ESP), a privately held, hospital-focused pharmaceutical company. The aggregate preliminary purchase price was approximately $471.3 million, including the cash paid to ESP stockholders of $325.0 million, the fair value of 9,853,770 shares of PDL's common stock issued to ESP stockholders totaling approximately $140.9 million, and estimated direct transaction costs of approximately $5.4 million. The ESP acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The results of operations of ESP from March 24, 2005 have been included in our first quarter consolidated condensed financial statements.

Also on March 23, 2005, ESP completed its acquisition of rights to manufacture, develop, market and distribute *Retavase*® in the United States and Canada. The aggregate purchase price was approximately $110.5 million, including the cash paid to Centocor of $110.0 million and estimated direct transaction costs of approximately $0.5 million.

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

Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of June 30, 2005, we had an accumulated deficit of approximately $360.8 million. Our expenses will continue to increase over the next several years because of the extensive resource commitments required to identify and develop antibody candidates to achieve regulatory approval, to market and sell products and to develop potential products. Also, over the next several years we expect to incur substantial additional expenses as we continue to invest in research and improve and expand our development and manufacturing capabilities.
Our operating expenses may also increase as some of our earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as we invest in additional manufacturing capacity, as we defend or prosecute our patents and patent applications, and as we invest in research or acquire additional technologies, product candidates or businesses.

The integration of the product rights, technologies, operations and personnel of PDL and ESP will be a complex, time consuming and expensive process and will require significant attention from management and other personnel, which may distract their attention from the day-to-day business of the combined company. The diversion of management's attention and any difficulties associated with

integrating ESP into our organization could have a material adverse effect on our operating results after the merger and could result in our not achieving the anticipated benefits of the merger.

In order to reach our goal to be cash flow positive on a quarterly basis beginning in the fourth quarter of 2005, we will have to continue to increase sales from historical levels for *Cardene* IV, *Retavase* and IV *Busulfex*. Accordingly, we will need to continue to effectively transition existing relationships with distributors, third-party vendors, manufacturers and customers of ESP. Although we have retained 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 and further grow such capabilities from ESP necessary to continue to successfully promote the ESP products. In addition, the markets for *Cardene* IV and *Retavase* are highly competitive, and we will be marketing against pharmaceutical, biopharmaceutical and specialty pharmaceutical companies with substantially greater revenues and experience in marketing products than we have.

Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market our proprietary products or maintain desired margins for products sold, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach a sustainable cash flow positive position and profitability are highly uncertain.

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

In addition, as of June 30, 2005 we have approximately $500 million in convertible notes outstanding, approximately $250 million of which are callable in each of 2008 and 2010. In order to be able to service our debt in the future, we will need to generate positive cash flows from our operations or obtain other financing.

Significant Events

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

Under terms of the agreement, PDL will receive an upfront payment of $40 million, and Biogen Idec will purchase $100 million of common stock from PDL. The closing of the transaction, including the stock purchase, is subject to antitrust review and approval, and other standard closing conditions. The purchase of the stock will be at fair market value.

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

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition

We currently recognize revenues resulting from the licensing and use of our technology and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the development, use, sale and importation of humanized antibodies. In addition, as a result of the acquisition of ESP, we recognize revenues from product sales, net of estimated allowances for cash discounts, product returns and rebates. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated discounts, product returns, bad debts, and rebates.

We enter into patent license, collaboration and humanization agreements that may contain multiple elements, such as upfront license fees, reimbursement of research and development expenses, milestones related to the achievement of particular stages in product development and royalties. As a result, significant

contract interpretation is sometimes required to determine the appropriate

accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element. We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our licensee confirms that we have met the requirements under the terms of the agreement, and when payment is reasonably assured. Changes in the allocation of the contract value between deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract. For example, as we did not establish fair value for all undelivered elements of the Roche Collaboration Agreement, including milestones and the reimbursement of research and development expenses, we are recognizing the $17.5 million upfront license fee that we received from Roche over the term of the Collaboration Agreement as services are provided.

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

Under our humanization agreements, the licensee typically pays an upfront fee for us to “humanize” an antibody. These upfront fees are recognized as the humanization work is performed, which is typically over three to six months. We follow this method because we can reliably estimate the progress of each project based on information from our scientists. Due to our extensive experience in humanizing antibodies, coupled with the short-term nature of the humanization contracts, the likelihood that the actual progress is materially different than that reflected in our revenues at the end of any particular reporting period is low. Historically, revenues recognized have approximated actual progress under each humanization agreement.

Sales Allowances and Rebate Accruals

We record estimated reductions to product sales for expected returns of products under our current policies, chargebacks, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are based on contractual terms, historical utilization rates experienced by ESP and expectations regarding future utilization rates for these programs. Estimates for product returns, including new products, are based on an on-going analysis of industry and historical return patterns experienced by ESP and the companies from which ESP acquired their products. Our current estimates include monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, reviewing inventory data available to us in monitoring channel inventory levels, the purchase of third-party data to monitor prescriptions as well as, for new products, a review of our products we have sold through the same or similar channels. In addition, our estimates are based on the historical chargeback data we receive from wholesalers and the applicable customer chargeback rates, returns and rebate thresholds we have from Wyeth and Centocor with respect to *Cardene* IV and *Retavase*, respectively. Further, we monitor the activities and clinical trials of our key competitors and assess the potential impact on our future sales and return expectations where necessary. If conditions become more competitive for any of the markets served by our drugs or if other circumstances change, we may take actions to increase our product return estimates or we may offer additional customer incentives. This would result in an incremental reduction of future revenue at the time the return estimate is changed or new incentives are offered. Product sales receivable allowances for chargebacks, returns and rebate accruals require substantial judgment. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made, based on actual results.

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

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, direct expenses related to each patient enrolled in a clinical trial are

recognized on an estimated cost-per-patient basis as services are performed. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from contract research organizations (CROs), such as estimated costs per patient, to calculate our accrual for direct clinical expenses at the end of each reporting period. For indirect expenses, which relate to site and other administrative costs to manage our clinical trials, we rely on information provided by the CRO, including costs incurred by the CRO as of a particular reporting date, to calculate our indirect clinical expenses. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial, which we confirm directly with the CRO. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred; however, our experience has been that our estimates at the end of any particular reporting period have been materially accurate.

Goodwill and Other Intangible Assets

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

Once the values for intangible assets are established, we must test intangible assets with definite useful lives for impairment in accordance with Financial Accounting Standards Board (FASB) Statement No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." When we conduct our impairment tests for intangibles, factors that are considered important in determining whether impairment might exist include significant changes in our underlying business and product candidates or other factors specific to each asset being evaluated. Any changes in key assumptions about the business and its prospects, or changes in market conditions or other externalities, could result in an impairment charge and such a charge could have a material adverse effect on our consolidated results of operations.

RESULTS OF OPERATIONS

Three and Six Months Ended June 30, 2005 and 2004

Revenues

	Three Months Ended June 30,			Six Months Ended June 30,		
(In thousands)	2005	2004	% Change	2005	2004	% Change
Product sales, net	$ 35,345	$ —	—%	$ 36,293	$ —	—%
Royalties	37,528	24,731	52%	70,692	46,741	51%
License and other	4,888	1,052	364%	9,591	6,670	43%
Total revenues	$ 77,761	$ 25,783	202%	$ 116,576	$ 53,411	118%

Product sales, net

We acquired marketed products from the acquisition of ESP, which closed on March 23, 2005. Total product sales in the second quarter of 2005, our first full quarter of ownership of the acquired ESP products, were $35.3 million. Net product sales of *Cardene* IV, IV *Busulfex* and *Retavase* totaled $33.8 million for the period. Off-patent brand sales for the period totaled $1.5 million. During the quarter, we increased our reserves for product sales by approximately $3.2 million due primarily to inventory levels of the off-patent brand products, in particular *Declomycin*, that are currently in the hands of the wholesaler channel. *Declomycin* sales to the end users have been adversely affected by a significant price increase in the context of the introduction of two generic competitors for this product in the second half of 2004.

In the first quarter of 2005, we recorded product sales solely for the period from March 24, 2005 to March 31, 2005.

As of June 30, 2005, we had approximately $34.0 million of product sales on hold. The product sales on hold consisted of *Cardene* of $20.6 million, *Retavase* of $10.6 million, and *Busulfex* and other ESP products of $2.8 million. Shipments of *Cardene*, and *Busulfex* and other ESP products were not shipped, as natural end-customer demand at the hospital level did not reflect the large orders at the wholesaler level. Instead, we believe these large orders at the wholesaler level reflect speculative purchasing in advance of anticipated price increases. Management has been in communication with the major wholesalers with the request that they only order product based on natural end-customer demand.

On March 23, 2005, ESP completed its acquisition of rights to manufacture, develop, market and distribute *Retavase* in the United States and Canada. We re-launched *Retavase* in April 2005. As a result of this re-launch, we had a stock-out situation on *Retavase*. During May and June, we implemented an allotment program, which provided product to wholesalers that stocked-out and for emergency requests. In addition, we have experienced a delay in transferring the product labeling from Centocor to ESP. We expect to have these issues resolved by the end of the third quarter of 2005.

Royalties

Royalty revenues increased during the three and six months ended June 30, 2005 compared to the comparable periods in 2004 due primarily to royalties recognized on sales of Genentech's *Avastin* product, which was launched in the first quarter of 2004. Royalty payments from sales of Genentech's products accounted for 51% and 53% of total royalty revenues during the three and six months ended June 30, 2005, respectively, up from 40% and 38% in the comparable period of 2004, respectively. Sales of MedImmune's product accounted for 40% and 40% of total royalty revenues for the three and six months ended June 30, 2005, respectively, down from 54% and 54% in the comparable periods in 2004.

In addition, the increase in royalty revenues is attributable to higher reported product sales for most products in our royalty portfolio during the first two quarters of 2005 as compared to the first two quarters of 2004. The largest portion of this increase relates to Genentech's *Herceptin* and *Avastin*, and MedImmune's *Synagis* humanized antibody products. Royalty payments from sales of *Herceptin*, *Avastin* and *Synagis* accounted for 26%, 17% and 40% of our royalty revenues for the three months ended June 30, 2005 as compared to 31%, 0% and 54% in the comparable period in 2004, respectively. Royalty payments from sales of *Herceptin*, *Avastin* and *Synagis* accounted for 29%, 17% and 40% of our royalty revenues for the six months ended June 30, 2005 as compared to 32%, 0% and 54% in the comparable period in 2004, respectively.

We expect that royalty revenues will continue to increase as sales of these products continue to increase. Further, we expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of *Synagis*, which results in higher royalty revenues reported to us in the first and second quarters of the year as compared to the third and fourth quarters.

License and Other

License and other revenues recognized during the first and second quarters of 2005 and 2004 primarily consisted of upfront licensing and patent rights fees, milestone payments related to licensed technology and license maintenance fees. Also included in license and other revenues for the first two quarters of 2005 are revenues recognized under our asthma collaboration with Roche, which we entered into in September 2004.

License and other revenues increased in the second quarter of 2005 compared to the second quarter of 2004 primarily due to the recognition in the second quarter of 2005 of an upfront license fee from Glycart Biotechnology AG, a milestone payment in connection with a license agreement with Progenics Pharmaceuticals, Inc., and revenue recognized under our asthma collaboration with Roche, with no corresponding revenue during the 2004 period.

License and other revenues decreased in the first half of 2005 compared to the first half of 2004 primarily due to the recognition in the first quarter of 2004 of upfront license fees from Genentech for its *Avastin* antibody product following approval by the U.S. Food and Drug Administration and an upfront license fee in connection with certain agreements signed with Seattle Genetics, Inc., with no such revenue during the 2005 period. Partially offsetting these decreases when compared to the first half of 2004 was revenue recognized under our asthma collaboration with Roche during the first quarter of 2005.

Costs and Expenses

(In thousands)	Three Months Ended June 30, 2005	2004	% Change	Six Months Ended June 30, 2005	2004	% Change
Cost of product sales	$ 20,135	$ —	—%	$ 21,272	$ —	—%
Research and development	40,339	32,009	26%	75,600	65,038	16%
Selling, general and administrative	19,806	7,450	166%	27,472	15,518	77%
Acquired in-process research and development	—	—	—	79,417	—	—
Total costs and expenses	$ 80,280	$ 39,459	103%	$ 203,761	$ 80,556	153%

Cost of Product Sales

Cost of product sales (COS) of $20.1 million and $21.3 million as a percentage of product sales was 57% and 59% for the three and six months ended June 30, 2005, respectively, with no such costs incurred in 2004COS largely reflects cost of goods sold, amortization of product rights on *Retavase* and the products acquired from ESP, royalty expenses, and certain start-up production

costs related to the transition of sales and shipping responsibilities to us from Centocor for *Retavase*. Amortization of product rights was 59% and 61% of COS for the three and six months ended June 30, 2005, respectively, with no such costs incurred in 2004. For the full year 2005, due principally to the amortization of product rights for our marketed products, we continue to expect COS to be in the range of approximately 55% to 58% of product sales, with continued quarter-to-quarter variability based on product mix changes and production results, acknowledging that there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing, or inventory related issues.

Research and Development

Research and development costs of $40.3 million in the second quarter of 2005 include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. The increase in the second quarter of 2005 compared to the second quarter of 2004 was primarily due to an increase in personnel headcount of approximately 126 employees in research and development from June 30, 2004 to June 30, 2005 and associated costs of approximately $4.6 million, an increase in outside services of $1.1 million, an increase in production material costs of $2.4 million, a decrease in contract manufacturing costs of $2.8 million and an increase in facility-related costs of $2.2 million.

The increase in research and development costs during the first six months of 2005 compared to the same period in 2004 was primarily due to an increase in research and development personnel headcount with associated costs of approximately $11.5 million, an increase in facility-related costs of $4.8 million, an increase in production material costs of $2.7 million, an increase in outside service costs of $1.6 million, a decrease in research and development licensing costs of $5.7 million, a decrease in contract manufacturing services of $4.8 million, and lower clinical development expenses for our major research and development projects of approximately $0.6 million. We expect our research and development expenses will increase further as we advance our product candidates into later stages of development and add new product candidates.

Below is a summary of products and the latest related stages of development for each product in clinical development, including the research and development expenses recognized in connection with each product.

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Six Months Ended June 30, 2005	2004
Current Product Candidates						
Daclizumab					$ 18,116	$ 15,612
	Asthma	Phase IIa	Roche	Completed		
	Multiple Sclerosis	Phase II		2007		
Ularitide (1)					1,144	N/A
	Decompensated Congestive Heart Failure	Phase II	Cardiopep GmbH	Completed 2005		
Terlipressin (2)					1,012	N/A
	Type 1 Hepatorenal Syndrome	Phase III	Orphan Therapeutics LLC	2006		

HuZAF	Crohn's Disease	Phase II	—	2005	2,013	5,523
Nuvion					12,940	10,611
	Severe steroid-refractory ulcerative colitis	Phase I/II	—	2005		
	Crohn's Disease	Phase II	—	2006		
M200	Solid tumors	Phase II	—	2006	10,502	11,400
Other (3)			—		29,873	21,892
	Total Research and Development Expenses				**$ 75,600**	**$ 65,038**

(1) We assumed development responsibility in Q2 2005. The Phase II study was completed by Cardiopep in Europe. PDL has worldwide development and commercialization rights to this product.
(2) Orphan Therapeutics has development responsibility for this molecule; PDL has exclusive marketing rights in the U.S. and Canada.
(3) No single clinical product included in "other" constitutes more than 5% of the total research and development expenses for the periods presented.

The information in the column labeled "Estimated Completion of Phase" is our current estimate of the timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates provided in the table. The clinical development portion of these programs may span as many as 7 to 10 years and any further estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing biopharmaceutical products, including significant and changing government regulation, the uncertainty of future preclinical and clinical study results and uncertainties associated with process development and manufacturing as well as marketing. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the "Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we can not accurately predict the timing and level of such expenses," "If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products," "Our clinical trial strategy may increase the risk of clinical trial difficulties," "If we do not attract and retain key employees, our business could be impaired," and "We may be unable to obtain or maintain regulatory approval for our products" sections of our Risk Factors.

Restructuring and Other Charges included in Research and Development Expenses

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials in June 2004, management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, we incurred a charge of approximately $305,000, including an adjustment in the fourth quarter of 2004 related to the extension of a sublease of the facilities, $288,000 of which was included in research and development expenses in the Statement of Operations in the quarter ended June 30, 2004. The restructuring charge included approximately $164,000 of severance-related amounts, $97,000 of which was included in the quarter ended June 30, 2004, $119,000 of committed costs for our New Jersey leased facility (net with expected proceeds from a short-term sublease entered into in October 2004), $169,000 of which was included in the quarter ended June 30, 2004, primarily related to lease expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned at the facility. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005, partially offset by expected proceeds from a short-term sublease entered into in October 2004. The balance of the severance costs was paid during the third quarter of 2004, and we expect to pay the facility-related costs through October 2005. The actual future cash requirements were adjusted from the accrual at June 30, 2004 due to subleasing the facility. We expect to pay the balance of the accrued facility related costs of approximately $16,000 at June 30, 2005 through October 2005.

Also in the second quarter of 2004, we completed the first phase of a physical inventory of substantially all of our laboratory equipment at our Fremont facilities. As a result, we recorded a charge to research and development expenses of $300,000, which represented the estimated amount of net book value of assets that are no longer in use. The physical inventory of these assets was completed in the fourth quarter of 2004.

Selling, General and Administrative Expenses

Selling, general and administrative costs of $19.8 million in the second quarter of 2005 include costs of personnel, professional services, consulting and other expenses related to our selling and administrative functions and an allocation of facility costs. Selling, general and administrative expenses for the three months ended June 30, 2005 increased from the comparable period in 2004 primarily due to increased personnel-related expenses of approximately $6.1 million and outside services of approximately $5.2 million.
The increase in selling, general and administrative expenses for the six months ended June 30, 2005 as compared to the 2004 period was primarily due to increased personnel-related expenses of approximately $6.1 million and increased outside services expenses of approximately $5.3 million. We expect that selling, general and administrative expenses will increase slightly for the second half of 2005, as compared to the first half of 2005 as we build out our sales force and support staff.

Acquired In-Process Research and Development

In connection with the March 2005 acquisition of ESP, we recorded charges for acquired in-process research and development of $79.4 million due to ESP's incomplete research and development programs that had not yet reached technological feasibility as of

March 23, 2005 and had no alternative future use as of that date. A summary and the status of these programs at the end of the second quarter of 2005 follows:

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

The nature of the remaining efforts for completion of ESP's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist which could prevent completion of development, including the uncertainty and timing of patient enrollment and uncertainties related to the results of the clinical trials, and obtaining FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that these potential products will be approved in the United States or the European Union or whether marketing approvals will have significant limitations on their use. The acquired products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals and the fact that the cost of sales to produce these products in a commercial setting has not been determined. As a result, we may make a strategic decision to discontinue development of a given product if we do not believe successful commercialization is possible. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 14%. This discount rate is a significant assumption and is based on our estimated weighted-average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets. In determining the value of the in-process research and development, the assumed commercialization dates for these potential products begins in 2007.

In connection with the April 2003 acquisition of Eos, we recorded charges for acquired in-process research and development of $37.8 million due to Eos' incomplete research and development programs that had not yet reached technological feasibility as of April 4, 2003 and had no alternative future use as of that date. There have been no significant changes to these acquired in-process research and development projects as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2004.

In addition, in 2003 we recorded a charge to acquired in-process research and development totaling approximately $48.2 million in connection with the amendment to our collaboration agreement with Roche in October 2003, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell *Zenapax*® (daclizumab) in all disease indications other than transplantation. This amount relates to the rights to autoimmune indications for daclizumab that were then being developed and tested in clinical studies, specifically to treat asthma and ulcerative colitis. There have been no significant changes to the acquired in-process research and development daclizumab projects as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2004.

Interest and Other Income, Net and Interest Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
(In thousands)	2005	2004	% Change	2005	2004	% Change
Interest and other income, net	$ 1,873	$ 2,583	(27)%	$ 4,808	$ 4,867	(1)%
Interest expense	(2,709)	(1,351)	100%	(4,851)	(2,736)	77%

Interest and Other Income and Expense

Interest income for the three and six months ended June 30, 2005 decreased from the comparable periods in 2004 due to the reduced interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates and lower invested balances.

Interest expense for the three and six months ended June 30, 2005 increased from the comparable periods in 2004 as a result of both our 2.00%, $250 million Convertible Senior Notes and our 2.75%, $250 million Convertible Subordinated Notes being outstanding during the first two quarters of 2005, compared to only our 2.75%, $250 million Convertible Subordinated Notes being outstanding in the first two quarters of 2004. We capitalized approximately $1.0 million and $1.8 million of our interest cost in the three and six months ended June 30, 2005, respectively, compared to $0.9 million and $1.7 million in the three and six months ended June 30, 2004, respectively.

Income Taxes

We have recorded a tax provision of approximately $87,000 and $56,000 for the six months ended June 30, 2005 and 2004,respectively.. Taxes during the six months ended June 30, 2005 are primarily related to state income taxes on income earned by ESP, foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee. We recorded a tax provision of $65,000 and $8,000 for the three months ended June 30, 2005 and 2004, respectively. Taxes during the three months ended June 30, 2005, and the three and six months ended June 30, 2004 are primarily related

to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee We do not expect to record any tax provision for federal income taxes based upon our projected tax loss for fiscal 2005.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have financed our operations primarily through public and private placements of equity and debt securities, revenue under agreements with third parties and interest income on invested capital. At June 30, 2005, we had cash, cash equivalents, marketable securities and restricted investments in the aggregate of $191.0 million, compared to $397.1 million at December 31, 2004.

Net cash used in operating activities for the six months ended June 30, 2005 was approximately $2.4 million, compared to $15.5 million in the comparable period in 2004. The change from the 2004 period was primarily due to an increase in revenues from product sales as a result of our acquisition of ESP, partially offset by an increase in research and development expenses in the 2005 period as compared to the 2004 period, which was primarily the result of higher spending to support our ongoing preclinical and clinical efforts, including an approximate 26% increase in research and development personnel from June 30, 2004 to June 30, 2005.

Net cash used in investing activities was $305.3 million for the six months ended June 30, 2005, compared to $200.3 million in the comparable period in 2004. The change from the 2004 period was primarily the result of $432.6 million in cash payments (net of cash received) related to the ESP and *Retavase* acquisitions in March 2005, which was partially offset by $150.5 million due to the timing of maturities of our marketable securities, and $23.3 million in capital expenditures. Capital expenditures in the first six months of 2005 and 2004 were primarily related to the development and construction activities for our manufacturing facility in Brooklyn Park, Minnesota.

Net cash provided by financing activities for the six months ended June 30, 2005 was $253.0 million compared to $11.1 million in the comparable period in 2004. The change from the 2004 period was primarily due to the issuance of 2.00%, $250 million Convertible Senior Notes in February 2005. In both periods, other financing activities related to the exercise of employee stock options partially offset by payments on our long-term debt obligations.

We estimate that our existing capital resources, including the cash proceeds from the 2005 Notes, will be sufficient to fund our current and future level of operations. Our future capital requirements will depend on numerous factors, including, among others, continued growth in sales of our marketed products; royalties from sales of products by third-party licensees, including *Synagis*, *Herceptin*, *Xolair*, *Raptiva*, *Zenapax*, *Mylotarg*, and *Avastin*; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; interest income; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; investment in existing and new research and development programs; time required to gain regulatory approvals; significant resources we will devote to constructing and qualifying our manufacturing facilities; our ability to obtain and retain funding from third parties under collaborative arrangements; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; successful integration of acquired businesses, including the transition to PDL existing relationships with partners, distributors, third-party vendors, manufacturers, and customers of acquired companies; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. In order to develop and commercialize our potential products we may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders.

Our material contractual obligations under lease, debt, construction, contract manufacturing and other agreements as of June 30, 2005 are as follows:

	Payments due by period				
(In thousands)	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
CONTRACTUAL OBLIGATIONS(1)					
Operating leases	$ 4,115	$ 6,474	$ 682	$ 254	$ 11,525
Long-term debt	1,365	2,308	2,278	4,935	10,886
Convertible debentures	11,875	23,750	263,438	257,500	556,563
Construction contracts	7,644	1,660	—	—	9,304
Contract manufacturing and other	7,116	—	—	—	7,116
Total contractual obligations	$ 32,115	$ 34,192	$ 266,398	$ 262,689	$ 595,394

(1) This table does not include (a) any milestone payments from us to third parties which may become payable under research collaborations or license agreements as the timing and likelihood of such payments are not known, or (b) any royalty payments from us to third parties as the amounts of such payments and / or likelihood of such payments are not known in any period presented above.

RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Quarterly Report on Form 10-Q, including the risk factors listed below. Any of these risks, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock. Additional risks not currently known to us also may harm our business.

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

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

In general, our expenses have exceeded revenues. As of June 30, 2005, we had an accumulated deficit of approximately $360.8 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:

- many 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 staffing and operations to meet our manufacturing requirements;
- we expand our 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 additional sales of existing products, new agreements with third-party business partners, significant royalties on sales of products licensed under our intellectual property rights or other uncertain sources of revenue, we will continue to incur operating losses and may require additional capital to fully execute our business strategy.

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

Cardene IV has accounted for a significant portion of the operating income and growth in sales of ESP. *Cardene* IV faces a competitive marketplace with branded and generic intravenous anti-hypertensive products being marketed in the U.S. 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 achieved. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for *Cardene* IV to continue its success, we will have to maintain and expand its position in the marketplace against these competitors' drugs.

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

Retavase is expected to account for a significant portion of our operating income and potential 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 gpIIb/IIIa inhibitor products. Moreover, *Retavase* competes for use in the management of acute myocardial infarction with TNKaseÔ and Activase from Genentech, Inc., a biotechnology company with significantly more resources and sales and marketing capabilities than PDL. 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 was marketed on behalf of Centocor by Scios, Inc. (Scios), a Johnson & Johnson company. We will require the continued cooperation of Centocor and Scios to successfully transfer the product to us and there can be no assurance that we will be successful in achieving this transition or our projected sales levels.

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

We will be required to manufacture *Retavase* for sale and distribution no later than 2011. *Retavase* is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth Biotechnology and Roche. While the rights to *Retavase* included the acquisition of at least 12 months of inventory, the manufacturing of this product for use as therapeutics in compliance with regulatory requirements will be complex, time-consuming and expensive. We will be required to effect the transfer of manufacturing from Centocor. The eventual transfer of manufacturing could result in delays in regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

We rely on third-party suppliers to provide ESP 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 products and are not familiar with the manufacturing process for these products. We have long-term agreements with various third parties to supply the ESP products. If there are supply problems with the third party manufacturers, in particular *Cardene* IV and *Retavase*, there may not be sufficient supplies of *Cardene* IV or *Retavase* to meet commercial demand, in which case our future results could suffer.

In addition, reliance on a third-party manufacturer entails risks, including reliance on the third party for regulatory compliance and adhering to the FDA's current Good Manufacturing Practices (cGMP) requirements, the possible breach of the manufacturing agreement by the third party, and the possibility

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

Our profitability will depend in significant part upon the continuing success of ESP's products.

ESP was founded in April 2002. While ESP was profitable in 2003 and 2004, it had a short operating history and there can be no assurance that we will be able to achieve profitable results from sales of acquired products. PDL has incurred losses since inception

and expects to continue to incur losses in the near-term. In order for the combined company to achieve a cash flow positive rate by the fourth quarter of 2005, we will need to achieve continued growth from *Cardene* IV, *Retavase* and IV *Busulfex* and continued growth in royalties from products licensed under PDL.

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

We sell our products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the U.S.. During the year ended December 31, 2004, revenues from the sales of ESP products to its three largest U.S. wholesalers totaled approximately 87% of its net revenues. Our reliance on a small number of wholesalers and distribution partners could cause revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners. In addition, as of June 30, 2005, these three U.S. wholesalers represented approximately 90% of ESP's outstanding accounts receivable. If any of these wholesalers or international partners fails to pay on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

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

At June 30, 2005, we had approximately $508.3 million of outstanding debt, including without limitation approximately $250 million in principal that remains outstanding under our 2.00% Convertible Senior Notes due February 15, 2012 (the 2005 Notes). In addition to the 2005 Notes, approximately $250 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2023 (the 2003 Notes), and we have debt service obligations related thereto. The 2005 Notes do not restrict our future incurrence of indebtedness and we may incur additional indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

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

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

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

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

We may not successfully integrate the ESP business and may not realize the anticipated benefits of the merger.

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

- demonstrating to the customers of PDL and ESP 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 development programs;
- preserving important relationships of both PDL and ESP 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 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 United States.

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

In addition, the integration of PDL and ESP will be a complex, time consuming and expensive process and will require significant attention from management and other personnel, which may distract their attention from the day-to-day business of the combined company. The diversion of management's attention and any difficulties associated with integrating ESP into 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 we can successfully integrate ESP in a timely manner or at all or that any of the anticipated benefits will be realized. Failure to do so could have a material adverse effect on the business and operating results of the combined company.

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

Upon completion of the merger, the shares of ESP preferred stock, common stock and options therefore converted into the right to receive up to $325.0 million in cash and 9,853,770 shares of PDL common stock. Based on this number of PDL shares issued in the acquisition of ESP, former ESP stockholders owned approximately 9% of the combined company's outstanding common stock at the time of the completion of the merger. We registered for resale the PDL shares issued in the acquisition of ESP, which has resulted in the registered sale of, and could result in the further registered sale of, a substantial number of shares of our common stock and which could lead to a decrease in the market price of our common stock. The issuance of these shares in connection with the merger also caused a significant reduction in the relative percentage interests in earnings, voting power, liquidation value and book and market value of all holders of common stock and securities convertible into common stock, including without limitation the 2003 Notes, the 2005 Notes and the PDL common stock issuable thereunder.

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

We are continuing to market and sell the products acquired as part of the ESP 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 continue to transition existing relationships with distributors, third party vendors, manufacturers and customers of ESP. Although we have retained 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 and further grow such capabilities from ESP necessary to continue to successfully promote the ESP products.

We cannot assure you that our customers will continue their current buying patterns; our customers may delay or defer purchasing decisions in response to changes in practices and policies by PDL. Any such delay or deferral in purchasing decisions by such customers could have a material adverse effect on the business or operating results of the combined company.

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

As a result of the merge with ESP, the combined company faces 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 and, as a result, on the market price of PDL's common stock.

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 (Section 404), 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 and for each year thereafter. The rules governing the standards

that must be met for management to assess the effectiveness of our internal controls over financial reporting are new and complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal controls over financial reporting successfully in 2004. In 2005, we will not only be required to conduct corresponding tests for our new enterprise resource planning software from SAP, but also must review and consider the requirements of SOX 404 as applied to our recently acquired operations from ESP. Since ESP operated as a private company, they were not required to, and did not complete the documentation, testing and possible remediation efforts that would have been required had they been subject to Section 404. Accordingly, we are reviewing the requirements to bring ESP into compliance with Section 404 and there can be no assurance that we will successfully and timely report on the effectiveness of our internal controls over financial reporting as of the end of 2005. The Section 404 compliance process has resulted, and will continue to result, in increased expenses and the devotion of significant management resources. If we cannot continue to favorably assess the effectiveness of our internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment in the future, investor confidence and our stock price could be adversely affected.

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

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

- the seasonality and rate of growth of sales of existing and licensed products;
- the existence of competing products;
- the market launch of recently acquired products;
- the response of wholesalers at announced or anticipated price changes for our products;
- uncertainty resulting from the purchase practices of wholesalers and inventory levels at wholesalers;
- product returns and rebates which could differ from our estimates and accruals;
- the continued safety of approved products;
- the marketing efforts of our licensees from whom we receive royalty payments;
- 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 2006, 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.

More than half 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 the Zenapax (daclizumab) antibody product. Although we have additional divisional patent applications pending in Japan, there can be no assurance that any patents will issue from such divisional applications or that the scope of such patents, if any, would be sufficient to cover third party antibody products.

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

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

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

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

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

Other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or we may not be able to market our products at all.

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

available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

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

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

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

We have not commercialized any antibody products. We are engaged in research activities intended to identify antibody product candidates that we may enter into clinical development. These research activities include efforts to discover and validate new targets for antibodies in our areas of therapeutic focus. We obtain new targets through our own drug discovery efforts and through in-licensing targets from institutions or other biotechnology or pharmaceutical companies. Our success in identifying new antibody product candidates depends upon our ability to discover and validate new targets, either through our own research efforts, or through in-licensing or collaborative arrangements. In order to increase the possibilities of identifying antibodies with a reasonable chance for success in clinical studies, part of our business strategy is to identify a number of potential targets. Our antibody product candidates are in various stages of development and many are in an early development stage. If we are unsuccessful in our research efforts to identify and obtain rights to new targets and generate antibody product candidates that lead to the required regulatory approvals and the successful commercialization of products, our ability to develop new products could be harmed.

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

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

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

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

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

Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of potentially new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical

activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or failures of our clinical trials as a result of many factors, all of which may increase the costs and expense associated with the trial, including:

- changes in regulatory policy during the period of product development;
- delays in obtaining 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, EMEA, investigational review boards or data safety monitoring boards may decide to temporarily suspend or permanently terminate ongoing trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to preclinical or clinical trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future. Despite the time and expense incurred, we cannot guarantee that we will successfully develop commercially viable products that will achieve FDA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

We are subject to extensive government regulation, which requires us to 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. 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 potential drug product where a change in the manufacturing process or manufacturing site is proposed, or competitive developments foreclosing the availability of expedited approval procedures. We may be required to support proposed changes with additional preclinical or clinical testing, which could delay the expected time line for concluding clinical trials.

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

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

In addition, we may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise because we have a relatively large number of potential products in clinical development. The approval process takes many years, requires the expenditure of substantial resources, and may involve post-marketing surveillance and

requirements for post-marketing studies. The approval of a product candidate may depend on the acceptability to the FDA of data from our clinical trials. Regulatory requirements are subject to frequent change. Delays in obtaining regulatory approvals may:

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

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

The "fast track" designation for development of any of our products may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood the product will receive regulatory approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA "fast track" designation for a particular indication. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although we have obtained a fast track designation from the FDA for *Nuvion* for the treatment of intravenous steroid-refractory ulcerative colitis and our partner Orphan Therapeutics has received fast track designation from the FDA for Terlipressin for Hepato-Renal Syndrome, Type 1, receipt of fast track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that *Nuvion* will receive regulatory approval for the treatment of intravenous steroid-refractory ulcerative colitis.

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

Research, preclinical testing and clinical trials may take many years to complete, and the time required can vary depending on the indication being pursued and the nature of the product. We may at times elect to use clinical strategies that seek to advance potential products through clinical development as rapidly as possible. For example, our recent projection for regulatory approval of *Nuvion* in the U.S. has been revised to reflect recent discussions with the FDA that will result in certain delays in the timeline for potential approval due to the need for additional Phase II/III safety data. We anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

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

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

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

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may result in our being unable to successfully achieve our projected development timelines, or potentially even lead us

to consider the termination of ongoing clinical trials or development of a product for a particular indication. For example, our current expectations for registrational studies and regulatory approval for *Nuvion* are dependent on our ability to timely enroll a worldwide clinical program.

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

In those instances where we have licensed rights to our technologies, the product development and marketing efforts and successes of our licensees will determine the amount and timing of royalties we may receive, if any. We have no assurance that any licensee will successfully complete the product development, regulatory and marketing efforts required to sell products. The success of products sold by licensees will be affected by competitive products, including potential competing therapies, that are marketed by the licensees or others. In February 2005, Biogen Idec, Inc. and Elan Corp. announced that they had voluntarily suspended supplying, marketing and the sale of Tysabri, a drug approved to treat multiple sclerosis and which is licensed under our humanization patents. Financial analyst and investor expectations, as well as our own financial plans beginning in 2005, included potential royalties from the sale of Tysabri. There can be no assurance that Tysabri will be returned to the market, the timing of such return, if ever, or that even if subsequently marketed and sold, the product will result in our receiving any significant royalties from the sales of Tysabri.

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

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

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

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

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

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

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

Our ability to enter into new relationships and the willingness of our existing partners to continue development of our potential products depends upon, among other things, our patent position with respect to such products. If we are unable to

successfully maintain our patents we may be unable to collect royalties on existing licensed products or enter into additional agreements.

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 antibody products on a commercial scale is uncertain, which may make it more difficult to sell our products.

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

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

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

- production yields;
- quality control and assurance;

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

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

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

obtain necessary regulatory approvals and to produce adequate commercial supplies of our potential products on a timely basis. Failure to do so could delay commercialization of some of our products and could impair our competitive position.

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

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

With respect to our M200 antibody product, ICOS Corporation (ICOS) has manufactured all of the drug material contemplated for use in our current 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 daclizumab marketed under the trade name 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 and the marketing and sale of our products could result in violations of law or regulations.

All of our products in development are subject to risks associated with applicable government regulations. The

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

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

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

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

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process and quality control procedures are required to comply with the applicable FDA 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, there may be a similar risk with respect to all products currently developed and marketed by ESP, including *Cardene* IV®, IV *Busulfex*®, and *Retavase*®.

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

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

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

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

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of our product candidates;
- their potential advantage over alternative treatment methods;
- reimbursement policies of government and third-party payers; and

- marketing and distribution support for our product candidates, including the efforts of our collaborators where they have marketing and distribution responsibilities.

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

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

We depend on outside vendors for the supply of raw materials used to produce our 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 payers may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

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

might not be permitted to market our future products and our business could suffer.

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

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. For example, during the period from January 1, 2004 to July 31, 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, including market reaction to various announcements regarding products licensed under our technology;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;

- initiation, termination or modification of agreements with our collaborative partners;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

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

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

Future changes in financial accounting standards, including changes in accounting for stock options, may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. For example, the FASB recently enacted SFAS 123R, which will require us to adopt a different method of determining the compensation expense of our employee stock options. SFAS 123R will have a significant adverse effect on our reported financial

conditions and may impact the way we conduct our business.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty for companies such as ours and insurance costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We may not have the ability to raise the funds to repurchase the 2003 Notes on the repurchase date or to finance any repurchase offer required by the indenture.

In August 2010, August 2013 and August 2018, respectively, holders of the 2003 Notes may require us to repurchase all or a portion of their 2003 Notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For 2003 Notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of 2003 Notes to be repurchased in August 2013 and August 2018, at our option, in cash, shares of our common stock or a combination of cash and shares of our common stock. In addition, if a repurchase event occurs (as defined in the indenture), each holder of the 2003 Notes may require us to repurchase all or a portion of the holder's 2003 Notes. We cannot assure you that there will be sufficient funds available for any required repurchases of these securities. In addition, the terms of any agreements related to borrowing which we may enter into from time to time may prohibit or limit our repurchase of 2003 Notes or make our repurchase of 2003 Notes an event of default under certain circumstances. If a repurchase event occurs at a time when a credit agreement prohibits us from purchasing the 2003 Notes, we could seek the consent of the lender to purchase the 2003 Notes or could attempt to refinance the debt covered by the credit agreement. If we do not obtain a consent, we may not repurchase the 2003 Notes. Our failure to repurchase tendered 2003 Notes would constitute an event of default under the indenture for the 2003 Notes, which might also constitute a default under the terms of our other debt, including the 2005 Notes. In such circumstances, our financial condition and the value of our securities could be materially harmed.

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

Holders of the 2005 Notes may require us to purchase all or any portion of their 2005 Notes upon a fundamental change, which generally is defined as the occurrence of any of the following: (1) our common stock is not traded on a national securities exchange or listed on The Nasdaq National Market; (2) any person acquires more than 50% of the total voting power of all shares of our capital stock; (3) certain mergers, consolidations, sales or transfers involving us occur; or (4) our board of directors does not consist of continuing directors. In certain situations, holders of the 2005 Notes will not have a repurchase right even if a fundamental change has occurred. In addition, we may not have sufficient cash funds to repurchase the 2005 Notes upon such a fundamental change. Although there are currently no restrictions on our ability to pay the purchase price, future debt agreements may prohibit us from repaying the purchase price. If we are prohibited from repurchasing the 2005 Notes, we could seek consent from our lenders at the time to repurchase the 2005 Notes. If we are unable to obtain their consent, we could attempt to refinance their debt. If we were unable to obtain 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 2003 Notes or 2005 Notes are converted into shares of our common stock, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

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

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

In accordance with U.S. generally accepted accounting principles, we accounted for the acquisition of ESP using the purchase method of accounting, which resulted in charges to earnings that could have a material adverse effect on the market value of

PDL's common stock. Under the purchase method of accounting, we allocated the total estimated purchase price to ESP's net tangible assets, amortizable intangible assets and in-process research and development based on their fair values as of the date of completion of the merger, and recorded the excess of the purchase price over those fair values as goodwill. The portion of the estimated purchase price allocated to in-process research and development in the amount of $79.4 million was expensed by the combined company in the first quarter of 2005. 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 incurred significant costs associated with the merger, which could adversely affect future liquidity and operating results.

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

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 and certain rights to *Retavase* required 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 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*, ularitide and M200;
- the cost and outcomes of regulatory submissions and reviews;
- the continuation or termination of third party manufacturing or sales and marketing arrangements;
- the cost and effectiveness of our sales and marketing programs;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights;
- our ability to extend the patent protection of our currently marketed products; and
- the establishment of additional strategic or licensing arrangements with other companies, or acquisitions.

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

Our industry is highly competitive. Our success will depend on our ability to acquire and develop products and apply technology, and our ability to establish and maintain markets for our products. Potential competitors in the U.S. and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions.

In addition, product sales from ESP products face significant competition from both brand-name and generic manufacturers that could

adversely affect the future sales of its products. Many of the marketed products are generic versions of brand-name products with declining total sales levels. Additionally, some of our brand-name products are subject to competition from generic products. As a result, we face competition for our marketed products from brand-name pharmaceutical companies and from companies focused on generic pharmaceutical markets. In addition, competitors may succeed in developing products and technologies that are more effective or less costly than our products, or that would render our products obsolete or noncompetitive.

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

Our ability to generate future revenue from products will be affected by reimbursement and drug pricing.

Acceptable levels of reimbursement of drug treatments by government authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, our combined portfolio of product candidates. We cannot be sure that reimbursement in the 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 products, and may not be able to obtain a satisfactory financial return on products.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the 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 our products. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that are successfully developed and approved. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

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

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

- the federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We maintain a non-trading investment portfolio of investment grade, highly liquid, debt securities, which limits the amount of credit exposure to any one issue, issuer, or type of instrument. We do not use derivative financial instruments for speculative or trading

purposes. We hold a $30.0 million five-year convertible note receivable 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 value of the Exelixis stock in our financial statements. Such a requirement could cause changes in the Exelixis stock price to contribute to fluctuation of our operating results from quarter to quarter. The securities in our investment portfolio are not leveraged and are classified as available-for-sale and therefore are subject to interest rate risk. We do not currently hedge interest rate exposure. As of June 30, 2005, there has been no material change in our interest rate exposure from that described in the Company's Annual Report on Form 10-K for the year ended December 31, 2004.

Because we translate foreign currencies into United States dollars for reporting purposes, currency fluctuations can have an impact on our results. For the six months ended June 30, 2005 and 2004, there was no material foreign currency exchange impact on our Consolidated Condensed Statements of Operations from our intercompany transactions. As of June 30, 2005, we did not engage in foreign currency hedging activities.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation as of June 30, 2005, our CEO and CFO, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q.

Changes in internal controls. Since our acquisition of ESP on March 23, 2005, we have expanded our internal controls over financial reporting to include consolidation of ESP's results of operations, as well as acquisition-related accounting and disclosures. We are in the process of evaluating and assessing whether these expanded internal controls have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting. Although we have expended significant resources, such evaluation and assessment is ongoing and we expect to have it completed in the third quarter of fiscal 2005.

Also, in April 2005, we implemented a new enterprise resource planning software, SAP, in part in order to increase the automation of our internal controls over financial reporting. We are in the process of evaluating and assessing whether this change in our internal controls has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Although we have expended significant resources, such evaluation and assessment is ongoing and we expect to have it completed in the third quarter of fiscal 2005.

There were no other changes in our internal controls over financial reporting during the quarter ended June 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Item 3 of our Annual Report on Form 10-K for the period ended December 31, 2004. No significant changes in the status of disclosed items have occurred since December 31, 2004.

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

The Company's 2005 Annual Meeting of Stockholders was held on June 8, 2005 in New York, New York. Of the 105,965,870 shares of common stock outstanding as of the record date, 87,324,539 shares were present at the meeting or represented by proxy, representing approximately 82% of the total votes eligible to be cast.

At the meeting, the stockholders voted on the election of (2) Class I directors to hold office until the Company's 2008 annual meeting as follows:

Nominee	For	Withheld
John S. Saxe, Esq.	53,571,641	33,752,898
L. Patrick Gage, Ph. D.	80,705,715	6,618,824

In addition to the election of Mr. Saxe and Dr. Gage, the following directors each have a term of office that continued after the meeting: Karen Dawes, Laurence Jay Korn, Max Link, Mark McDade and Cary L. Queen.

At the meeting, the stockholders approved a proposal for the 2005 Equity Incentive Plan, as follows:

For	Against	Abstain	Broker Non-Votes
57,840,753	10,082,109	222,559	19,179,118

At the meeting, the stockholders approved a proposal to amend the 2002 Outside Directors Stock Option Plan as follows:

For	Against	Abstain	Broker Non-Votes
58,092,687	9,828,165	224,569	19,179,118

At the meeting, the stockholders approved a proposal to amend the Certificate of Incorporation to change the name of the Company to PDL BioPharma, Inc. as follows:

For	Against	Abstain	Broker Non-Votes
86,117,313	962,262	244,964	0

At the meeting, the stockholders voted to ratify the appointment of Ernst & Young LLP as the Company's Independent Registered Public Accounting Firm for the fiscal year ending December 31, 2005 as follows:

For	Against	Abstain	Broker Non-Votes
86,460,667	785,852	78,020	0

Finally, at the meeting, the stockholders did not approve a proposal to approve any adjournments of the meeting to another time or place, if necessary, in the judgment of the proxy holders, for the purpose of soliciting additional proxies in favor of any of the foregoing proposals as follows:

For	Against	Abstain	Broker Non-Votes
36,620,678	37,568,545	13,135,316	0

ITEM 6. EXHIBITS

2.1 Amended and Restated Agreement and Plan of Merger by and among the Company, Big Dog Bio, Inc., a Delaware corporation and wholly owned subsidiary of the Company, and ESP Pharma Holding, dated as of March 22, 2005. (Incorporated by reference to Exhibit 2.1 to Registration Statement on Form S-3 filed March 25, 2005.)

2.2 Asset Purchase Agreement between Centocor, Inc., a Pennsylvania corporation, and ESP Pharma, Inc., a Delaware corporation and wholly owned subsidiary of ESP Pharma Holding Company, Inc., dated as of January 31, 2005. (Incorporated by reference to Exhibit 2.2 to Current Report on Form 8-K filed March 25, 2005.) (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)

3.1 Restated Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K filed March 31, 1993.)

3.2 Certificate of Amendment of Certificate of Incorporation. (Incorporated by reference to Exhibit 3.3 to Annual Report on Form 10-K filed March 14, 2002.)

3.3 Amended and Restated Bylaws of Protein Design Labs, Inc. effective as of June 8, 2005. (Incorporated by reference to Exhibit 99.3 to Current Report on Form 8-K filed June 14, 2005.)

4.1 Indenture between the Company and J.P. Morgan Trust Company, National Association, a national banking association, dated July 14, 2003. (Incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-3 filed September 11, 2003.)

4.2 Registration Rights Agreement for the Company's 2.75% Convertible Subordinated Notes due 2023, between the Company and the Initial Purchasers dated July 14, 2003. (Incorporated by reference to Exhibit 4.2 to Registration Statement on Form S-3 filed September 11, 2003.)

4.3 Indenture between the Company and J.P. Morgan Trust Company, National Association, as trustee, dated as of February 14, 2005. (Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed February 14, 2005.)

4.4 Registration Rights Agreement between the Company and Goldman, Sachs & Co., Citigroup Global Markets Inc. and UBS Securities LLC dated as of February 14, 2005. (Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed February 14, 2005.)

10.1 Offer letter for employment between the Company and George Jue, dated as of April 8, 2005.

10.2 Protein Design Labs, Inc. 2005 Equity Incentive Plan. (Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed June 14, 2005.)

10.3 Protein Design Labs, Inc. 2002 Outside Directors Stock Option Plan, as amended on June 8, 2005. (Incorporated by reference to Exhibit 99.2 to Current Report on Form 8-K filed June 14, 2005.)

31.1 Certification required by Rule 13a-14(a) or Rule 15d-14(a).

31.2 Certification required by Rule 13a-14(a) or Rule 15d-14(a).

32.1 Certification by the Chief Executive Officer and the Chief Financial Officer of Protein Design Labs, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

SIGNATURES

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

Dated: August 8, 2005

PROTEIN DESIGN LABS, INC.
(Registrant)

/s/ Mark McDade

Mark McDade
Chief Executive Officer
(Principal Executive Officer)

/s/ Glen Sato

Glen Sato
Senior Vice President and Chief
Financial Officer

/s/ George Jue

George Jue
Vice President, Finance and Corporate Controller
(Principal Accounting Officer)

EXHIBIT 10.1

April 6, 2005

Mr. George Jue
[*]
[*]

Dear George:

On behalf of Protein Design Labs, Inc., I am pleased to extend you an offer for the position of Vice President, Finance & Corporate Controller, reporting to Glen Sato, Sr. Vice President & CFO. Your appointment as an officer of PDL is subject to approval by PDL's Board of Directors.

The monthly salary for this position is $17,916.67 ($215,000.00/annually). We offer our employees an attractive benefits package, including a comprehensive medical policy and dental plan, as well as life insurance coverage. You are also eligible to participate in PDL's 2005 performance bonus program, which is paid in the first quarter of 2006.

You will also receive options to purchase 105,000 shares of Protein Design Labs Common Stock under a PDL stock option plan. This offer is subject to the approval of the Board of Directors and your execution of our standard Stock Option Agreement. The options will vest over four years, with one-fourth of the options vesting after one year of employment and the remainder vesting in equal monthly increments over the remaining three years.

PDL is prepared to offer you a hiring bonus of $15,000.00. The bonus amount shall be payable and included with your first paycheck from PDL. If you voluntarily resign your position or your employment is terminated for cause prior to your one-year anniversary with PDL, the entire $15,000.00 will be immediately due and payable to PDL.

For purposes of federal immigration law, you will be required to provide PDL documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire.

As a Protein Design Labs employee, you are free to resign at any time, just as Protein Design Labs is free to terminate your employment at any time, with or without cause. There will be no express or implied agreements to the contrary.

To indicate your acceptance of our offer, please sign and date one copy of this letter in the space provided below and return it to [*], in the enclosed envelope by the date indicated below. This letter, along with an agreement relating to proprietary rights between you and PDL, sets forth the terms of your employment with PDL and supersedes any prior representations or agreements, whether written or oral. This letter may not be modified or amended except by a written agreement, signed by PDL and by you.

We are very excited at the prospect of your joining Protein Design Labs as a key contributor. This offer will remain open until April 8, 2005, at which time it will expire if not previously accepted.

Sincerely,

/s/ Laurie Torres	/s/ George Jue
Laurie Torres	George Jue
Vice President, Human Resources	
	April 8, 2005
	Date

EXHIBIT 31.1

CERTIFICATIONS

I, Mark McDade, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protein Design Labs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2005

/s/ Mark McDade

Mark McDade
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Glen Sato, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protein Design Labs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2005

/s/ Glen Sato
Glen Sato
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATIONS

Mark McDade, Chief Executive Officer and Glen Sato, Chief Financial Officer of Protein Design Labs, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

(1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

A signed original of this written statement required by Section 906 has been provided to the Securities and Exchange Commission or its staff upon request.

Dated: August 8, 2005

By:

/s/ Mark McDade
Mark McDade
Chief Executive Officer

/s/ Glen Sato
Glen Sato
Chief Financial Officer