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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 March 31, 2006

OR

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

Commission File Number: 0-19756

PDL BIOPHARMA, 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 ☐

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

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

As of May 3, 2006 there were 114,467,120 shares of the Registrant’s Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PDL BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three months ended March 31,	
	2006	2005
Revenues:		
Product sales, net	$ 36,795	$ 948
Royalties	43,970	33,164
License, collaboration and other	9,695	4,703
Total revenues	90,460	38,815
Costs and expenses:		
Cost of product sales	22,959	1,137
Research and development	61,771	35,261
Selling, general and administrative	32,159	7,666
Acquired in-process research and development	—	79,417
Other acquisition-related charges	366	—
Total costs and expenses	117,255	123,481
Operating loss	(26,795)	(84,666)
Interest and other income, net	3,330	2,935
Interest expense	(2,650)	(2,142)
Loss before income taxes	(26,115)	(83,873)
Income tax expense	115	22
Net loss	$ (26,230)	(83,895)
Basic and diluted net loss per share	$ (0.23)	$ (0.87)
Shares used in the computation of basic and diluted net loss per share	112,472	96,754

See accompanying notes.

PDL BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except per share data)

	March 31, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 124,203	$ 183,377
Marketable securities, including $3.4 million and $6.8 million of restricted investments at March 31, 2006 and December 31, 2005, respectively	171,862	101,617
Accounts receivable, net of allowances of $12.0 million and $12.8 million at March 31, 2006 and December 31, 2005, respectively	21,249	19,116
Inventories	20,312	17,728
Deferred tax assets	4,778	9,244
Prepaid and other current assets	25,953	18,272
Short-term note receivable	30,000	30,000
Total current assets	398,357	379,354
Long-term marketable securities	49,999	48,928
Land, property and equipment, net	267,897	266,053
Goodwill	68,934	57,783
Other intangible assets, net	375,214	397,266
Other assets	12,943	13,770
Total assets	$1,173,344	$1,163,154
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,803	$ 2,728
Accrued compensation	12,672	16,401
Royalties payable	7,999	3,295
Other accrued liabilities	25,541	37,662
Deferred revenue	12,137	11,290
Current portion of other long-term debt	663	676
Total current liabilities	67,815	72,052
Convertible notes	499,998	499,998
Deferred tax liabilities	5,122	—
Long-term deferred revenue	59,826	57,743
Other long-term debt	7,246	7,296
Total liabilities	640,007	637,089
Stockholders' equity:		
Common stock, par value $0.01 per share, 250,000 shares authorized; 113,469 and 112,062 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	1,135	1,121
Additional paid-in capital	1,000,343	969,118
Deferred stock-based compensation	—	(1,998)
Accumulated deficit	(466,339)	(440,109)
Accumulated other comprehensive loss	(1,802)	(2,067)
Total stockholders' equity	533,337	526,065
Total liabilities and stockholders' equity	$1,173,344	$1,163,154

See accompanying notes.

PDL BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three months ended March 31,	
	2006	**2005**
Cash flows from operating activities:		
Net loss	$ (26,230)	$ (83,895)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Acquired in-process research and development	—	79,417
Depreciation	7,605	3,230
Amortization of convertible notes offering costs	587	444
Amortization of intangible assets	11,052	1,723
Stock-based compensation expense	6,146	148
Excess stock option income tax benefit	138	—
Changes in assets and liabilities:		
Accounts receivable	(2,133)	—
Interest receivable	(563)	(311)
Inventories	(2,584)	(125)
Other current assets	1,907	(7,048)
Other assets	239	304
Accounts payable	6,075	1,418
Accrued liabilities	(2,896)	(2,832)
Deferred revenue	2,930	(1,072)
Total adjustments	28,503	75,296
Net cash provided by (used in) operating activities	2,273	(8,599)
Cash flows from investing activities:		
Purchases of marketable securities	(98,851)	—
Maturities of marketable securities	24,949	132,736
Maturities of restricted securities	3,414	3,438
Cash paid for ESP Pharma acquisition, net of cash acquired	—	(322,577)
Cash paid for *Retavase* acquisition	—	(110,000)
Sale of intangible assets	2,750	—
Purchase of land, property and equipment	(9,449)	(14,975)
Net cash used in investing activities	(77,187)	(311,378)
Cash flows from financing activities:		
Proceeds from issuance of common stock	15,803	2,105
Proceeds from issuance of convertible notes	—	241,831
Payments on other long-term obligations	(63)	(277)
Net cash provided by financing activities	15,740	243,659
Net decrease in cash and cash equivalents	(59,174)	(76,318)
Cash and cash equivalents at beginning of period	183,377	91,395
Cash and cash equivalents at end of period	$124,203	$ 15,077

See accompanying notes.

PDL BIOPHARMA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2006
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

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

Basis of Presentation and Responsibility for Quarterly Financial Statements

The accompanying condensed consolidated 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 for the year ended December 31, 2005 filed with the Securities and Exchange Commission. The Condensed Consolidated Balance Sheet as of December 31, 2005 is derived from our audited consolidated financial statements as of that date.

Our revenues, expenses, assets and liabilities vary during each quarter of the year. Therefore, the results and trends in these interim condensed consolidated 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, Inc. (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 since we generally recognize royalty revenue in the quarter subsequent to sales by our licensees (see Royalties section below). In addition, as a result of the closing of our acquisition of ESP Pharma Holding Company, Inc. (ESP Pharma) on March 23, 2005, the results of operations of ESP Pharma from March 24, 2005 are included in our condensed consolidated financial statements (see Note 2).

Principles of Consolidation

The condensed consolidated 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 period amounts have been made in our Condensed Consolidated Balance Sheets to conform to the current period 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.

Segment and Concentrations Disclosure

In accordance with Statement of Financial Accounting Standards (SFAS) No. 131, “Disclosure About Segments of an Enterprise and Related Information”, we are required to report operating segments and related disclosures about our products, services, geographic areas and major customers. Our chief operating decision-maker (CODM) is comprised of our executive management with the oversight of our board of directors. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a company-wide or aggregate basis. Accordingly, we operate as one segment. Our facilities are located primarily within the United States.

Sales of *Cardene* IV, IV *Busulfex* and *Retavase* accounted for 97% and 39% of total product sales and total revenues, respectively, in the first quarter of 2006. Sales of *Cardene* IV, IV *Busulfex* and *Retavase* were minimal in the first quarter of 2005 since we acquired these products on March 23, 2005.

Royalty, license and other revenues from Genentech, Inc. (Genentech) in the first quarters of 2006 and 2005 accounted for 31% and 48% of total revenues, respectively. Royalty, license and other revenues from MedImmune in the first quarters of 2006 and 2005 accounted for 16% and 33% of total revenues, respectively. No other revenue from any other source exceeded 10% of total revenues for any periods presented.

Stock-Based Compensation

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

In November 2005, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. 123R-3, “Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards.” An entity shall follow either the transition guidance for the additional paid-in capital (APIC) pool in paragraph 81 of Statement 123(R) or the alternative transition method described in the FASB Staff Position (FSP). Paragraph 81 of SFAS 123(R) indicates that for purposes of calculating the pool of excess tax benefits available to absorb tax deficiencies recognized subsequent to the adoption of Statement 123(R), an entity shall include the net excess tax benefits that would have qualified as such had the entity adopted SFAS 123(R) for recognition purposes. The FSP provided an alternative transition method for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R). The FSP includes simplified methods to establish the beginning balance of the APIC pool related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and Condensed Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that are outstanding upon our adoption of SFAS 123(R). We are reviewing the two methods and will elect an appropriate method by the end of 2006.

Employee Stock Plans

We have six stock-based employee compensation plans. The exercise price of all stock options granted under our plans is equal to the fair value of our common stock on the grant date. The option term for options granted prior to mid-July 2005 is ten years, and the option term for all options granted subsequent to mid-July 2005 is seven years.

Under the 1991 Stock Option Plan, options generally vest at the rate of 25% at the end of the first year, with the remaining balance vesting monthly over the next three years in the case of employees, and ratably over two or five years in the case of advisors and consultants. This 1991 Plan was terminated in 1999. The shares remaining available for grant or which subsequently become available upon the termination of options outstanding under the 1991 Plan, if any, are added automatically to the 1999 Stock Option Plan. Options may be granted under the 1999 Option Plan with an exercise price and vesting period established at the discretion of the Board of Directors.

Under the 1999 Nonstatutory Option Plan, options may be granted to employees, prospective employees and consultants and any parent or subsidiary corporation with an exercise price and vesting period established at the discretion of the Board of Directors.

The 2002 Directors Plan provides for automatic annual option grants to outside directors which vest monthly over one year from the grant date and have an exercise price equal to the market price of our stock on the grant date.

We can grant certain equity incentives to our service providers under the 2005 Equity Incentive Plan. These incentives include stock appreciation rights, restricted stock and restricted stock unit awards, performance share and performance unit awards, deferred compensation awards and other stock-based or cash-based awards. The issuance and terms of such equity incentive awards pursuant to the 2005 Plan are at the discretion of the Board of Directors.

The 1993 Employee Stock Purchase Plan enables full-time employees who own less than 5% of the outstanding shares to purchase shares of our common stock based on a percentage of their compensation, up to certain limits. The purchase price per share must equal at least the lower of 85% of the market value on the date offered or on the date purchased.

Prior to the Adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), we accounted for stock-based awards under the intrinsic value method, which followed the recognition and measurement principles of APB 25 and related interpretations. Accordingly, we recognize no compensation expense in our Condensed Consolidated Statements of Operations with respect to options awarded to our employees and directors with exercise prices greater than or equal to the fair value of the underlying common stock at the date of grant. However, we recognize compensation expense in our Condensed Consolidated Statements of Operations with respect to the modification of certain employee stock option awards and the issuance of restricted stock to certain employees.

We account for stock options granted to non-employees at fair value using the Black-Scholes option-pricing model in accordance with Emerging Issues Task Force Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.” Stock options granted to non-employees and stock options that are modified and continue to vest when an employee has a change in employment status are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense over the service period in which the non-employee provides services to the Company.

The table below illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123, “Accounting for Stock-Based Compensation”, as amended by SFAS No. 148, “Accounting for Stock-Based Compensation – Transition and Disclosures,” to our stock-based employee compensation plans. For purposes of this pro forma disclosure, the value of the options was estimated using the Black-Scholes option-pricing model. Disclosures for the three months ended March 31, 2006 are not presented because stock-based payments were accounted for under SFAS 123(R) during this period.

(in thousands, except per share amounts)	**Three Months Ended March 31, 2005**
Reported net loss	$ (83,895)
Deduct: Stock-based compensation expense determined under the fair value based method for all awards, net of taxes	(3,925)
Pro forma net loss	$ (87,820)
Basic and diluted net loss per share	
As reported	$ (0.87)
Pro forma	$ (0.91)

Adoption of SFAS 123(R)

Employee stock-based compensation expense recognized in the first quarter of 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We adopted SFAS 123(R) using the modified prospective application transition method, which requires that compensation expense be recognized in the financial statements for all awards granted after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method does not require restatement of prior periods to reflect the impact of SFAS 123(R). Upon adopting SFAS 123(R), we changed from the multiple-option approach to the single-option approach to value options granted effective January 1, 2006 and amortize the fair value of these awards using straight-line attribution. We believe that the single-option approach with straight-line attribution better reflects the level of service to be provided over the vesting period of our awards. We continue to expense the unvested awards granted prior to January 1, 2006 under the multiple-option approach with graded-vesting attribution. In addition, we eliminated the remaining balance of the deferred stock-based compensation against APIC. We did not capitalize any employee stock-based compensation costs in inventory as a component of cost of product sales during the first quarter of 2006 as the amount was immaterial. Substantially all of the products sold in the first quarter of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs; therefore, we did not record any employee stock-based compensation expense as a component of cost of product sales in the first quarter of 2006. We will analyze the impact of capitalizing employee stock-based compensation costs in inventory and recognize the related expenses in cost of product sales in future periods.

Employee stock-based compensation expense recognized under SFAS 123(R) was as follows:

(in thousands, except per share amounts)	Three months ended March 31, 2006
Research and development	3,440
Selling, general and administrative	2,562
Total employee stock-based compensation expense	6,002
Tax benefit related to employee stock-based compensation expense	—
Net effect on net loss	$ 6,002
Effect on basic and diluted net loss per share	$ (0.05)

Valuation Assumptions

The employee stock-based compensation expense recognized under FAS 123(R) for the first quarter of 2006 and presented in the pro forma disclosure required under FAS 123 for the first quarter of 2005 was determined using the Black-Scholes option valuation model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted average assumptions used are as follows:

	Employee Stock Option Plans March 31,		Employee Stock Purchase Plan March 31,	
	2006	2005	2006	2005
Expected term (in years)	4.1	2.7	0.5	0.5
Volatility	44%	66%	39%	47%
Risk-free interest rate	4.5%	3.4%	4.3%	3.0%
Dividend yield	0%	0%	0%	0%

Expected Term: Our expected term represents the period that our stock-based awards are expected to be outstanding and was determined based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior as influenced by changes to the terms of stock-based awards.

Expected Volatility: Expected volatility is based on both the historical volatility of our common stock and implied volatility derived from the market prices of traded options of our common stock.

Expected Dividend: We have not issued any dividends and do not anticipate paying any cash dividends in the foreseeable future. We therefore have assumed a dividend yield of zero for purposes of these fair value estimations.

Risk-Free Interest Rate: We base the risk-free interest rate on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term equal to the expected term of our options at the time of grant.

Stock Option Activity

A summary of our stock option activity during the quarter ended March 31, 2006 is presented below:

Option	Total Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2005	14,342,264	$17.89
Granted	362,500	30.11
Forfeited	(314,362)	16.16
Exercised	(1,055,841)	14.97
Expired	(13,005)	47.82
Outstanding as of March 31, 2006	13,321,556	18.47
Exercisable as of March 31, 2006	7,789,073	18.12

The weighted-average grant-date fair value for options granted during the three months ended March 31, 2006 was $12.16 per share and $7.31 per share in the corresponding quarter of 2005. During the three months ended March 31, 2006, a total of $15.8 million of cash was received from stock options exercised by employees compared to $2.1 million in the corresponding quarter of 2005.

The weighted-average remaining contractual life of options outstanding and exercisable as of March 31, 2006 was 6.5 years and 5.6 years, respectively. The aggregate intrinsic value of options outstanding and exercisable as of March 31, 2006 was $194.9 million and $118.4 million, respectively. The aggregate intrinsic value of options exercised during the first quarters of 2006 and 2005 was $17.3 million and $2.3 million, respectively. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing prices of our common stock of $32.80 and $15.99 on March 31, 2006 and 2005, respectively, which would have been received by the option holders had all option holders exercised their options as of that date. Total unrecognized compensation cost related to nonvested stock options outstanding as of March 31, 2006 was $27.0 million, which is expected to be recognized over a weighted-average period of 2.6 years.

Restricted Stock

We did not grant any restricted stock during the first quarter of 2006. None of the 103,200 shares of the outstanding nonvested restricted stock at December 31, 2005, with a weighted-average grant-date fair value of $21.88, was vested during the first quarter of 2006. Total unrecognized compensation cost related to nonvested restricted stock outstanding as of March 31, 2006 was $1.8 million, which is expected to be recognized over a weighted-average period of 3.3 years.

Employee Stock Purchase Plan (ESPP)

The compensation cost in connection with our ESPP for the three months ended March 31, 2006 was $0.4 million.

2. ESP Pharma Acquisition

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma. We acquired ESP Pharma consistent with our business strategy of becoming a commercial enterprise that derives the majority of its revenues from sales of proprietary products. The ESP Pharma acquisition was accounted for as a business combination in accordance with SFAS No. 141, “Business Combinations” (SFAS 141). In addition to the issuance of 7,330,182 shares of PDL common stock and cash payment of $325.0 million to ESP Pharma stockholders, we deposited 2,523,588 shares of common stock into an escrow account to be held for a period of between six months and one year from the date of the close of the acquisition, pursuant to the terms of an Escrow Agreement entered into in connection with the Amended and Restated Agreement and Plan of Merger. We also incurred direct transaction costs of $5.4 million.

On the acquisition date in March 2005, we believed beyond a reasonable doubt that the 2,523,588 shares placed into escrow would ultimately be issued to former ESP Pharma stockholders and, therefore, we included value of such shares in the calculation of the purchase price due to various liabilities identified subsequently. However, during the second, third and fourth quarters of 2005, we incurred various costs and liabilities that related to ESP Pharma operations prior to our acquisition of the business. Specifically, we experienced a significant volume of product returns related to products sold by ESP Pharma prior to our acquisition of the business (pre-acquisition sales). During the fourth quarter of 2005, we determined that the value of these shares should not have been included in purchase consideration until the underlying contingencies are resolved and they are released from the escrow in favor of the former ESP Pharma stockholders. As there was reasonable doubt that substantially all of the shares held in the escrow account ultimately

would be released to the ESP Pharma stockholders at the end of this escrow period, we excluded the value for all these shares in the computation of the revised purchase price. This revision reduced the original recorded goodwill and stockholders' equity by approximately $36.1 million at March 31, 2005.

On September 22, 2005, we made a claim against 952 of the shares held in escrow based on ESP Pharma's breaches of certain representations and warranties under the Amended and Restated Agreement and Plan of Merger. This claim went uncontested and these 952 shares were removed from the escrow account and cancelled. Pursuant to the terms of the Escrow Agreement, 1,260,842 shares were released from escrow to the ESP Pharma stockholders on September 23, 2005. In connection with the release of these shares from escrow, we recorded an additional $35.3 million of goodwill, which represents the fair value of the shares released on that date.

During the fourth quarters of 2005 and during the first quarter of 2006, prior to the first anniversary of the acquisition of ESP Pharma, we delivered several claims against a total of 911,059 of the shares of common stock held in escrow. These claims are based on ESP Pharma's breaches of certain representations and warranties under the Amended and Restated Agreement and Plan of Merger, primarily as a result of higher sales returns than allowable under the acquisition agreement and tax related items. The ESP Pharma stockholders disputed all of the claims we made. Pursuant to the terms of the Escrow Agreement, the 350,735 shares of common stock held in escrow against which we had not made a claim were released to the ESP Pharma stockholders on March 23, 2006. In connection with the release of these shares, during the first quarter of 2006, we recorded an additional $11.2 million of goodwill. On April 10, 2006, we resolved one of the disputed claims with the ESP Pharma stockholders and, as a result, 50,673 shares of common stock in escrow were released to the ESP Pharma stockholders. We are in the process of resolving the disputed claims against the remaining 860,386 shares of common stock in escrow. We believe all current claims against these 860,386 shares are valid and we anticipate they will be resolved in our favor and these shares will be cancelled.

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

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

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

Net liabilities	$ (14,640)
Goodwill	31,262
Intangible assets	339,200
Acquired in-process research and development	79,417
	$435,239

The $339.2 million value assigned to the intangible assets relates to product rights for the six products sold by ESP Pharma. During 2005, we concluded that the carrying amount of the product rights for the off-patent branded products, representing four of the six products purchased, was impaired as the estimated fair value of these product rights was less than the net carrying value. Accordingly, we recorded an impairment charge in 2005 to reduce the carrying value of these product rights to the fair value. During 2005, we also

classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (SFAS 144). In addition, we wrote down inventory by $1.1 million related to the off-patent branded product inventory on hand as of December 31, 2005 based on its expected realizable amount. We completed the sale of these products in the first quarter of 2006. We are amortizing the value assigned to the remaining two products, *Cardene* IV and IV *Busulfex*, over 10 and 12 years, or a weighted-average period of 10.4 years, the estimated useful lives of these assets, respectively.

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

As we did not identify any pre-acquisition contingencies on the acquisition date, under SFAS 141, charges incurred subsequent to our acquisition of ESP Pharma that are associated with pre-acquisition operations are included in the Condensed Consolidated Statements of Operations. Accordingly, we recognized other acquisition-related charges totaling approximately $0.4 million during the first quarter of 2006. As such charges directly relate to ESP Pharma operations prior to our acquisition of the business, we recognized them as operating expenses rather than as a reduction to current year product sales.

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

Program	Description	Status of Development	Value (in thousands)
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for type I hepatorenal syndrome (HRS)	Our third-party licensor, Orphan Therapeutics, LLC (Orphan Therapeutics) holds the IND and is conducting a Phase 3 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 acute decompensated heart failure	Our third-party licensor, CardioPep Pharma GmbH (CardioPep), has conducted SIRIUS II, a double-blind, placebo-controlled Phase 2 study	55,652
			$ 79,417

The nature of the remaining efforts for completion of research and development of these 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 U.S. Food and Drug Administration (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.

3. Net Loss Per Share

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

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

(in thousands)	As of March 31, 2006	2005
Stock options	13,322	15,975
Common stock in escrow	911	2,524
Restricted stock	103	—
Convertible notes	22,970	22,970
Total	37,306	41,469

4. Comprehensive Loss

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

(in thousands)	Three Months Ended March 31, 2006	2005
Net loss	$(26,230)	$(83,895)
Other comprehensive loss:		
Change in unrealized gains and losses on marketable securities	265	(1,272)
Total comprehensive loss	$(25,965)	$(85,167)

5. Inventories

Inventories consisted of the following:

(in thousands)	March 31, 2006	December 31, 2005
Raw materials	$10,955	$ 6,249
Work-in-process	7,919	9,332
Finished goods	1,438	2,147
Total	$20,312	$ 17,728

6. Other Intangible Assets, Net

Other intangible assets, net consisted of the following:

(in thousands)	March 31, 2006	December 31, 2005
Product rights	$362,302	$ 383,868
Core technology	11,937	12,348
Licensed research technology	975	1,050
Total	$375,214	$ 397,266

7. Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(in thousands)	March 31, 2006	December 31, 2005
Consulting and services	$ 7,295	$ 9,757
Off-patent branded product sale deposit and accruals	—	9,175
Accrued clinical and pre-clinical trial costs	9,801	6,287
Sales rebates	1,516	1,938
Accrued interest	1,485	4,454
Construction-in-process	1,452	1,694
Income taxes payable	2,345	2,829
Other	1,647	1,528
Total	$25,541	$ 37,662

8. 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 quarters ended March 31, 2006 and 2005, we recognized net periodic benefit costs of approximately $89,000 and $71,000, respectively. This expense includes service cost, interest cost, and amortization of prior service cost.

9. Income Taxes

We recorded tax provisions of approximately $115,000 and $22,000 for the three months ended March 31, 2006 and 2005, respectively. Taxes during the three months ended March 31, 2006 were primarily related to federal alternative minimum taxes and foreign taxes on income earned by our foreign operations reduced by a state tax benefit from the current net loss for those states for which we are in a deferred tax liability position. Taxes during the three months ended March 31, 2005 were primarily related to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee.

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 the risk factors set forth below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

OVERVIEW

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

Our products are sold through our hospital-focused sales force which focuses on the cardiac, neurological and intensive care unit departments of a hospital. *Cardene* IV is the only branded, U.S.-approved dihydropyridine class calcium channel blocker delivered intravenously that is indicated for short-term treatment of hypertension when oral therapy is not feasible or desirable. *Retavase* is indicated for use in the management of heart attacks (acute myocardial infarction, or AMI) in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. IV *Busulfex*, an IV formulation of busulfan, is a chemotherapeutic agent used as part of a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. IV *Busulfex* provides not only an anti-tumor effect to eradicate residual malignancy, but also ablation of the bone marrow, which makes space for the new source of stem cells, and immunosuppression to prevent graft rejection.

We have licensed and will continue to offer to license our patents covering numerous humanized antibodies in return for license fees, annual maintenance payments, and royalties on product sales. By making certain modifications to the mouse antibody that make it more like a human antibody, our technology enhances the utility of such antibodies, while retaining their biological activity, for human therapeutic use. We believe our technology for the creation of humanized therapeutic monoclonal antibodies is widely validated in our industry, based on the existence of multiple approved and licensed antibodies. Eight of the nine humanized antibodies currently approved by the FDA are licensed under our patents and generated royalties to us in 2005: Genentech Inc.'s (Genentech) *Avastin*™, *Herceptin*®, *Xolair*® and *Raptiva*®; MedImmune, Inc.'s (MedImmune) *Synagis*®; Wyeth's *Mylotarg*®; Elan Corporation, Plc's (Elan) *Tysabri*® and Hoffmann-La Roche's (Roche) *Zenapax*®. Almost half of our revenues generated in the first quarter of 2006 were from royalties paid for use of our patented antibody humanization technology as applied to mouse antibodies. In October 2005 we signed a Second Amended and Restated Worldwide Agreement with Roche pursuant to which Roche will pay us royalties at a reduced rate only once *Zenapax* product sales have reached a certain threshold. As such, we received a significantly lower royalty payment from Roche's sale of *Zenapax* in the first quarter of 2006 than in prior quarters and expect to receive minimal to no royalty revenue from Roche's sale of *Zenapax* going forward. In February 2005, Biogen Idec and Elan announced that they had voluntarily suspended supplying, marketing and selling *Tysabri*. Although we received a marginal amount of royalties in the first and second quarters of 2005 from Elan's sale of *Tysabri* prior to this voluntary suspension, we have not received any such royalties since that time. Although Biogen Idec and Elan have submitted data in support of *Tysabri* to the FDA for approval, there can be no assurance that *Tysabri* will be returned to the market, the timing of such return, if ever, or that even if subsequently marketed and sold, the product will result in our receiving any significant royalties from any future sales of *Tysabri*.

Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of March 31, 2006, we had an accumulated deficit of approximately $466.3 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 identify, develop and manufacture our potential products, invest in research and improve and expand our development, marketing 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.

In order to achieve profitability, we will have to continue to increase sales levels for our existing products, *Cardene* IV, *Retavase* and IV *Busulfex* as well as effectively manage our operating expenses. We have a limited history of product marketing and sales and the markets for *Cardene* IV and *Retavase* are highly competitive. Our competitors include pharmaceutical, biopharmaceutical and specialty pharmaceutical companies with substantially greater revenues and experience in marketing products than we have. If we do not achieve our near term objectives we may continue to incur substantial operating losses.

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

In addition, as of March 31, 2006 we have approximately $500.0 million in convertible notes outstanding, approximately $250.0 million of which are callable in each of 2008 and 2010, and due in 2023 and 2012, respectively. In order to be able to service our debt in the future, we will need to generate positive cash flows from our operations or obtain other financing.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

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

Revenue Recognition

We recognize revenues from product sales, net of estimated allowances for cash discounts, product returns, chargebacks, bad debts and rebates. We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated discounts, product returns, chargebacks, bad debts, and rebates.

We currently recognize revenues resulting from the licensing and use of our technology and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the development, use, sale and importation of humanized antibodies.

We enter into patent license, collaboration and humanization agreements that may contain multiple elements, such as upfront license fees, reimbursement of research and development expenses, milestones related to the achievement of particular stages in product development and royalties. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element.

We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our licensee confirms that we have met the requirements under the terms of the agreement, and when payment is reasonably assured. Changes in the allocation of the contract value between deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract. For example, as we did not establish fair value for all undelivered elements of the Co-Development and Commercialization Agreement with Roche (the Roche Collaboration Agreement), including milestones and the reimbursement of research and development expenses, we are recognizing the $17.5 million upfront license fee that we received from Roche over the term of the Roche Collaboration Agreement as services are provided. Similarly, we did not establish fair value for all undelivered elements of the multiple products of the Collaboration Agreement with Biogen Idec (the Biogen Idec Collaboration Agreement). The $40.0 million upfront license fee, milestones and the reimbursement of research and development expenses that we received from Biogen Idec will be recognized over the term of the Biogen Idec Collaboration Agreement as services are provided with respect to the specific products under development to which the upfront license fees and reimbursement relate. As we share research and development expenses equally under this arrangement, we recognize expense incurred as research and development expenses and recognize reimbursement as other revenue.

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

Sales Allowances and Rebate Accruals

We record estimated reductions to product sales for expected returns of products under our current policies, chargebacks, wholesaler service fees, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are based on contractual terms, historical utilization rates and expectations regarding future utilization rates for these programs. Estimates for wholesaler service fees are based on a certain percentage of sales per wholesaler contract terms. Estimates for product returns, including new products, are based on an on-going analysis of industry and historical return patterns. 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 to assess the potential impact on our future sales and return expectations.

If conditions or other circumstances change for any of the markets served by our drugs, we may take actions to revise our product return estimates or we may offer additional customer incentives. These revisions could result in an incremental reduction of future revenue at the time the return estimate is changed or new incentives are offered. Account receivable allowances for chargebacks, returns and rebates require substantial judgment. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made.

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 contractual payment terms, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region, and a review of the local economic environment and its potential impact on government funding and reimbursement practices. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an inability to make payments, additional allowances may be required. We believe that the allowance for doubtful accounts is adequate to cover anticipated losses under current conditions; however, significant deterioration in any of the above factors could materially change these expectations and result in an increase to our allowance for doubtful accounts.

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business, we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements vary

from contract to contract, are subject to negotiation and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, 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 actually may be incurred.

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 Statement of Financial Accounting Standards (SFAS) 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. We did not record any impairment charge during the first quarter of 2006 or 2005.

Stock-Based Compensation

Effective January 1, 2006, we account for employee stock-based compensation in accordance with SFAS No. 123, “Share Based Payment (Revised 2004)” (SFAS 123(R)), which supersedes our previous accounting under Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees” (APB 25), and related interpretations. We adopted SFAS 123(R) using the modified prospective application transition method, which requires that compensation expense be recognized in the financial statements for all awards granted after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method does not require restatement of prior periods to reflect the impact of SFAS 123(R). Upon adopting SFAS 123(R), we changed from the multiple-option approach to the single-option approach to value options granted effective January 1, 2006 and amortize the fair value of these awards under the straight-line attribution. We believe that the single-option approach with straight-line attribution better reflects the level of service to be provided over the vesting period of our awards. We continue to expense the unvested awards granted prior to January 1, 2006 under the multiple-option approach with graded-vesting attribution.

Under the provisions of SFAS 123(R), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Expected volatility is based on both the historical volatility of our common stock and implied volatility derived from the market prices of traded options of our common stock. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value employee stock-based awards granted in future periods.

Further, SFAS 123(R) requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. Accordingly, in the first quarter of 2006, we recognized employee stock-based compensation related to SFAS 123(R) of $6.0 million as part of our operating expenses, with an allocation of $3.4 million to R&D expense and $2.6 million to SG&A expense. We did not recognize any related tax benefit and we did not capitalize any employee stock-based compensation costs in inventory as a component of cost of product sales during the first quarter of 2006 as the amount was immaterial. Substantially all of the products sold in the first quarter of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs; therefore, we did not record any employee stock-based compensation expense as a component of cost of product sales in the first quarter of 2006. We will analyze the impact of capitalizing employee stock-based compensation costs in inventory and recognize the related expenses in cost of product sales in the future periods.

Total unrecognized compensation cost related to nonvested stock options and restricted stock outstanding as of March 31, 2006 was $27.0 million and $1.8 million, respectively, and is expected to be recognized over a weighted average period of 2.6 years and 3.3 years, respectively. There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized under FAS 123(R) during the three months ended March 31, 2005.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2006 and 2005

Revenues

(in thousands)	Three Months Ended March 31, 2006	2005	% Change
Product sales, net	$36,795	$ 948	*
Royalties	43,970	33,164	33%
License, collaboration and other	9,695	4,703	106%
Total revenues	$90,460	$38,815	133%

* Calculation not meaningful

Product sales, net

In the first quarter of 2006, total net product sales from our marketed products were $36.8 million, of which *Cardene* IV, IV *Busulfex* and *Retavase* totaled $35.7 million, or approximately 97%. Total net product sales for the first quarter of 2005 were minimal, as we did not have product sales until March 23, 2005, when we acquired six marketed products in connection with our acquisition of ESP Pharma. Product sales recognized for the period March 24 through March 31, 2005 were from these six products, the majority of which related to *Cardene* IV and IV *Busulfex*. Affecting our net product sales in the first quarter of 2006 were price increases for *Cardene* IV and IV *Busulfex* that were effective in January 2006. We did not increase prices for *Retavase* in the first quarter of 2006 and a more competitive market for thrombolytics may impact our ability to obtain price increases in the future for this product. We expect sales of our currently marketed products generally will continue to increase as a whole as we continue to actively market them.

Royalties

The increase in royalty revenues to $44.0 million during the three months ended March 31, 2006 from $33.2 million during the same period in 2005 was due primarily to higher reported product sales of *Avastin* and *Herceptin*, which are marketed by Genentech, and, to a lesser extent, *Synagis*, which is marketed by MedImmune. Royalty payments from sales of Genentech's products accounted for 65% of total royalty revenues during the three months ended March 31, 2006, up from 55% in the comparable period of 2005.

Royalty payments from sales of *Herceptin*, *Synagis* and *Avastin* accounted for 34%, 32% and 24% of our royalty revenues for the three months ended March 31, 2006 as compared to 31%, 39% and 17% in the comparable period in 2005, respectively.

We expect that, with the exception of *Zenapax* royalties from Roche and *Tysabri* royalties from Elan, we generally will continue to experience royalty revenue growth based on the assumed continued growth in product sales underlying our royalty revenues. As per the terms of our Second Amended and Restated Worldwide Agreement with Roche, Roche will pay us royalties at a reduced rate only once *Zenapax* product sales have reached a certain threshold and we expect to receive minimal to no royalty revenue from Roche's sale of *Zenapax* going forward. In addition, because Elan ceased the sale of *Tysabri* and the return of *Tysabri* to the market, if ever, remains uncertain, we do not expect to receive any royalty revenue from Elan for the sale of *Tysabri* in the foreseeable future. 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 three months of 2006 and 2005 primarily consisted of upfront licensing and patent rights fees, milestone payments related to licensed technology, license maintenance fees and revenue recognized under our collaboration agreements.

License, collaboration and other revenues increased 106% to $9.7 million in the first quarter of 2006 from $4.7 million in the corresponding quarter of 2005 primarily due to revenue recognized from our collaboration with Biogen Idec, which was entered into in August 2005.

Costs and Expenses

(in thousands)	Three Months Ended March 31, 2006	2005	% Change
Cost of product sales	$ 22,959	$ 1,137	*
Research and development	61,771	35,261	75%
Selling, general and administrative	32,159	7,666	320%
Acquired in-process research and development	—	79,417	(100)%
Other acquisition-related charges	366	—	*
Total costs and expenses	$117,255	$123,481	(5)%

* Calculation not meaningful

Cost of Product Sales

Cost of product sales (COS) relates to our marketed products and consists primarily of cost of goods sold, royalty expenses and amortization of product rights on the products acquired from ESP Pharma and from *Retavase*, which was re-launched under our label beginning April 2005. COS increased significantly in the three months ended March 31, 2006 as compared to the same period in the prior year because we did not have any product sales or COS until March 23, 2005, when we completed the ESP Pharma acquisition. COS of $23.0 million and $1.1 million as a percentage of product sales was 62% and 120% for the three months ended March 31, 2006 and 2005, respectively. Amortization of product rights, related to the acquisition of our marketed products, was 46% and 93% of COS for the three months ended March 31, 2006 and 2005, respectively. For the full year 2006, due principally to the amortization of product rights for our marketed products, we continue to expect COS to be in the range of approximately 45% to 48% of product sales, and we expect continued quarter-to-quarter variability based on product mix changes and production results, acknowledging that there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing, or inventory related issues.

Research and Development

Research and development costs consist primarily of costs of personnel to support our research and development activities, milestone payments and technology licensing fees, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility and overhead costs. Beginning with the first quarter of 2006, research and development costs also include stock-based compensation expense of $3.4 million accounted for under SFAS 123(R) as a component of personnel related costs. The $26.5 million increase in research and development costs in the first quarter of 2006 compared to the corresponding quarter of 2005 was primarily due to increases in personnel related costs of $8.2 million, clinical development expenses for our major research and development projects of $7.0 million, facility-related costs of $4.1 million, outside services costs of $3.6 million, information technology-related costs of $2.6 million, and research and development licensing costs of $1.1 million.

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

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

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Three Months Ended March 31, 2006	2005
					(in thousands)	
Current Product Candidates						
Daclizumab					$ 12,036	$ 7,402
	Healthy Volunteer SC	Phase 1	Roche	2006		
	Asthma IV	Phase 2a	Roche	Completed		
	Multiple Sclerosis Combination	Phase 2	Biogen Idec	2007		
Ularitide (1)					3,599	N/A
	Acute Decompensated Heart Failure	Phase 2	CardioPep Pharma	Completed		
Terlipressin (2)					782	N/A
	Type 1 Hepatorenal Syndrome	Phase 3	Orphan Therapeutics	2006		
HuZAF					914	859
	Crohn's Disease	Phase 2	—	Completed		
	Rheumatoid Arthritis	Phase 2	Biogen Idec	2006		
Nuvion					9,813	6,731
	IV steroid-refractory ulcerative colitis	Phase 2/3	—	2007		
	Crohn's Disease	Phase 2	—	2006		
M200					5,344	3,826
	Solid tumors	Phase 2	Biogen Idec	2006		
Other (3)			—		29,283	16,443
Total Research and Development Expenses					**61,771**	**$ 35,261**

(1) We assumed development responsibility in Q1 2005. The Phase 2 study was completed by CardioPep in Europe. We have worldwide development and commercialization rights to this product.

(2) Orphan Therapeutics has development responsibility for this molecule; we have exclusive marketing rights in the U.S. and Canada.

(3) No other clinical product included in "other" constitutes more than 5% of the total research and development expenses for the periods presented. Also includes expenses for terminated and out-licensed product candidates.

The information in the column labeled "Estimated Completion of Phase" is our current estimate of the timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates provided in the table. The clinical development portion of these programs may span as many as seven to 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 expensive, and costs may fluctuate unexpectedly," "We are subject to extensive government regulation, which requires us to invest significant resources in development, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize our products," "Our clinical trial strategy may increase the risk of clinical trial difficulties," "If we do not attract and retain key employees, our business could be impaired," and "We may be unable to obtain or maintain regulatory approval for our products and the marketing and sale of our products could result in violations of law or regulations" sections of our Risk Factors.

Selling, General and Administrative Expenses

Selling, general and administrative costs generally consist of costs of personnel, professional services, consulting and other expenses related to our selling and administrative functions and an allocation of facility costs. Beginning with the first quarter of 2006, selling, general and administrative costs also include stock-based compensation expense of $2.6 million accounted for under SFAS 123(R) as a component of personnel related costs. Selling, general and administrative expenses for the three months ended March 31, 2006 increased 320% to $32.2 million from $7.7 million during the comparable period in 2005. This increase was primarily due to increases in personnel-related expenses of $17.7 million, outside services of $8.4 million and facility-related expenses of $1.6 million. These increases were partially offset by decreases in information technology-related costs allocated out to research and development expenses of $2.6 million. The majority of the increase in personnel-related expenses was attributable to the addition of the sales, sales management, operations and marketing teams, located in our New Jersey offices, in connection with our acquisition of ESP Pharma on March 23, 2005.

We expect that selling, general and administrative expenses will continue to increase slightly for the remainder of 2006 as we operate our expanded sales force and support staff and initiate or continue promotional programs for our products.

Acquired In-Process Research and Development

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

In addition, during the fourth quarter of 2003, we recorded a charge to acquired in-process research and development totaling approximately $48.2 million in connection with the amendment to our collaboration agreement with Roche in October 2003, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell daclizumab (*Zenapax*) in all disease indications other than transplantation. This amount relates to the rights to autoimmune indications for daclizumab that were then being developed and tested in clinical studies, specifically to treat asthma and ulcerative colitis.

There have been no significant changes to the in-process projects since December 31, 2005. Since the earliest acquisition date, we have incurred an additional $75.5 million in research and development expenditures related to completing the in-process projects.

Interest and Other Income, Net and Interest Expense

(in thousands)	Three Months Ended March 31, 2006	2005	% Change
Interest and other income, net	$ 3,330	$ 2,935	13%
Interest expense	(2,650)	(2,142)	24%
Total interest and other income, net and interest expense	$ 680	$ 793	(14)%

Interest income for the three months ended March 31, 2006 increased from the comparable period in 2005 due to the increased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of higher interest rates and higher invested balances.

Interest expense for the three months ended March 31, 2006 increased from the comparable period in 2005 as a result of both our 2.00%, $250.0 million Convertible Senior Notes (the 2005 Notes) and our 2.75%, $250.0 million Convertible Subordinated Notes (the 2003 Notes) being outstanding during the entire first quarter of 2006, compared to the 2005 Notes being outstanding only for half of the first quarter of 2005 as the 2005 Notes was issued in mid-February 2005.

Income Taxes

We recorded tax provisions of approximately $115,000 and $22,000 for the three months ended March 31, 2006 and 2005, respectively. Taxes during the three months ended March 31, 2006 were primarily related to federal alternative minimum taxes and foreign taxes on income earned by our foreign operations reduced by a state tax benefit from the current net loss for those state for which we are in a deferred tax liability position. Taxes during the three months ended March 31, 2005 were primarily related to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have financed our operations primarily through public and private placements of equity and debt securities, royalty revenue, license and other revenue under agreements with third parties, interest income on invested capital and, more recently, product sales. At March 31, 2006, we had cash, cash equivalents, marketable securities and restricted investments in the aggregate of $346.1 million, compared to $333.9 million at December 31, 2005.

Net cash provided by operating activities for the three months ended March 31, 2006 was approximately $2.3 million, compared to net cash used in operating activities of $8.6 million in the corresponding period in 2005. The $2.3 million net cash provided by operating activities in the first three months of 2006 was primarily attributable to our product sales and revenues from royalties, which were offset partially by the increase in spending for advancing clinical programs and our expansion into sales and marketing activities.

Net cash used in investing activities was $77.2 million for the three months ended March 31, 2006, compared to $311.4 million in the comparable period in 2005. The $77.2 million net cash used for investing activities in the first three months of 2006 was attributable to $98.9 million in purchases of marketable securities and $9.4 million in capital expenditures, which were partially offset by $28.3 million in maturities of our marketable and restricted securities and $2.8 million from the sale of intangible assets.

Net cash provided by financing activities for the three months ended March 31, 2006 was $15.7 million, compared to $243.7 million in the comparable period in 2005. The $15.7 million net cash provided by financing activities in the first three months of 2006 was due to the issuance of our common stock of $15.8 million, partially offset by payments on other long-term obligations of $0.1 million.

We estimate that our existing capital resources will be sufficient to fund our operations through 2006 and the foreseeable future. Our future capital requirements will depend on numerous factors, including, among others, continued growth in sales of our marketed products; royalties from sales of products by third-party licensees, including *Avastin, Herceptin, Synagis, Xolair, Raptiva*, and *Mylotarg*; 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; significant resources we will need to expend to update or modify our manufacturing facilities as new products are introduced or manufacturing processes are revised; significant resources we will need to expend in the long term to refurbish or replace our manufacturing facilities due to obsolescence; our ability to obtain and retain funding from third parties under collaborative arrangements; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; successful integration of acquired businesses, including the transition to us of existing relationships with partners, distributors, third-party vendors, manufacturers, and customers of acquired companies; and the costs 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.

There have been no material changes to our contractual obligations since December 31, 2005 as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005.

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 March 31, 2006, we had an accumulated deficit of approximately $466.3 million. We expect our expenses to increase primarily because of the extensive resource commitments required to achieve regulatory approval and commercial success for our portfolio of existing products and potential products. For example, over the next several years, we will incur substantial additional expenses as we continue to invest in life cycle management of our existing products, develop and manufacture our potential products, invest in research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our partners or licensees may not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may not achieve sustained positive cash flow from operations that we have currently projected. We may also incur acquisition-related charges to our ESP or *Retavase* transactions, which would adversely affect our operating results. The amount of net losses and the time required to reach sustained profitability from our proprietary products are highly uncertain.

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

- many of our earlier stage potential products move into later stage clinical development;
- additional potential products are selected as clinical candidates for further development;
- we pursue clinical development of our potential products in new indications;
- we invest in life cycle management initiatives for our existing products;
- we invest in staffing and operations to meet our manufacturing requirements;
- we expand our commercial infrastructure to market and sell our products;
- we defend or prosecute our patents and patent applications; and
- we invest in research or acquire additional technologies, product candidates or businesses.

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

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

In the quarter ended March 31, 2006, sales of *Cardene* IV, IV *Busulfex* and *Retavase* accounted for 97% of total product sales and 39% of total revenues. We expect that revenue from these products will continue to represent a significant and possibly growing portion of our total revenue. The patents which we own or hold licenses to that cover *Cardene* IV, IV *Busulfex* and *Retavase* will expire between 2009 and 2015. We are developing or may develop new dosage forms, formulations or manufacturing processes and we are identifying or may identify new indications for these products or otherwise develop new intellectual property with respect to these products. As a result of these efforts, we may secure additional or extended patent or marketing or other nonpatent statutory exclusivity rights. If obtained, these additional rights may extend the life cycle of these products and permit us to maintain or expand our position in the marketplace and sustain our revenue stream from the sale of these products. If we do not succeed in our efforts to effectively extend the life cycle of any of these products, we likely would be exposed to significantly more competition from generic versions of these products upon expiration of the patents that cover these products. Competition from generic forms of any of our products likely would cause significant declines in the amount of revenue and profit margins we recognize from the sale of that product.

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

Cardene IV has accounted for a significant portion of the operating income and growth in our sales since we acquired it in our acquisition of ESP Pharma in March 2005. *Cardene* IV faces a competitive marketplace with branded and generic intravenous anti-hypertensive products being marketed in the United States and it may be harder to continue to penetrate this market at the recent rate of growth. While we expect to increase committed sales and marketing resources in an effort to ensure the continued growth of *Cardene* IV, there can be no assurance that we can continue the rapid growth rate that ESP Pharma achieved. Some of our competitors

have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive and other related drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for *Cardene* IV to continue its success, we will have to maintain and expand its position in the marketplace against these competitors' drugs.

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

Retavase is expected to account for a significant portion of our operating income from product sales and potential growth in cash flow from operations. *Retavase* is sold into a thrombolytic market that has recently been declining due to the more widespread use of stents and gpIIb/IIIa inhibitor products. Moreover, *Retavase* competes for use in the management of acute myocardial infarction with *TNKase*™ and *Activase*® from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we possess. While we believe that our planned investment in additional promotional efforts may increase the market acceptance of *Retavase*, there can be no assurance that we can increase the market share of *Retavase*, or that even if we are able to increase our market share, that the anti-thrombolytic market will not decline significantly regardless of our efforts. In addition, the product was previously marketed on behalf of Centocor by Scios, a Johnson & Johnson company. We recently completed the transfer of the product from these companies but will require the continued cooperation of Centocor and Scios to successfully transfer the manufacturing of the product to our operations, and there can be no assurance that we will be successful in achieving this transition or our projected sales levels.

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

We will be required to manufacture *Retavase* for sale and distribution no later than 2011. *Retavase* is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth RTP Inc. and Roche. While the rights to *Retavase* included the acquisition in March 2005 of at least 12 months of inventory, the manufacturing of this product for use as a therapeutic in compliance with regulatory requirements will be complex, time-consuming and expensive. We are required to effect the transfer of manufacturing from Centocor in a timely manner. The eventual transfer of manufacturing could result in delays in regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

We rely on third-party suppliers to provide our products for sale and certain clinical candidates for trials. If we are unable to continue those manufacturing arrangements successfully or at a reasonable cost, our potential future results could suffer.

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

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

Achieving future profitability or revenue growth will depend in significant part upon the continuing success of our product *Retavase* and the products we acquired in our acquisition of ESP Pharma.

We have incurred losses since inception. In order for us to achieve future profitability, we will need to achieve continued growth from *Cardene* IV, *Retavase* and IV *Busulfex* as well as continued growth in royalties from products licensed under our intellectual property rights.

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

We sell our products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the quarter ended March 31, 2006, revenues from the sales of our products to our three largest U.S. wholesalers totaled approximately 89% of our gross product sales. Our reliance on a small number of wholesalers and distribution partners could cause revenues to fluctuate from quarter to quarter based on the buying, return and payment patterns of these wholesalers and distribution partners. In addition, as of March 31, 2006, these three U.S. wholesalers represented approximately 93% of our outstanding accounts receivable. We recently had significant adjustments to returns of off-patent branded products acquired in our acquisition of ESP Pharma. These adjustments were due primarily to unexpected returns from wholesalers. We believe these unexpected returns resulted from overstocking of inventory by wholesalers in anticipation of future price increases that did not occur, and therefore have affected the rate of returns. We continue to monitor current levels of inventory at the wholesalers consistent with our forecasts of end user demand. Nevertheless, in the absence of a written agreement with a wholesaler or distribution partner, there can be no assurance that our wholesalers and distribution partners will maintain inventory levels consistent with our forecast of end user demand. Due to enhanced inventory management and enforcement of product return policy, we do not believe that we will experience the same level of returns for products sold subsequent to the acquisition date and we have established reserves based on these expectations. If returns exceed our expectations, revenues would be adversely affected. In addition, if any of these wholesalers fails to pay on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

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

At March 31, 2006, we had approximately $507.2 million of outstanding long-term debt, including $250.0 million in principal that remains outstanding under our 2.00% Convertible Senior Notes due February 15, 2012 (the 2005 Notes). In addition to the 2005 Notes, approximately $250.0 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2023 (the 2003 Notes), and we have debt service obligations related thereto. The 2005 Notes do not restrict our future incurrence of indebtedness and we may incur additional indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including:

- 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 continue to integrate the ESP Pharma business and may not realize the anticipated benefits of the merger.

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

- demonstrating to our customers that the merger will not result in adverse changes in client service standards or business focus and helping customers conduct business successfully with the combined company;
- coordinating sales and marketing efforts as a combined company;
- retaining key sales-related employees;
- coordinating and rationalizing commercialization and development activities to enhance life cycle management and development programs;
- continuing the establishment of new trade practices and relationships with wholesalers;
- management distraction from the business of the combined company;
- consolidating and rationalizing corporate and administrative infrastructures, including establishment of appropriate internal control and staffing levels to manage a much larger business enterprise;
- integrating and documenting ESP Pharma-related processes and controls in conformance with the requirements of the Sarbanes-Oxley Act of 2002; and
- operating the combined company at multiple sites in the United States.

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

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

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

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

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

As a result of the merger with ESP Pharma, we face challenges inherent in efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. The inability to manage successfully the geographically more diverse and substantially larger combined organization and the inability to retain or replace key employees could have a material adverse effect on the operating results of the combined company and, as a result, on the market price of our common stock.

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

We have agreements with pharmaceutical and other companies to develop, manufacture and market certain of our potential products. In some cases, we are relying on our partners to manufacture such products and essential components for those products, to design and conduct clinical trials, to compile and analyze the data received from these trials, to obtain regulatory approvals and, if approved, to market these licensed products. As a result, we may have little or no control over the manufacturing, development and marketing of these potential products and little or no opportunity to review the clinical data prior to or following public announcement. In addition, the design of the clinical studies may not be sufficient or appropriate for regulatory review and approval and we may have to conduct further studies in order to facilitate approval.

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

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

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

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

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

- the commitment of each partner's management to the continued development of the licensed products or technology;
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts; and

- the relative advantages of alternative products or technology being marketed or developed by each partner or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. The rules governing the standards that must be met for management to assess the effectiveness of our internal control over financial reporting are new and complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal control over financial reporting successfully in 2004 and 2005.

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

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

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

- the seasonality and rate of growth of sales of existing and licensed products;
- the existence of competing products;
- our ability to market and sell recently acquired products;
- the response of wholesalers at announced or anticipated price changes for our products;
- uncertainty resulting from the purchase practices of wholesalers and inventory levels at wholesalers;
- product returns, reimbursements and rebates which could differ from our estimates and accruals;
- the continued safety of approved products;
- the marketing and promotional efforts of our licensees from whom we receive royalty payments;
- the timing of royalty reports;
- our ability to successfully defend and enforce our patents;

- the effect of taxes and estimates or adjustments to estimates for federal and state taxes that may impact our reported net income in any particular quarter; and
- the effect of new accounting pronouncements or interpretations of existing guidance, in particular as they may affect the accounting treatment of reimbursement of research and development expenses under collaborative arrangements.

We receive a significant portion of our royalty revenues from sales of *Synagis*, which is marketed by MedImmune. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties paid to us in our first and second quarters than in other quarters. The seasonality of *Synagis* sales is expected to continue to contribute to fluctuation of our revenues from quarter to quarter.

License and other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees, payments for manufacturing and clinical development services, and payments for the achievement of milestones under new and existing agreements with third-party business partners. In addition, based on current accounting principles and guidance, we currently recognize reimbursement of expenses under our existing collaborative arrangements as revenue at the time the work is performed under the collaboration. In the event that there is a change in the accounting principles or guidance that would result in a "netting" of revenues and expenses during the period in which the work is performed, our revenues would be reduced and netted with related expenses, although our net loss would not change. Nevertheless, a change to this effect would likely reduce our reported rate of growth in licensed and other and total revenues from historical periods due to this change in accounting. The recognition of license and other revenue that we otherwise would defer and recognize over a period of time under applicable accounting principles may be accelerated in certain circumstances. In such a case, it may cause our revenue during that period to be higher than it otherwise would have been had the circumstances not occurred. For example, if a licensee of ours terminates a development program for which we received an upfront non-refundable fee that required our ongoing performance, the recognition of the revenue would be accelerated and recognized in the period in which the termination occurred. In addition, revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

Our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing and the unpredictable nature of clinical trial and related expenses, including 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, the recognition of clinical trial and other expenses that we otherwise would recognize over a period of time under applicable accounting principles may be accelerated in certain circumstances. In such a case, it may cause our expenses during that period to be higher than they otherwise would have been had the circumstances not occurred. For example, if we terminate a clinical trial for which we paid non-refundable upfront fees to a clinical research organization and in which we did not accrue all of the patient costs, the recognition of the expense associated with those fees that we were recognizing as we accrued patient costs would be accelerated and recognized in the period in which the termination occurred.

In addition, our expenses or other operating results may fluctuate due to the accounting treatment of securities we own or may purchase or securities we have issued or may issue. For example, we began recognizing expense for stock-based awards exchanged for employee services in the first quarter of 2006 under SFAS 123(R) and, as a result, our expenses are significantly higher than prior to the adoption of SFAS 123(R). In addition, we hold a $30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. (Exelixis) that matures in May 2006. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the change in the value of the Exelixis stock in our financial statements such that changes in the Exelixis stock price contribute to fluctuations of our operating results from quarter to quarter.

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

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

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European antibody humanization patent. We appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (entitlement to priority, novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. In February 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office, currently scheduled to take place on July 10, 2006 through July 13, 2006. Due to a schedule conflict, we have requested that the oral proceeding take place later in 2006. We are awaiting response from the European Patent Office to our request. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if the opponents are successful, our ability to collect

royalties on European sales of antibodies humanized by others would depend on: (i) the scope and validity of our second European patent; and (ii) whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents and, if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to our related patents in other jurisdictions, including the United States. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related United States and Japanese patents.

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

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

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

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

Our ability to maintain and increase our revenues from licensing is dependent upon third parties entering into new patent licensing arrangements, exercising rights under existing patent rights agreements, paying royalties under existing patent licenses with us and not terminating those existing licenses with us. To date, we have been successful in obtaining and maintaining such licensing arrangements, and in receiving royalties on product sales, from parties whose products may be covered by our patents. However, there can be no assurance that we will continue to be successful in our licensing efforts in the future. In the past we have experienced challenges in our licensing efforts, such as the disagreement we had with Genentech in 2003 over whether its *Xolair* antibody product was covered under our humanization patents. Although we have reached an amicable settlement with Genentech that is intended to resolve such disagreements, Genentech or other companies may, in the future terminate their licensing agreements with us, or seek to challenge our U.S. patents through litigation or patent office proceedings, such as re-examinations or interferences. If we experience difficulty in enforcing our patent rights through licenses, or if our licensees, or prospective licensees, challenge our antibody humanization patents, our revenues and financial condition could be adversely affected, and we could be required to undertake additional actions, including litigation, to enforce our rights. Such efforts would increase our expenses and could be unsuccessful.

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

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

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. These proceedings could be expensive, last

several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation in claim scope could reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

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

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

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

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

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

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

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

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

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

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

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

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

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

- changes in regulatory policy during the period of product development;
- delays in obtaining sufficient supply of materials to enroll and complete clinical studies according to planned timelines;
- delays in obtaining regulatory approvals to commence a study;
- delays in identifying and reach agreement on acceptable terms with prospective clinical trial sites;
- delays in the enrollment of patients;
- lack of efficacy during clinical trials; or
- unforeseen safety issues.

Completion of clinical trials may take several years or more. The length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly according to the type, complexity, proprietary and intended use of the product candidate and is difficult to predict. Further, we, the FDA, European Medicines Agency (EMEA), investigational review boards or data safety monitoring boards may decide to temporarily suspend or permanently terminate ongoing trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to preclinical or clinical trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future. Despite the time and expense incurred, we cannot guarantee that we will successfully develop commercially viable products that will achieve FDA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

We are subject to extensive government regulation, which requires us to invest significant resources in development, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize our products.

Our product candidates under development are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, research, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, quality control, adverse event reporting, advertising, promotions, sale and distribution of biopharmaceutical products. If we market our products abroad, they will also be subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain. To obtain regulatory approval for the commercial sale of any of our potential products or to promote these products for expanded indications, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in indications for which approval is requested. We have had, and may in the future have, clinical setbacks that prevent us from obtaining regulatory approval for our potential products.

Early clinical trials such as Phase 1 and 2 trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed. We may decide, or the FDA may require us, to make changes in our plans and protocols. Such changes may relate, for example, to changes in the standard of care for a particular disease indication, comparability of efficacy and toxicity of potential drug product where a change in the manufacturing process or manufacturing site is proposed, or competitive developments foreclosing the availability of expedited approval procedures. We may be required to support proposed changes with additional preclinical or clinical testing, which could delay the expected time line for concluding clinical trials.

Larger or later stage clinical trials may not produce the same results as earlier trials. Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials.

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

In addition, we may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise because we have a relatively large number of potential products in clinical development. The approval process takes many years, requires the expenditure of substantial resources, and may involve post-marketing surveillance and requirements for post-marketing studies. The approval of a product candidate may depend on the acceptability to the FDA of data from our clinical trials. Regulatory requirements are subject to frequent change. Delays in obtaining regulatory approvals may:

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

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

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

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA “fast track” designation for a particular indication. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although we have obtained a fast track designation from the FDA for *Nuvion* for the treatment of intravenous steroid-refractory ulcerative colitis and our partner Orphan Therapeutics has received fast track designation from the FDA for terlipressin for Hepatorenal Syndrome, Type 1, receipt of fast track

designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that *Nuvion* or terlipressin will receive regulatory approval for the treatment of intravenous steroid-refractory ulcerative colitis.

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

Research, preclinical testing and clinical trials may take many years to complete, and the time required can vary depending on the indication being pursued and the nature of the product. We may at times elect to use clinical strategies that seek to advance potential products through clinical development as rapidly as possible. We anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

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

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

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

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

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

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

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

To be successful, we must attract additional and retain qualified clinical, manufacturing, commercial, scientific and management personnel. To achieve our objectives, we expect to expand our operations and increase the number of our employees significantly. If we are unsuccessful in attracting and retaining qualified personnel, particularly at the management level, our business could be impaired. We have been successful in hiring and retaining key personnel in the past; however, we face significant competition for experienced, management level personnel. For example, our former CFO resigned in October 2005, and our current CFO just joined us in April 2006. If other positions in finance remain or become vacant, our ability to operate effectively, including our ability to report on and attest to, the effectiveness of our internal control over financial reporting, could be adversely affected.

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

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

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

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

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

Failure to successfully operate our manufacturing plant, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis could delay commercialization of our products. In addition, our collaborations with Roche and Biogen Idec involving daclizumab may be significantly negatively impacted by our failure to successfully operate and receive regulatory approval of our Brooklyn Park, Minnesota manufacturing facility.

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

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

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

With respect to our M200 antibody product, ICOS has manufactured all of the drug material contemplated for use in our current Phase 2 clinical studies. Biogen Idec and we will need to demonstrate that the M200 drug material produced will be sufficiently bioequivalent to the ICOS-produced drug material to use in future clinical studies in order to avoid delays in development or regulatory approval for this antibody product.

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

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

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

Any product that our collaborative partners or we succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success.

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

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

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

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

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

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

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

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

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

- delays;

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

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

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

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

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

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

We depend on outside vendors for the supply of raw materials used to produce our products and product candidates. Once a supplier's materials have been selected for use in the manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third-party suppliers were to cease production or otherwise fail to supply us

with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

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

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

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

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

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

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. The FDA and other health care policies may change, and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. Cost containment measures, whether instituted by health care providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payers may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

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

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

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. For example, during the period from January 1, 2006 to May 3, 2006, our common stock closed as high as $32.80 per share and as low as $21.10 per share. Additionally, the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The following are some of the factors that may have a significant effect on the market price of our common stock:

- developments or disputes as to patent or other proprietary rights;
- disappointing sales of our marketed products;
- approval or introduction of competing products and technologies;
- disappointing sales of products from which we receive royalties;

- withdrawal from the market of an approved product from which we receive royalties;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- changes in reimbursement policies;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- disputes or disagreements with collaborative partners;
- developments in our relationships with customers;
- market reaction to announcements by other biotechnology or pharmaceutical companies, including market reaction to various announcements regarding products licensed under our technology;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- initiation, termination or modification of agreements with our collaborative partners;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

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

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

Future changes in financial accounting standards, including changes in accounting for stock options, may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. For example, the compensation expense reported under SFAS 123(R) has had, and will continue to have, a significant adverse effect on our reported financial condition beginning in 2006 and may impact the way we conduct our business.

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

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

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

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

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

If any or all of our outstanding 2003 Notes or 2005 Notes are converted into shares of our common stock, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

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

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

In accordance with U.S. generally accepted accounting principles, we accounted for the acquisition of ESP Pharma, our acquisition of *Retavase* and our acquisition of certain rights with respect to daclizumab using the purchase method of accounting, which resulted in charges to earnings in the year of acquisition and which will result in ongoing expenses due to the amortization and depreciation of certain assets acquired in those transactions. Under the purchase method of accounting, we allocated the total estimated purchase price to ESP Pharma's net tangible assets, amortizable intangible assets and in-process research and development based on their fair values as of the date of completion of the merger, and recorded the excess of the purchase price over those fair values as goodwill. The portion of the purchase price of ESP Pharma allocated to in-process research and development in the amount of $79.4 million was expensed by the combined company in the first quarter of 2005. We will incur additional depreciation and amortization expense over the useful lives of certain of the net tangible and intangible assets acquired in connection with the acquisition transactions. In addition, to the extent the value of acquired intangible assets becomes impaired in the future, as experienced with the review for impairment of

the off-patent branded products in the third quarter of 2005, we may be required to incur material charges relating to the impairment of such assets, and possibly goodwill as well. These depreciation, amortization, in-process research and development and potential impairment charges could have a material impact on the combined company's results of operations and the market value of our common stock.

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

The acquisition of ESP Pharma and certain rights to *Retavase* required cash payments of approximately $435.5 million. While we believe we have sufficient funds for our anticipated operations, we will need to generate significantly greater revenues to achieve and then maintain profitability on an annual basis. The product development, including clinical trials, manufacturing and regulatory approvals of product candidates currently in development, and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future funding requirements, which may be significantly greater than we expect, depend upon many factors, including:

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

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

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

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

For the year ended December 31, 2004, approximately 34% of the ESP Pharma net product sales resulted from the sale of the off-patent products *Tenex*, *Sectral*, *Ismo* and *Declomycin*. These products historically accounted for a majority of the cash flow from operations of ESP Pharma. We do not consider these products as strategic assets and made the decision to sell the related intangible assets and inventory for these products in the third quarter of 2005. The related intangible assets and inventory were classified as held for sale since September 30, 2005. Because the estimated fair market value of the related intangible assets was lower than the carrying value, an impairment loss of approximately $15.2 million was recognized in the third quarter 2005 and an additional $0.3 million

impairment loss was recognized in the fourth quarter of 2005 (see Note 4 to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K). We completed the sale of *Declomycin* in February 2006, and the remaining three off-patent branded products in March 2006.

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

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

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

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

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

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

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

ITEM 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 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 March 31, 2006, 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, 2005.

Because we translate foreign currencies into United States dollars for reporting purposes, currency fluctuations can have an impact on our results. For the three months ended March 31, 2006 and 2005, there was no material foreign currency exchange impact on our Condensed Consolidated Statements of Operations from our intercompany transactions. As of March 31, 2006, we did not engage in foreign currency hedging activities.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer, Chief Financial Officer (who joined us in early April 2006) and Principal Accounting Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 ("the Exchange Act")) as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer concluded that our disclosure controls and procedures are effective in reaching a reasonable level of assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission's rules and forms.

Changes in internal controls.

There were no changes in our internal controls over financial reporting during the quarter ended March 31, 2006 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. We continue to improve and refine our internal controls and our compliance with existing controls is an ongoing process.

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, 2005. No significant changes in the status of disclosed items have occurred since December 31, 2005.

ITEM 1A. RISK FACTORS

Other than with respect to the new risk factor set forth below, there have been no material changes from the risk factors disclosed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2005.

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

In the quarter ended March 31, 2006, sales of *Cardene* IV, IV *Busulfex* and *Retavase* accounted for 97% of total product sales and 39% of total revenues. We expect that revenue from these products will continue to represent a significant and possibly growing portion of our total revenue. The patents which we own or hold licenses to that cover *Cardene* IV, IV *Busulfex* and *Retavase* will expire between 2009 and 2015. As we seek to enhance the usefulness and value of our products, we are developing or may develop new dosage forms, formulations or manufacturing processes and we are identifying or may identify new indications for these products or otherwise develop new intellectual property with respect to

these products. As a result of these efforts, we may secure additional or extended patent or marketing or other nonpatent statutory exclusivity rights. If obtained, these additional rights may extend the life cycle of these products and permit us to maintain or expand our position in the marketplace and sustain our revenue stream from the sale of these products. If we do not succeed in our efforts to effectively extend the life cycle of any of these products, we likely would be exposed to significantly more competition from generic versions of these products upon expiration of the patents that cover these products. Competition from generic forms of any of our products likely would cause significant declines in the amount of revenue and profit margins we recognize from the sale of that product.

ITEM 6. EXHIBITS

10.1	Offer letter between the Company and Mr. Andrew L. Guggenhime dated February 3, 2006.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act.
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of PDL BioPharma, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

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: May 9, 2006

PDL BIOPHARMA, INC.
(Registrant)

/s/ Mark McDade

Mark McDade
Chief Executive Officer
(Principal Executive Officer)

/s/ Andrew L. Guggenhime

Andrew L. Guggenhime
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

/s/ George Jue

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

Exhibit 10.1

February 3, 2006

Andrew L. Guggenhime
[*]
[*]

Dear Andrew:

On behalf of Protein Design Labs, Inc., I am pleased to extend you an offer for the position of Senior Vice President and Chief financial Officer, reporting to Mark McDade, CEO. Your appointment as an officer of PDL is subject to approval by PDL's Board of Directors. The compensation package described below is contingent upon formal approval by PDL's Compensation Committee.

The salary for this position is $305,000.00 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 2006 performance bonus program (payable in 2007), with an annual target bonus of 37.5%.

You will also receive options to purchase 65,000 shares of Protein Design Labs Common Stock under a PDL stock option plan. 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. In addition, you will receive 7,500 shares of restricted stock, which vest annually over four years. This offer is subject to the approval of the Board of Directors and your execution of our standard Stock Option Agreement.

PDL is prepared to offer you a hiring bonus of $20,000.00. 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 $20,000.00 will be immediately due and payable to PDL. If you voluntarily resign your position or your employment is terminated for cause after your one-year anniversary but prior to your two-year anniversary with PDL, $10,000 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 Laurie Torres, in the enclosed envelope. 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 and look forward to seeing you on your first day of employment, April 3, 2006.

Sincerely,

/s/ Mark McDade
Mark McDade
CEO, Protein Design Labs

/s/ Andrew Guggenhime
Andrew Guggenhime

March 7, 2006
Date

EXHIBIT 31.1

CERTIFICATIONS

I, Mark McDade, Chief Executive Officer of PDL BioPharma, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of PDL BioPharma, Inc.;

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

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

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

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

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

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

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 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: May 9, 2006

/s/ Mark McDade

Mark McDade
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATIONS

I, Andrew L. Guggenhime, Senior Vice President and Chief Financial Officer of PDL BioPharma, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of PDL BioPharma, Inc.;

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

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

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

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

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

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

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 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: May 9, 2006

/s/ Andrew L. Guggenhime

Andrew L. Guggenhime
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

I, Mark McDade, Chief Executive Officer, and Andrew L. Guggenhime, Senior Vice President and Chief Financial Officer of PDL BioPharma, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on his knowledge:

(1) the Quarterly Report on Form 10-Q for the quarter ended March 31, 2006 of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

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

Dated: May 9, 2006

By:

/s/ Mark McDade

Mark McDade
Chief Executive Officer

/s/ Andrew L. Guggenhime

Andrew L. Guggenhime
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)