Table of Contents

UNITED STATES
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 September 30, 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 and Zip Code)

(510) 574-1400
(Registrant's telephone number, including area code)

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 November 3, 2006, there were 115,226,181 shares of the Registrant's Common Stock outstanding.

Table of Contents

PDL BIOPHARMA, INC.

INDEX

Table of Contents

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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Product sales, net	$ 41,064	$ 43,594	$ 117,650	$ 83,094
Royalties	42,533	26,003	140,524	96,695
License, collaboration and other	27,795	7,536	48,754	17,127
Total revenues	111,392	77,133	306,928	196,916
Costs and expenses:				
Cost of product sales	17,433	22,209	61,874	43,481
Research and development	70,880	49,480	195,263	125,080
Selling, general and administrative	26,672	26,795	84,167	54,267
Acquired in-process research and development	—	—	—	79,417
Other acquisition-related charges	2,615	6,266	5,910	9,473
Asset impairment charges	1,656	15,225	2,556	15,225
Total costs and expenses	119,256	119,975	349,770	326,943
Operating loss	(7,864)	(42,842)	(42,842)	(130,027)
Interest and other income, net	5,042	2,027	12,436	6,835
Interest expense	(3,693)	(2,671)	(9,465)	(7,522)
Loss before income taxes	(6,515)	(43,486)	(39,871)	(130,714)
Income tax expense	208	1,680	441	1,767
Net loss	$ (6,723)	$ (45,166)	$ (40,312)	$(132,481)
Net loss per basic and diluted share	$ (0.06)	$ (0.43)	$ (0.36)	$ (1.30)
Shares used in computation of net loss per basic and diluted share	113,868	105,272	113,293	101,910

See accompanying notes.

PDL BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data or where otherwise noted)

	September 30, 2006 (unaudited)	December 31, 2005 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 205,133	$ 183,377
Marketable securities, including $0 million and $6.8 million of restricted investments at September 30, 2006 and December 31, 2005, respectively	178,992	101,617
Accounts receivable, net of allowances of $13.5 million and $12.8 million at September 30, 2006 and December 31, 2005, respectively	16,479	19,116
Inventories	22,102	17,728
Deferred tax assets	4,778	9,244
Prepaid and other current assets	10,824	18,272
Short-term note receivable	—	30,000
Total current assets	438,308	379,354
Long-term marketable securities	34,874	48,928
Restricted cash	3,269	—
Land, property and equipment, net	269,256	266,053
Goodwill	69,954	57,783
Other intangible assets, net	369,484	397,266
Other assets	11,638	13,770
Total assets	$ 1,196,783	$1,163,154
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,406	$ 2,728
Accrued compensation	17,220	16,401
Royalties payable	4,114	3,295
Other accrued liabilities	63,888	37,662
Deferred revenue	8,973	11,290
Current portion of other long-term liabilities	631	676
Total current liabilities	100,232	72,052
Convertible notes	499,998	499,998
Deferred tax liabilities	5,066	—
Long-term deferred revenue	40,250	57,743
Other long-term liabilities	10,550	7,296
Total liabilities	656,096	637,089
Stockholders' equity:		
Common stock, par value $0.01 per share, 250,000 shares authorized; 114,128 and 112,062 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	1,141	1,121
Additional paid-in capital	1,020,565	969,118
Deferred stock-based compensation	—	(1,998)
Accumulated deficit	(480,421)	(440,109)
Accumulated other comprehensive loss	(598)	(2,067)
Total stockholders’ equity	540,687	526,065
Total liabilities and stockholders’ equity	$ 1,196,783	$1,163,154

See accompanying notes.

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

	Nine Months Ended September 30,	
	2006	2005
Cash flows from operating activities:		
Net loss	$ (40,312)	$(132,481)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Acquired in-process research and development	—	79,417
Asset impairment charges	2,556	15,225
Depreciation	23,542	11,214
Amortization of convertible notes offering costs	1,759	1,620
Amortization of intangible assets	33,177	26,506
Stock-based compensation expense	17,740	510
Loss on disposal of fixed assets	78	—
Tax benefit from employee stock options	—	300
Excess tax benefit from stock-based compensation arrangements	(450)	—
Changes in assets and liabilities:		
Accounts receivable, net	2,637	(26,231)
Interest receivable	(816)	(157)
Inventories	(4,494)	48
Other current assets	11,914	(9,123)
Other assets	372	459
Accounts payable	2,843	4,243
Accrued liabilities	40,064	2,727
Deferred tax liabilities	5,066	—
Deferred revenue	(19,810)	39,286
Total adjustments	116,178	146,044
Net cash provided by operating activities	75,866	13,563
Cash flows from investing activities:		
Purchases of marketable securities	(277,913)	—
Maturities of marketable securities	210,048	147,060
Maturities of restricted securities	6,829	6,876
Repayment of note receivable	30,000	—
Adjustment to goodwill related to ESP Pharma acquisition	365	15,655
Cash paid for ESP Pharma acquisition, net of cash acquired	—	(322,558)
Cash paid for *Retavase* acquisition	—	(110,000)
Purchase of intangible assets	(18,777)	—
Sale of intangible assets	2,750	—
Proceeds from sale of equipment	109	—
Purchase of land, property and equipment	(26,932)	(32,564)
Transfer to restricted cash	(3,269)	—
Net cash used in investing activities	(76,790)	(295,531)
Cash flows from financing activities:		
Proceeds from issuance of common stock	22,521	131,117
Proceeds from issuance of convertible notes	—	241,831
Excess tax benefit from stock-based compensation arrangements	450	—
Payments on other long-term obligations	(291)	(609)
Net cash provided by financing activities	22,680	372,339
Net increase in cash and cash equivalents	21,756	90,371
Cash and cash equivalents at beginning of the period	183,377	91,395
Cash and cash equivalents at end of the period	$ 205,133	$ 181,766

See accompanying notes.

PDL BIOPHARMA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 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 three 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 several investigational compounds in Phase 2 or Phase 3 clinical development for severe or life-threatening diseases. We have entered into collaborations with other pharmaceutical or biotechnology companies for the joint development, manufacture and commercialization of certain of these compounds. Our research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases.

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) that 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). 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 Sheet to conform to the current period presentation. In addition, we reclassified certain prior period charges from contra-revenues to other acquisition-related charges for *Retavase* product returns that related to products sold by Centocor, Inc. prior to our acquisition of the rights to the product in March 2005. In the second quarter of 2006, we reclassified such amounts to be consistent with the accounting treatment for other similar charges incurred subsequent to our acquisition of ESP Pharma in March 2005 that were associated with pre-acquisition operations. The impact of the reclassification increased product sales, net, and other acquisition-related charges by approximately $1.9 million and $1.0 million for the nine-month periods ended September 30, 2006 and 2005, respectively.

Management Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

In accordance with our product returns reserve policy, we review the estimated rate for product sales returns on a quarterly basis. In June 2006, based on product returns experienced in the quarter, additional visibility into channel inventory levels and activity and enhancements made to our estimation process, we revised our estimates for product sales returns to better reflect the projected future level of returns. The effect of this change in estimate was to reduce product sales, net, in June 2006 by approximately $5.6 million, which increased net loss per basic and diluted share by approximately $0.05 for the nine-month period ended September 30, 2006.

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 make 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.

The following table summarizes revenues from our customers and licensees who individually accounted for 10% or more of our total revenues for the three and nine months ended September 30, 2006 and 2005 (as a percentage of total revenues):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Customers				
Cardinal Health, Inc.	13%	19%	18%	16%
McKesson Corp.	13%	20%	13%	17%
AmerisourceBergen Corp.	11%	16%	13%	12%
Licensees				
Genentech, Inc. (Genentech)	37%	29%	36%	31%
MedImmune, Inc. (MedImmune)	*	*	10%	15%

* Represents less than 10%

Other Acquisition-Related Charges

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

Stock-Based Compensation

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

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" (FSP 123R-3). We must follow either the transition guidance for the additional paid-in capital (APIC) pool in paragraph 81 of SFAS 123(R) or the alternative transition method described in FSP 123R-3. 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 SFAS 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. FSP 123R-3 provided an alternative transition method for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R). FSP 123R-3 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.

We account for stock options granted to persons other than employees or directors at fair value using the Black-Scholes option-pricing model in accordance with 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 such persons and stock options that are modified and continue to vest when an employee has a change in employment status are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense during the service period over which the non-employee provides services to us. The stock-based compensation expense related to non-employees for the three- and nine-month periods ended September 30, 2006 was $21,000 and $0.2 million, respectively, compared to $0.1 million and $0.2 million, respectively, for the corresponding periods of 2005.

Stock-Based Incentive Plans

We have four active stock-based incentive plans under which we may grant stock-based awards to our employees, officers, directors and consultants. The total number of shares of common stock authorized for issuance, shares of common stock issued upon exercise of options or as restricted stock that have vested and are no longer subject to forfeiture, subject to outstanding awards and available for grant under each of these plans as of September 30, 2006 is set forth in the table below:

Title of Plan	Total Shares of Common Stock Authorized	Total Shares of Common Stock Issued	Total Shares of Common Stock Subject to Outstanding Awards	Total Shares of Common Stock Available for Grant
1999 Stock Option Plan	9,568,694	2,103,559	5,574,102	1,891,033
1999 Nonstatutory Stock Option Plan	11,000,000	3,130,740	7,252,365	616,895
2002 Outside Directors Stock Option Plan	480,000	40,000	233,500	206,500
2005 Equity Incentive Plan	2,300,000	25,175	1,378,788(1)	896,037
1991 Nonstatutory Stock Option Plan(2)	14,131,306	13,119,034	1,012,272(3)	—

(1) Includes 137,525 restricted shares of our common stock that had not vested and were subject to forfeiture as of September 30, 2006.

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

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

Stock options granted to employees under our plans in connection with the start of employment customarily vest over four years with 25% of the shares subject to such an option vesting on the first anniversary of the grant date and

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

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

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

Employee Stock Purchase Plan

In addition to the stock-based incentive plans described above, we adopted the 1993 Employee Stock Purchase Plan (ESPP), which is intended to qualify as an “employee stock purchase plan” under Section 423 of the Internal Revenue Code of 1986, as amended. Full-time employees who own less than 5% of our outstanding shares of common stock are eligible to contribute a percentage of their base salary, subject to certain limitations, over the course of six-month offering periods for the purchase of shares of common stock. The purchase price for shares of common stock purchased under our ESPP equals 85% of the fair market value of a share of common stock at the beginning or end of the relevant six-month offering period, whichever is lower. Of the 2,400,000 shares authorized for issuance under our ESPP, as of September 30, 2006, 1,919,805 have been issued and 480,195 remain available for future issuance.

Prior to the Adoption of SFAS 123(R)

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

The table below illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123, “Accounting for Stock-Based Compensation,” (SFAS 123) as amended by SFAS No. 148, “Accounting for Stock-Based Compensation – Transition and Disclosures,” to our stock-based compensation plans prior to the adoption of SFAS 123(R). For purposes of this pro forma disclosure, the value of the options was estimated using the Black-Scholes option-pricing model. Disclosures for the three and nine months ended September 30, 2006 are not presented in the table below because stock-based compensation to employees and directors were accounted for under SFAS 123(R) during these periods and recognized in our Condensed Consolidated Statements of Operations.

(in thousands, except per share amounts)	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss, as reported	$ (45,166)	$ (132,481)
Add: Stock-based employee compensation expense included in reported net loss, net of taxes	121	265
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards, net of taxes	(5,303)	(14,095)
Pro forma net loss	$ (50,348)	$ (146,311)
Net loss per basic and diluted share:		
As reported	$ (0.43)	$ (1.30)
Pro forma	$ (0.48)	$ (1.44)

Adoption of SFAS 123(R)

We calculated stock-based compensation expense recognized in the three and nine months ended September 30, 2006 under SFAS 123(R) based on the number of awards ultimately expected to vest, net of estimated forfeitures. SFAS 123(R) requires us to estimate forfeiture rates at the time of grant and revise such rates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We adopted SFAS 123(R) using the modified prospective application transition method, which requires that we recognize compensation expense in our consolidated financial statements for all awards granted to employees and directors after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method does not require restatement of prior periods to reflect the impact of SFAS 123(R). Upon adopting SFAS 123(R), we changed from the multiple-option approach to the single-option approach to value stock-based awards with a measurement date on or subsequent to January 1, 2006. In addition, we are amortizing the fair value of these awards using the straight-line attribution method. We believe that the single-option approach with straight-line attribution better reflects the level of service to be provided over the vesting period of our awards. We continue to expense the nonvested awards granted prior to January 1, 2006 under the multiple-option approach with graded-vesting attribution. In addition, in connection with the adoption of SFAS 123(R), we eliminated the remaining balance of the deferred stock-based compensation against APIC.

During the three and nine months ended September 30, 2006, we capitalized stock-based compensation costs of $27,000 and $55,000, respectively, under SFAS 123(R) in inventory. Since substantially all of the products sold in the first nine months of 2006 were manufactured prior to January 1, 2006 when we did not capitalize stock-based compensation expense in inventory, we did not recognize any stock-based compensation expense as a component of cost of product sales in the first nine months of 2006. However, we will recognize the related expenses in cost of product sales in the period the related inventories are sold.

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

(in thousands, except per share amounts)	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	$ 3,499	$ 10,171
Selling, general and administrative	2,472	7,323
Total stock-based compensation expense	5,971	17,494
Tax benefit related to stock-based compensation expense	—	—
Net effect on net loss	$ 5,971	$ 17,494
Effect on net loss per basic and diluted share	$ (0.05)	$ (0.15)

Valuation Assumptions

The stock-based compensation expense recognized under SFAS 123(R) for the three and nine months ended September 30, 2006 and presented in the pro forma disclosure required under SFAS 123 for the three and nine months ended September 30, 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 were as follows:

	Stock Option Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Weighted Average:				
Expected term (in years)	4.0	3.5	4.0	3.1
Volatility	48%	63%	48%	64%
Risk-free interest rate	5.0%	3.9%	5.0%	3.7%
Dividend yield	0%	0%	0%	0%

	Employee Stock Purchase Plan			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Weighted Average:				
Expected term (in years)	0.5	0.5	0.5	0.5
Volatility	46%	38%	43%	42%
Risk-free interest rate	5.2%	3.6%	4.8%	3.4%
Dividend yield	0%	0%	0%	0%

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

Stock Option Activity

A summary of our stock option activity since December 31, 2005 is presented below:

Options	Total Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2005	14,342,264	$ 17.89		
Granted	3,329,012	19.62		
Forfeited	(748,785)	17.77		
Exercised	(1,479,904)	13.91		
Expired	(129,085)	28.50		
Outstanding as of September 30, 2006	15,313,502	$ 18.57	6.13	$ 47,446
Exercisable as of September 30, 2006	8,736,165	$ 18.07	5.45	$ 35,457

Aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the closing prices of our common stock of $19.20 on September 30, 2006, which would have been received by the option holders had all

option holders exercised their options as of that date. Total unrecognized compensation cost related to nonvested stock options outstanding as of September 30, 2006 was $44.4 million, excluding forfeitures, which we expect to recognize over a weighted-average period of 2.8 years.

Additional information regarding our options granted and exercised for the three and nine months ended September 30, 2006 and 2005 is set forth in the following tables:

	Options Granted			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Weighted average grant-date fair value per share	$ 7.52	$ 10.88	$ 8.35	$ 8.79

(in thousands)	Options Exercised			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Cash received	$ 2,407	$ 19,536	$20,580	$29,687
Aggregate intrinsic value	$ 1,225	$ 27,756	$21,538	$37,146

Restricted Stock

A summary of our restricted stock activity since December 31, 2005 is presented below:

	Restricted Stock	
	Number of shares	Weighted-average grant-date fair value
Nonvested at December 31, 2005	103,200	$ 21.88
Awards granted	59,500	$ 19.09
Awards vested	(25,175)	$ (21.73)
Awards canceled/expired/forfeited	—	$ —
Nonvested at September 30, 2006	137,525	$ 20.70

Total unrecognized compensation cost related to nonvested restricted stock outstanding as of September 30, 2006 was $2.7 million, which we expect to recognize over a weighted-average period of 3.2 years. A total of 25,175 shares of restricted stock vested during the three and nine months ended September 30, 2006.

ESPP

The stock-based compensation expense in connection with our ESPP discussed above for the three and nine months ended September 30, 2006 was $0.4 million and $1.2 million, respectively.

Recent Accounting Pronouncements

In July 2006, the FASB issued Interpretation No. 48, “Accounting for Uncertainty in Income Taxes,” which is effective for fiscal years beginning after December 15, 2006. The interpretation prescribes a recognition threshold

and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition. We will adopt the interpretation on January 1, 2007. We are in the process of determining the impact of the interpretation, if any, on our financial position and results of operations.

2. ESP Pharma Acquisition and Subsequent Divestitures of Off-Patent Branded Products

In March 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma. We acquired ESP Pharma consistent with our business strategy of becoming a commercial enterprise that derives the majority of its revenues from sales of proprietary products. The ESP Pharma acquisition was accounted for as a business combination in accordance with SFAS No. 141, “Business Combinations” (SFAS 141). In addition to the issuance of 7,330,182 shares of PDL common stock and cash payment of $325.0 million to ESP Pharma stockholders, we deposited 2,523,588 shares of common stock into an escrow account to be held for a period of between six months and one year from the date of the close of the acquisition, pursuant to the terms of an Escrow Agreement entered into in connection with the Amended and Restated Agreement and Plan of Merger. 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 released to former ESP Pharma stockholders and, therefore, we included the value of such shares in the calculation of the purchase price on the acquisition date. However, during the second, third and fourth quarters of 2005, we incurred various costs and recognized certain 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 escrow shares should not have been included in the purchase consideration until the underlying contingencies were resolved and the shares were released from 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 revised the purchase price to exclude the value of these shares. This revision reduced the original recorded goodwill and stockholders’ equity by approximately $36.1 million at March 31, 2005.

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

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

In April 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. Accordingly, we recorded an additional $1.5 million of goodwill. We have not been able to resolve any of the remaining disputed claims since that time.

In July 2006, we filed a demand for arbitration with Judicial Arbitration and Mediation Services to resolve the disputed claims against the remaining 860,386 shares of common stock in escrow. In September 2006, the ESP Pharma stockholders responded to our demand for arbitration denying all of our claims. An arbitrator has not yet been chosen in this matter and no arbitration proceedings have been scheduled or occurred. We believe all current claims against these 860,386 shares are valid and we will vigorously assert our claims against these shares in the arbitration proceeding; however, we cannot be certain of the outcome at this time.

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

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

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

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

The $339.2 million value assigned to the intangible assets related to product rights for the six products – *Cardene* IV, IV *Busulfex*, *Declomycin*, *Sectral*, *Tenex* and *Ismo* – acquired by us. During 2005, we concluded that the carrying amount of the product rights for the off-patent branded products, consisting of *Declomycin*, *Sectral*, *Tenex* and *Ismo*, was impaired as the estimated fair value of these product rights was less than the net carrying value. Accordingly, we recorded an impairment charge in 2005 to reduce the carrying value of these product rights to the fair value. During 2005, we also classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights in accordance with SFAS 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. 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 selling, general and administrative expense in our Condensed Consolidated Statements of Operations during the three months ended March 31, 2006.

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

period product sales. We recorded a total of $1.0 million and $2.5 million, respectively, in the three and nine months ended September 30, 2006 compared to $5.8 million and $8.6 million in the corresponding periods of 2005 for other acquisition-related charges, excluding charges related to *Retavase*.

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 clinical stage research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date. A summary of these programs follows:

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

Orphan Therapeutics, LLC (Orphan Therapeutics), our third-party licensor and the holder of the Investigational New Drug application for terlipressin, conducted a Phase 3 trial of terlipressin in patients with type 1 HRS in the United States. In August 2006, we announced that the trial did not meet its primary endpoint. Orphan Therapeutics continues to analyze the study data and we and Orphan Therapeutics are scheduled to discuss the findings with the U.S. Food and Drug Administration (FDA) in November 2006. Our discussions with the FDA will impact our future decisions regarding the potential future development of terlipressin.

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

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 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. For example, the Phase 3 trial of terlipressin did not meet its primary endpoint and, pending discussions with the FDA, the FDA may require that additional trials be performed prior to applying for marketing approval. 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. We may not successfully commercialize these acquired products 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 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, the assumed exercise of stock options and restricted stock and the assumed issuance of stock under our ESPP using the treasury stock method, and the assumed conversion of convertible notes using the if-converted method. For all periods presented, we incurred a net loss and, as such, we did not include the effect of the common equivalent shares outstanding 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 Condensed Consolidated Statements of Operations and excluded from the table presented in the Stock-Based Compensation section in Note 1 above:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Stock options	14,936	15,642	14,090	15,605
Common stock in escrow	860	2,428	984	1,724
Restricted stock	130	90	115	30
ESPP	150	111	141	92
Convertible notes	22,970	22,970	22,970	21,224
Total	39,046	41,241	38,300	38,675

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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net loss	$(6,723)	$(45,166)	$(40,312)	$(132,481)
Other comprehensive loss:				
Change in unrealized gains and losses on marketable securities, net of taxes	703	(475)	1,469	(932)
Total comprehensive loss	$(6,020)	$(45,641)	$(38,843)	$(133,413)

5. Balance Sheet Details

Restricted Cash

Included in the balance of cash and cash equivalents as of September 30, 2006 is restricted cash of $0.2 million, which represents a letter of credit related to car leases for our sales force that expires in less than one year. In July 2006, we recorded an additional $3.3 million as non-current restricted cash that is pledged and serves as a security deposit under the lease agreements we entered into in July 2006 for our new headquarter facilities in Redwood City, California to which we plan to move in 2007. No restricted cash was included in the balance of cash and cash equivalents as of December 31, 2005.

Short-Term Note Receivable

In May 2006, we received payment on the $30.0 million five-year convertible note receivable from Exelixis, Inc., which matured in May 2006.

Inventories

Inventories consisted of the following:

(in thousands)	September 30, 2006	December 31, 2005
Raw materials	$ 10,186	$ 6,249
Work-in-process	5,835	9,332
Finished goods	6,081	2,147
Total	$ 22,102	$ 17,728

Goodwill

The increase in goodwill from December 31, 2005 to September 30, 2006 was primarily attributable to the release of 0.4 million shares of common stock held in escrow in connection with the ESP Pharma acquisition, which was partially offset by a $0.2 million reduction due to a settlement of certain pre-acquisition tax issues and a $0.4 million reduction due to the lapsing of certain pre-acquisition tax liabilities of ESP Pharma. See Note 2 for further details.

Other Intangible Assets, Net

Acquisition of Cardene Rights

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

In connection with the transaction, during the three months ended September 30, 2006, we recorded $10.7 million of the purchase price, which was allocated to each element of the arrangement based on each element's relative fair value, as follows (in thousands):

Inventories	$ 1,273
Intangible assets	3,776
Research and development expense	5,621
	$10,670

We determined the fair value of the elements in the arrangement consistent with the objective of measuring fair value under SFAS No. 142, "Goodwill and Other Intangible Assets." The fair value of the inventories and intangible assets acquired included both *Cardene* IR and *Cardene* SR products. Since we are not going to sell the *Cardene* IR product going forward, we wrote off the fair value attributable to *Cardene* IR inventories and recorded $0.2 million as asset impairment charges during the third quarter of 2006. We expect to amortize the $3.8 million we allocated to intangible assets relating to *Cardene* SR over a period of three years, which approximates the remaining patent life. We also recognized $5.6 million of the purchase price as research and development expenses, representing the net present value of the estimated royalty amounts we potentially saved related to preliminary research pertaining to potential products that are outside the scope of the existing *Cardene* U.S. patents. These research efforts were incomplete and had not yet reached technological feasibility as of the date of the transaction with Roche.

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

Retavase Product Rights

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

Asset Impairments

In September 2006, we concluded that the carrying amount of one of our intangible assets relating to the distribution of *Retavase* was impaired due to revised royalty revenue forecasts for the product. In accordance with SFAS 144, we prepared a cash flow analysis and compared the sum of the cash flows over the term of the agreement to the carrying value of the asset as of September 30, 2006. As the sum of the future cash flows was less than the carrying value of the asset, we calculated the net present value of the cash flows and recognized $1.5 million, the difference between the carrying value and the discounted cash flows, as an asset impairment charge during the third quarter of 2006. After recognizing the impairment charge, the book value of this intangible asset as of September 30, 2006 was approximately $0.2 million. Total asset impairment charges during the three months ended September 30, 2006 were $1.7 million, including the impairment discussed above related to the write-off of the fair value attributable to *Cardene* IR inventories.

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

In March 2005, we acquired rights to both branded and off-patent branded products as a result of acquisition of ESP Pharma. In June 2005, we engaged a financial advisor to help us divest the rights to our off-patent branded products. During the third quarter of 2005, we received inquiries from multiple potential buyers to acquire the rights to the off-patent branded products and the related inventory. Based on the indications of interest that we received, we concluded that the net carrying value of these product rights and related inventory was impaired at September 30, 2005 and recorded an impairment charge of $15.2 million to reduce the net carrying value of these product rights to $11.0 million.

Other intangible assets, net consisted of the following:

(in thousands)	September 30, 2006			December 31, 2005		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Product rights	$421,617	$ (63,247)	$358,370	$416,500	$ (32,632)	$383,868
Assembled workforce	1,410	(1,410)	—	1,410	(1,410)	—
Core technology	16,053	(4,939)	11,114	16,053	(3,705)	12,348
Licensed research technology	—	—	—	1,500	(450)	1,050
Net intangible assets	$439,080	$ (69,596)	$369,484	$435,463	$ (38,197)	$397,266

Amortization expense for our intangible assets was recorded in cost of product sales, research and development expense and selling, general and administrative expense during the three and nine months ended September 30, 2006 and 2005 as set forth below:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Cost of product sales	$10,661	$11,907	$31,791	$24,872
Research and development	412	486	1,386	1,622
Selling, general and administrative	—	—	—	14
Total amortization expense	$11,073	$12,393	$33,177	$26,508

The expected future amortization expense is as follows:

(in thousands)	Product Rights	Core Technology
For the year ending December 31,		
2006 (remaining three months)	$ 11,265	$ 412
2007	45,062	1,647
2008	45,062	1,646
2009	44,858	1,647
2010	43,793	1,646
Thereafter	168,330	4,116
Total amortization expense	$ 358,370	$ 11,114

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(in thousands)	September 30, 2006	December 31, 2005
Consulting and services	$ 30,928	$ 9,757
Off-patent branded product sale deposit and accruals	—	9,175
Accrued clinical and pre-clinical trial costs	19,252	6,287
Sales rebates	2,834	1,938
Accrued interest	1,484	4,454
Construction-in-process	—	1,694
Milestone payment related to purchase of rights to *Cardene*	3,500	—
Income taxes payable	1,898	2,829
Other	3,992	1,528
Total	$ 63,888	$ 37,662

6. Postretirement Benefit Plan

In June 2003, we established a postretirement health care plan, which covers medical, dental and vision coverage for certain of our former officers and their dependents. During the three- and nine-month periods ended September 30, 2006, we recognized net periodic benefit costs of approximately $0.1 million and $0.3 million, respectively, compared to approximately $36,000 and $0.2 million, respectively, for the corresponding periods in 2005. This expense includes service cost, interest cost and amortization of prior service cost.

7. Income Taxes

Income tax expense during the three and nine months ended September 30, 2006 was 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 and the lapsing of certain contingent tax liabilities of ESP Pharma for the tax year ended December 31, 2002. Income tax expense during the three months and nine months ended September 30, 2005 was primarily related to state income taxes on income earned by ESP Pharma, federal alternative minimum taxes on the consolidated income and foreign taxes on income earned by our foreign operations.

8. Collaborations

In September 2004, PDL entered into a Co-Development and Commercialization Agreement with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and other respiratory diseases (Asthma Collaboration). In connection with the Asthma Collaboration, we received a $17.5 million upfront license fee. The Asthma Collaboration also provided that Roche and PDL would globally co-develop daclizumab in treating asthma, equally share development expenses and co-promote the product in the United States.

On August 22, 2006, Roche elected to discontinue its involvement in the Asthma Collaboration and, on that date, we had approximately $18.8 million in deferred license, collaboration and other revenue related to unearned amounts that we had received from Roche specifically related to the Asthma Collaboration. As we had and continue to have no further obligations to Roche under the Asthma Collaboration, we recognized $18.8 million, representing the previously unearned revenue as of the date on which Roche elected to discontinue its involvement in the Asthma Collaboration, as license, collaboration and other revenue during the third quarter of 2006. In October 2006, we earned and received a $5.0 million milestone payment from Roche related to the Asthma Collaboration.

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 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 currently have several investigational compounds in Phase 2 or Phase 3 clinical development for severe or life-threatening diseases. We have entered into collaborations with other pharmaceutical or biotechnology companies for the joint development, manufacture and commercialization of certain of these compounds. Our research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases, with the aim of placing, on average, one new candidate into clinical studies every 12 months.

Commercial Products

We market *Cardene* IV, *Retavase* and IV *Busulfex* through our hospital-focused sales force, which focuses on the emergency cardiac, neurological and intensive care units of hospitals. In addition, with our recent acquisition of various *Cardene*-related rights from Roche, we began selling *Cardene* SR in September 2006. However, because *Cardene* SR is primarily prescribed in physicians' offices, we do not plan to use our hospital-focused sales force to market *Cardene* SR and do not plan to expand our sales force to market this product. Our commercial products are summarized below:

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

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

- *Retavase* is indicated for use in the management of heart attacks (acute myocardial infarction, or AMI) in adults for the improvement of the efficiency of heart muscle contraction following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. The thrombolytics market in which *Retavase* competes has been declining due to physicians' increased use of

emergency surgical procedures to treat AMI, and we expect that this market will continue to decline in the foreseeable future. While we believe that opportunities may exist to expand our market share within the thrombolytics segment, the overall market dynamics for thrombolytics in the treatment of AMI will continue to have a significant impact on our total sales opportunity over the next several years. Our patent protection in the United States on *Retavase* expires in March 2014.

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

Products in Development

We have several investigational compounds in clinical development for severe or life-threatening diseases, some of which we are developing in collaboration with other pharmaceutical or biotechnology companies. Our research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases with the aim of placing, on average, one new candidate into clinical studies every 12 months. The table below lists various investigational compounds we are developing either on our own or in collaboration, other than those compounds for which we have not yet filed an investigational new drug application with the FDA. Not all clinical trials for each product candidate are listed below.

Product Candidate	Indication/Description	Development Status	Collaborator
Terlipressin	Type 1 hepatorenal syndrome	Phase 3	Orphan Therapeutics
Nuvion (visilizumab)	IV steroid-refractory ulcerative colitis	Phase 2/3	—
Ularitide	Acute decompensated heart failure	Phase 2 (EU)	—
	Acute decompensated heart failure	Phase 1 (US)	—
Daclizumab	Asthma	Phase 2a	—
	Multiple sclerosis	Phase 2b	Biogen Idec
	Transplant maintenance	Phase 2	Roche
Volociximab (M200)	Solid tumors	Phase 2	Biogen Idec
HuZAF (fontolizumab)	Rheumatoid arthritis	Phase 2 Ceased Sep ‘06	Biogen Idec
PDL063	Multiple myeloma	IND filed	—

Terlipressin. Terlipressin is a synthetic, 12 amino acid, vasoactive peptide that is being developed by Orphan Therapeutics, LLC and is currently being studied in a Phase 3 clinical trial for patients with type 1 hepatorenal syndrome (HRS), a life-threatening complication of end-stage liver cirrhosis. We hold all marketing and distribution rights to terlipressin in the United States and Canada. Terlipressin has been marketed for over 20 years in many European and Asian countries as a treatment for another complication of liver cirrhosis, esophageal variceal hemorrhage.

The Phase 3 study of terlipressin did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo. Orphan Therapeutics continues to analyze the study data and we and Orphan Therapeutics plan to discuss the findings with the FDA to inform future decisions regarding the potential future development of terlipressin.

Nuvion (visilizumab). Nuvion is a humanized monoclonal antibody that binds to CD3, a protein found on the outer membrane of T cells. T cells are white blood cells that play a role in inflammatory and immune-mediated processes in the body. Nuvion is currently being tested in a Phase 2/3 clinical trial in patients with intravenous steroid-refractory ulcerative colitis (IVSR-UC) and Phase 2 studies in patients with Crohn's disease (CD). We hold all worldwide rights to the development, manufacturing and sales of Nuvion.

Ularitide. Ularitide is a synthetic form of urodilatin, a naturally occurring human natriuretic peptide that is involved in regulating blood pressure and the excretion of water and sodium from the kidneys. Urodilatin is produced in the kidney and excreted into the urine, and thus exists in low levels naturally in the systemic blood circulation. When injected into the blood, ularitide appears to cause diuresis (urine output) and natriuresis (sodium excretion), as well as vasodilation.

In April 2006, we completed the Scientific Advice procedure with the EMEA for our Phase 3 trial of ularitide for the treatment of acute decompensated heart failure and began planning for a two-study, 3,300-patient Phase 3 trial. Because this trial was significantly larger in scope than what we had previously anticipated, and because we have not previously conducted such a large-scale clinical trial, we also initiated partnering discussions for this program at the same time we were planning for the Phase 3 trials. In September 2006, we decided to delay the Phase 3 trial of ularitide because, based on our partnering discussions, potential partners would want to have active involvement in the registration program for ularitide. Our delay of the European-focused Phase 3 trials of ularitide will not affect our ongoing planning for a U.S.-based dose-ranging Phase 1 study to define dose-limiting toxicity.

Daclizumab. Daclizumab is a humanized monoclonal antibody that binds to the alpha chain (CD25) of the interleukin-2 (IL-2) receptor on activated T cells, which are white blood cells that play a role in inflammatory and immune-mediated processes in the body. We and our partner, Biogen Idec, are currently testing daclizumab in a Phase 2 study in patients with multiple sclerosis. In addition, we and our partner, Roche, plan to conduct Phase 2 studies of daclizumab in patients requiring renal transplant as a possible maintenance therapy to prevent rejection of the transplanted organ. Since Roche's election to terminate its co-development of daclizumab in treating asthma with us, we have begun evaluating opportunities to establish a new collaboration and would need to partner this program in order to further develop daclizumab in treating asthma.

Volociximab (M200). Volociximab is a chimeric monoclonal antibody that inhibits the functional activity of a5ß1 integrin, a protein found on activated endothelial cells that are involved in the formation of blood vessels. We and our partner, Biogen Idec, are currently investigating volociximab in Phase 2 clinical trials in patients with advanced solid tumors.

HuZAF (fontolizumab). HuZAF targets gamma interferon, a protein that stimulates several types of white blood cells and that has been shown by academic researchers to play a role in certain autoimmune diseases. In July 2006, we and our partner, Biogen Idec, jointly agreed to terminate further development of HuZAF in rheumatoid arthritis because HuZAF did not show positive results from the related Phase 2 trial that we conducted together with Biogen Idec. We and Biogen Idec do not currently have any plans for development of HuZAF in other indications.

PDL063. PDL063 is an antibody that binds to a cell surface glycoprotein that is highly expressed on myeloma cells but minimally expressed on normal cells. PDL063 may induce anti-tumor effects through antibody-dependent cellular cytotoxicity activity on myeloma cells. We plan to begin a Phase 1 trial of PDL063 in relapsed refractory multiple myeloma in the fourth quarter of 2006.

Royalty, License and Collaboration Revenue

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

We have licensed and will continue to offer to license our humanization patents in return for license fees, annual maintenance payments and royalties on product sales. The nine humanized antibody products listed below are currently approved for use by the FDA and are licensed under our patents.

Licensee	Product Name
Genentech, Inc. (Genentech)	Avastin™
	Herceptin®
	Xolair®
	Raptiva®
	Lucentis™
MedImmune, Inc. (MedImmune)	*Synagis*®
Wyeth	*Mylotarg*®
Elan Corporation, Plc (Elan)	*Tysabri*® (1)
Roche	*Zenapax*® (2)

(1) In February 2005, sales of *Tysabri* were suspended and we received only a marginal amount of royalties prior to this suspension. Although *Tysabri* was reintroduced for marketing in July 2006, it is too early to determine whether royalties will be significant.

(2) Roche is obligated to pay us royalties on *Zenapax* only once product sales have reached a certain threshold, and we do not expect to receive royalty revenue from Roche's sales of *Zenapax* going forward.

Various third parties are developing humanized monoclonal antibodies for use in a variety of indications. The FDA is reviewing registration applications for two of these humanized monoclonal antibodies, six are in Phase 3 clinical studies, more than 25 are in Phase 2 clinical studies and a few dozen more are in earlier stages of development. We believe that our humanization patents would likely cover a number of these humanized monoclonal antibodies under development. Although there are a significant number of humanized monoclonal antibodies under development that our patents likely would cover, we know that (i) many of these clinical trials may be terminated prior to registration, (ii) the clinical trials and registration process for these potential products may take several years, (iii) even if approved, these products may not be commercially successful and (iv) the FDA, EMEA or other relevant regulatory bodies may suspend or terminate any marketing approval after a product is approved.

We have a collaboration agreement with Roche to jointly develop and commercialize daclizumab (in transplantation, marketed as *Zenapax*) for the treatment of organ transplant patients on longer-term maintenance therapy (transplant maintenance). This collaboration agreement also governed the joint development and commercialization of daclizumab for the treatment of asthma and other respiratory diseases; however, in August 2006, following a portfolio review at Roche, Roche elected to discontinue its involvement in the development of daclizumab in treating asthma and other respiratory diseases in accordance with the terms of the collaboration agreement. Currently, we are looking for a partner with which to continue to develop daclizumab in treating asthma. Roche's decision has no effect on our ongoing collaboration with Roche to co-develop daclizumab in transplant maintenance, and we and Roche intend to proceed with planned Phase 2 studies for the transplant maintenance indication during 2007. As a result of Roche's termination of the collaboration to co-develop daclizumab in treating asthma, we recognized approximately $18.8 million of previously deferred license, collaboration and other revenue during the three months ended September 30, 2006. Subsequent to September 30, 2006, we earned and received from Roche an additional $5.0 million milestone payment under this agreement, which we expect to recognize as license, collaboration and other revenue in the fourth quarter of 2006. As a result of the termination of our collaboration with Roche for daclizumab in treating asthma, we will not receive any further milestone payments related to this collaboration that we would have received had it not been terminated.

We have a collaboration agreement with Biogen Idec for the joint development, manufacture and commercialization of daclizumab in multiple sclerosis (MS) and indications other than transplant and respiratory diseases, and for shared development and commercialization of volociximab (M200) and *HuZAF* (fontolizumab) in all indications. In August 2006, we announced that we and Biogen Idec will discontinue development of *HuZAF* in rheumatoid

arthritis and that we and Biogen Idec do not currently have any plans for development of *HuZAF* in other indications. Under our collaboration agreements with Roche and Biogen Idec, we will share with our partners equally the costs of all development activities. These agreements require each party to undertake extensive efforts in support of the collaboration and require the performance of both parties to be successful. We anticipate recognizing an increasing amount of revenue and expenses as we progress with these collaborations.

We continue to evaluate potential opportunities to partner certain programs or capabilities of our drug development and commercialization with other pharmaceutical or biotechnology companies and expect that we will enter into other collaboration agreements in the future.

Summary of Third Quarter of 2006

In the third quarter of 2006, our total revenues were $111.4 million, a 44% increase from $77.1 million in the comparable period in 2005. This revenue growth was driven primarily by an increase in license, collaboration and other revenue, an increase in royalties from our licensees and, to a lesser degree, growth in sales of our three marketed products. The increase in license, collaboration and other revenue was principally attributable to the recognition of $18.8 million of previously deferred revenue during the third quarter of 2006 due to Roche's election to discontinue its co-development of daclizumab in treating asthma and other respiratory diseases. Of the total revenues we generated in the third quarter of 2006, approximately 38% were from royalty payments we received, 37% were from the sale of our products and 25% were from license, collaboration and other revenue, compared to 34%, 56%, and 10%, respectively, in the corresponding period of 2005. Our net loss for the third quarter of 2006 was $6.7 million, compared to $45.2 million in the prior-year period. In the first nine months of 2006, net cash provided by operating activities was $75.9 million, an increase from $13.6 million in the comparable period in 2005. At September 30, 2006, we had cash, cash equivalents, marketable securities and restricted cash and investments of $422.3 million, compared to $333.9 million at December 31, 2005. As of September 30, 2006, we had $507.0 million in total debt outstanding, which included $500.0 million in convertible notes, $250.0 million of which are callable in each of 2008 and 2010 and due in 2023 and 2012, respectively.

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

During the third quarter of 2006, the events noted below occurred:

- In July 2006, we began manufacturing products for use in clinical trials in our manufacturing facility in Brooklyn Park, Minnesota.
- In July 2006, we entered into agreements to lease two buildings with a total of approximately 450,000 square feet of space located in Redwood City, California, for 15 years, beginning January 2007 and ending December 2021, with the right to extend the lease terms by up to 10 years. We plan to move our corporate headquarters from Fremont, California, to this facility in Redwood City, California, in the second half of 2007. Pursuant to the lease agreements, we have the right to take delivery of the two buildings in October 2006 and November 2006, respectively, at which time we will start recognizing rent expense.
- In July 2006, we and Biogen Idec jointly agreed to terminate further development of *HuZAF* in rheumatoid arthritis because *HuZAF* did not show positive results from the related Phase 2 trial that we conducted together with Biogen Idec. We and Biogen Idec do not currently have any plans for development of *HuZAF* in other indications.
- In early August 2006, we announced that the Phase 3 study of terlipressin did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo. Orphan Therapeutics continues to analyze the study data, and we and Orphan Therapeutics plan to discuss the findings with the FDA to inform future decisions regarding the potential future development of terlipressin.

- In August 2006, Roche decided to discontinue its involvement in the development of daclizumab in treating asthma, which both we and Roche had been co-developing since 2004. This decision, following a portfolio review at Roche, has no effect on our ongoing collaboration with Roche to co-develop daclizumab in transplant maintenance, and we and Roche intend to proceed with planned Phase 2 studies for the transplant maintenance indication during 2007.
- In September 2006, we acquired from Roche all rights to *Cardene* owned by them, including rights to the *Cardene* trademark and the *Cardene* Sustained Release product (*Cardene* SR). As a result of this transaction, we now own rights to all formulations of *Cardene*.
- In September 2006, we decided to delay the planned two-study, 3,300-patient Phase 3 trial of ularitide because, based on our partnering discussions, potential partners would want to have active involvement in the registration program for ularitide. Our delay of the European-focused Phase 3 trials of ularitide will not affect our ongoing planning for a U.S.-based dose-ranging Phase 1 study to define dose-limiting toxicity.

Economic and Industry-wide Factors

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

- Our business will depend in significant part on our ability to develop and commercialize innovative new drugs. Drug development, however, is highly uncertain and very expensive, typically requiring tens to hundreds of millions invested in research, development and manufacturing elements. Identifying drug candidates to study in clinical trials requires significant investment and may take several years. In addition, the clinical trial process for drug candidates is usually lengthy, expensive and subject to high rates of failure throughout the development process. As a result, a majority of the clinical trial programs for drug candidates are terminated prior to applying for regulatory approval. Even if a drug receives FDA or other regulatory approval, such approval could be conditioned on the need to conduct additional trials, or we could be required to or voluntarily decide to suspend marketing of a drug as a result of safety or other events.
- Our industry is subject to extensive government regulation, and we must make significant expenditures to comply with these regulations. For example, the FDA regulates, among other things, the development, testing, research, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, quality control, adverse event reporting, advertising, promotions, sale and distribution of our products. The development and marketing of our products outside of the United States is subject to similar extensive regulation by foreign governments, which regulations are not harmonized with the regulations of the United States.
- The manufacture of drugs and antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. If we are unable to manufacture product or product candidates in accordance with FDA and European good manufacturing practices, we may not be able to obtain or retain regulatory approval for our products. We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture all of our potential products on a commercial scale, and we are currently reliant on third-party manufacturers for all of our formulated and fully-packaged final products.
- Our business success is dependent in significant part on our success in establishing intellectual property rights, either internally or through in-license of third-party intellectual property rights, and protecting our intellectual property rights. If we are unable to protect our intellectual property, we may not be able to compete successfully and our sales and royalty revenues and operating results would be adversely affected. Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages or may be reduced in scope. Proceedings to protect intellectual property rights are expensive, last several years and could result in a significant reduction in the scope or invalidation of our patents, which could adversely affect our results of operations.
- To be successful, we must attract and retain qualified clinical, manufacturing, commercial, scientific and management personnel. Although we face significant competition for experienced personnel, we believe we have been successful in hiring and retaining key personnel in the past.

See also the “Risk Factors” section of this quarterly report for additional information on these economic and industry-wide and other factors and the impact they could have on our business and results of operations.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

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

Revenue Recognition

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

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

We enter into patent license, collaboration and humanization agreements that may contain multiple elements, such as upfront license fees, reimbursement of research and development expenses, milestones related to the achievement of particular stages in product development and royalties. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting under Emerging Issues Task Force Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables,” for revenue recognition purposes and, if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element under Staff Accounting Bulletin No. 104, “Revenue Recognition.”

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

In addition, we 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 chargebacks, government rebate programs and cash discounts are based on contractual terms, historical utilization rates and expectations regarding future utilization rates for these programs. Estimates for wholesaler service fees are based on a certain percentage of sales

per wholesaler contract terms. Estimates for product returns are based on an on-going analysis of industry and historical return patterns, monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, reviewing channel inventory data available to us and reviewing third-party data purchased in order to monitor prescriptions. Further, we monitor the activities and clinical trials of our key competitors to assess the potential impact on our future sales and return expectations.

If conditions or other circumstances change for any of the markets in which we compete, we may take actions to revise our product return estimates or we may offer additional customer incentives. These revisions could result in an incremental reduction of revenue at the time the return estimate is changed or new incentives are offered. For example, in June 2006, based on product returns experienced in the quarter, additional visibility into channel inventory levels and activity and enhancements made to our estimation process, we changed our estimates for product sales returns to better reflect the projected future level of returns. The effect of this change in estimate was to reduce product sales, net, in June 2006 by approximately $5.6 million, which increased net loss per basic and diluted share by approximately $0.05 for the nine months ended September 30, 2006. Accounts receivable allowances for chargebacks, wholesaler service fees and product returns, as well as rebate accruals, require substantial judgment. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

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

Clinical Trial Expenses

We base our cost accruals for clinical trials on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business, we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements vary from contract to contract, are subject to negotiation and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, we recognize direct expenses related to each patient enrolled in a clinical trial on an estimated cost-per-patient basis as services are performed. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from 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 we actually may incur.

Goodwill and Other Intangible Assets

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

Once the values for intangible assets are established, we must test intangible assets with definite useful lives for impairment in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” 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.

Stock-Based Compensation

Effective January 1, 2006, we account for certain 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 we recognize compensation expense 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 stock-based awards with a measurement date on or subsequent to January 1, 2006. In addition, we are amortizing the fair value of these awards using the straight-line attribution method. We believe that the single-option approach with straight-line attribution better reflects the level of service to be provided over the vesting period of our awards. We continue to expense the nonvested awards granted prior to January 1, 2006 under the multiple-option approach with graded-vesting attribution. Although total stock-based compensation cost under both methods is comparable, under the multiple-option approach, stock-based compensation expense in the earlier periods of the option term would be higher than in later periods, compared to the single-option approach.

Under the provisions of SFAS 123(R), we estimate the fair value of our stock awards to employees and directors 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 stock option exercises and forfeitures by employees and directors 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 stock-based awards granted to employees and directors in future periods.

Further, SFAS 123(R) requires that we recognize certain stock-based compensation costs over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees and directors. Accordingly, in the third quarter of 2006, we recognized stock-based compensation under SFAS 123(R) of $6.0 million as part of our operating expenses, with an allocation of $3.5 million to research and development expense and $2.5 million to selling, general and administrative expense. For the nine months ended September 30, 2006, we recognized $17.5 million of stock-based compensation under SFAS 123(R) as part of our operating expenses, with $10.2 million and $7.3 million, respectively, allocated to research and development expense and selling, general and administrative expense. We did not recognize any related tax benefit during the three or nine months ended September 30, 2006.

During the three months ended September 30, 2006, we capitalized employee stock-based compensation costs under SFAS 123(R) in inventory. Since substantially all of the products sold in the first nine months of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs, we did not recognize any employee stock-based compensation expense as a component of cost of product sales in the first nine months of 2006. However, we will recognize the related expenses in cost of product sales in the period the related inventories are sold.

Total unrecognized compensation cost related to nonvested stock options and restricted stock outstanding as of September 30, 2006, excluding forfeitures, was $44.4 million and $2.7 million, respectively, and is expected to be recognized over a weighted average period of 2.8 years and 3.2 years, respectively. There was no stock-based compensation expense recognized under SFAS 123(R) during the three and nine months ended June 30, 2005 because we adopted SFAS 123(R) after those periods.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," which is effective for fiscal years beginning after December 15, 2006. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. We will adopt the Interpretation on January 1, 2007. We are in the process of determining the impact of the interpretation on our financial position and results of operations.

RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2006 and 2005

Revenues

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	% Change	2006	2005	% Change
Product sales, net	$ 41,064	$43,594	(6)%	$117,650	$ 83,094	*
Royalties	42,533	26,003	64%	140,524	96,695	45%
License, collaboration and other	27,795	7,536	269%	48,754	17,127	185%
Total revenues	$111,392	$77,133	44%	$306,928	$196,916	56%

* Percentage change is not included because periods are not comparable.

Our total revenues increased by $34.3 million, or 44%, and $110.0 million, or 56%, in the three and nine months ended September 30, 2006, respectively, from the comparable periods in 2005 for reasons discussed below.

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	% Change	2006	2005	% Change
Cardene	$28,692	$21,452	34%	$ 77,845	$38,263	*
Retavase	7,187	11,620	(38)%	21,786	25,602	*
IV *Busulfex*	5,185	5,369	(3)%	16,902	11,610	*
Total marketed products	41,064	38,441	7%	116,533	75,475	*
Off-patent branded products	—	5,153	(100)%	1,117	7,619	*
Total product sales, net	$41,064	$43,594	(6)%	$117,650	$83,094	*

* Percentage change is not included because periods are not comparable.

Product sales, net

For the three months ended September 30, 2006, total net product sales decreased 6%, or $2.5 million, from the comparable period in 2005. Since we divested the rights to our off-patent branded products in the first quarter of 2006, product sales in the third quarter of 2006 consisted only of our current marketed products, the sales of which increased by 7% from the comparable period in 2005. The increase in net product sales of our current products was primarily due to an increase in the sales volume of *Cardene* IV and to a lesser extent, price increases for *Cardene* IV and IV *Busulfex* that were effective January 2006, partially offset by a decline in *Retavase* sales.

For the nine months ended September 30, 2006, total net product sales increased $34.6 million from the comparable period in 2005. Because we first acquired commercial products in late March 2005, the comparable 2005 period includes net product sales for only approximately six months, as compared to nine months of sales for the 2006 period. Net product sales of our currently marketed products was $116.5 million during the nine months ended September 30, 2006 compared to $75.5 million during the comparable 2005 period. The $41.0 million increase from the 2005 period was primarily attributable to increases in product sales volumes of *Cardene* IV and IV *Busulfex* and, to a lesser extent, because of price increases for these two products in January 2006. This increase, however, was partially offset by a significant decline in Retavase sales volumes as well as charges of $5.6 million, which related to a change in estimate for our product returns reserve that occurred in the second quarter of 2006. The increase in product sales volume of *Cardene* IV and IV *Busulfex* was due primarily to the fact that we had nearly three additional months of sales in 2006 than the comparable period in 2005, which included only about a weeks' worth of sales in the first quarter of 2005, and also to modest increases in sales volumes in the second and third quarters of 2006 compared to the same periods in 2005. We expect that net sales of our currently marketed products, as a group, will continue to increase, principally driven by expected *Cardene* sales growth.

Cardene

Net product sales of *Cardene* increased by $7.2 million, or 34%, in the three months ended September 30, 2006 from the comparable period in 2005. This increase was primarily due to our successful promotional strategies to increase our market share in this emerging market and consisted primarily of an increase in the sales volume of *Cardene* IV and, to a lesser extent, higher average per unit sales prices due to our increase of *Cardene* IV prices in January 2006 and the addition of *Cardene* SR sales of $0.3 million in September 2006. We expect our market share of *Cardene* IV to continue to increase and that growth in sales of *Cardene* IV will in large part drive our anticipated product sales growth in the foreseeable future.

Net product sales of *Cardene* increased by $39.6 million in the nine months ended September 30, 2006 from the comparable period in 2005. As discussed above, this increase was primarily due to the fact that the 2006 period included nine months of sales, while the 2005 period included only approximately six months.

Retavase

Net product sales of *Retavase* decreased by $4.4 million, or 38%, in the three months ended September 30, 2006 from the comparable period in 2005. Net product sales of *Retavase* decreased by $3.8 million, or 15%, in the nine months ended September 30, 2006 from the comparable period in 2005, notwithstanding the fact that the 2006 period included nine months of sales and the 2005 period included only six months of sales. These decreases were primarily due to a reduction in sales volume as a result of the decline of the thrombolytics market in which *Retavase* competes because of physicians' increased use of emergency surgical procedures to treat AMI, and we expect that this market will continue to decline in the foreseeable future. Despite the continuing decline of the thrombolytics market, we believe that opportunities exist for us to expand our market share through focused sales and promotional efforts. However, the competitiveness of the market for thrombolytics may limit our ability to obtain price increases in the future.

IV *Busulfex*

Net product sales of IV *Busulfex* decreased by $0.2 million, or 3%, in the three months ended September 30, 2006 from the comparable period in 2005. This slight decrease was due to a reduction in sales volume, which was partially offset by a price increase that was effective in January 2006. We expect IV *Busulfex* product sales volume to increase in the future as we expand our international sales through our distribution partners.

Net product sales of IV *Busulfex* increased by $5.3 million in the nine months ended September 30, 2006 from the comparable period in 2005. As discussed above, this increase was primarily due to the fact that the 2006 period included nine months of sales while the 2005 period included only approximately six months and, to a lesser extent, a price increase for IV *Busulfex* that was effective in January 2006.

Royalties

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
Licensee	**Product Name**	**2006**	**2005**	**2006**	**2005**
Genentech	*Avastin*	36%	33%	29%	21%
	Herceptin	51%	41%	40%	32%
MedImmune	*Synagis*	*	*	21%	31%

* Represents less than 10%.

Royalty revenues increased by $16.5 million and $43.8 million, or 64% and 45%, in the three and nine months ended September 30, 2006, respectively, from the comparable periods in 2005. These increases were primarily due to higher reported product sales of *Avastin* and *Herceptin*, which are marketed by Genentech, and were offset partially by the elimination of royalties from product sales of *Zenapax*, which is marketed by Roche.

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 do not expect to receive royalty revenue from Roche's sales of *Zenapax* going forward. *Tysabri* was reintroduced to the market in July 2006, but it is too early to determine the significance of the impact on our future royalty revenues**.** Further, we expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of *Synagis*, 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, Collaboration and Other

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2006**	**2005**	**% Change**	**2006**	**2005**	**% Change**
License and milestone from collaborations	$ 17,203	$ 2,376	624%	$21,450	$ 6,497	230%
R&D services from collaborations	9,443	4,160	127%	24,029	5,003	380%
License and other	1,149	1,000	15%	3,275	5,627	(42)%
Total revenue from license, collaboration and other	$ 27,795	$ 7,536	269%	$48,754	$17,127	185%

License, collaboration and other revenues recognized during the three and nine months ended September 30, 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 $20.3 million and $31.6 million in the three and nine months ended September 30, 2006, respectively, from the comparable periods in 2005 primarily due to the recognition of $18.8 million of previously deferred revenue during the three months ended September 30, 2006, as a result of the discontinuation of our co-development collaboration with Roche for daclizumab in treating asthma, and revenue recognized from our other collaborations with Biogen Idec and Roche, which we entered into in August 2005 and October 2005, respectively.

On August 22, 2006, Roche elected to discontinue its involvement in the asthma collaboration and, on that date, we had approximately $18.8 million in deferred license, collaboration and other revenue related to unearned amounts that we had received from Roche specifically related to this collaboration. As we had and continue to have no further obligations to Roche under the asthma collaboration, we recognized $18.8 million, representing the unearned revenue as of the date on which Roche elected to discontinue its involvement in the asthma collaboration, as license, collaboration and other revenue during the third quarter of 2006. The $18.8 million of deferred revenue consisted of $15.2 million, which represented the unamortized portion of the $17.5 million upfront license fee that we received from Roche at the onset of the asthma collaboration, and $3.6 million, which represented research and development expense reimbursements that we received from Roche during the term of the asthma collaboration, but that we had not yet recognized because the associated research and development services had not yet been completed. Subsequent to September 30, 2006, we earned and received from Roche an additional $5.0 million milestone payment under this agreement, which we expect to recognize as license, collaboration and other revenue in the fourth quarter of 2006. As a result of the termination of our collaboration with Roche for daclizumab in treating asthma, we will not receive any further milestone payments related to the asthma collaboration that we would have received had it not been terminated.

We continue to evaluate potential opportunities to partner certain programs or capabilities of our drug development, manufacturing and commercialization with other pharmaceutical or biotechnology companies and if we enter into other collaboration agreements in the future, our license, collaboration and other revenues would likely increase.

Costs and Expenses

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	% Change	2006	2005	% Change
Cost of product sales	$ 17,433	$ 22,209	(22)%	$ 61,874	$ 43,481	42%
Research and development	70,880	49,480	43%	195,263	125,080	56%
Selling, general and administrative	26,672	26,795	— %	84,167	54,267	55%
Acquired in-process research and development	—	—	— %	—	79,417	(100)%
Other acquisition-related charges	2,615	6,266	(58)%	5,910	9,473	(38)%
Asset impairment charges	1,656	15,225	(89)%	2,556	15,225	(83)%
Total costs and expenses	$119,256	$119,975	(1)%	$349,770	$326,943	7%

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, on the product rights to *Retavase*, which we acquired from Centocor and re-launched in April 2005, and, beginning September 2006, on the rights to *Cardene* that we acquired from Roche. COS of $17.4 million and $22.2 million as a percentage of product sales was 42% and 51% for the three months ended September 30, 2006 and 2005, respectively. COS of $61.9 million and $43.5 million as a percentage of product sales was 53% and 52% for the nine months ended September 30, 2006 and 2005, respectively. COS increased 42% in the nine months ended September 30, 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.

Amortization of product rights was 61% and 54% of COS for the three months ended September 30, 2006 and 2005, respectively. For the nine months ended September 30, 2006 and 2005, amortization of product rights was 51% and 57% of COS, respectively. Excluding amortization of product rights, COS as a percentage of product sales was 16% and 24% for the three months ended September 30, 2006 and 2005, respectively, and 26% and 22% for the nine months ended September 30, 2006 and 2005, respectively.

For the three months ended September 30, 2006, the decrease in COS, excluding amortization of product rights, as a percentage of product sales as compared to the same period in the prior year was due to a more profitable product mix, particularly with respect to higher sales of Cardene IV, a lower average royalty rate paid on sales of *Cardene* IV and lower manufacturing and inventory-related costs when compared to the 2005 period. Specifically, in the third quarter of 2005, we recorded a write-down of $1.0 million to adjust the value of the off-patent branded inventories to their net realizable values in anticipation of the divestiture of such products in the first quarter of 2006.

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

For the nine months ended September 30, 2006, the increase in COS, excluding amortization of product rights, as a percentage of product sales as compared to the same period in the prior year was attributable to a higher effective royalty rate related to sales of *Cardene* IV in the 2006 period as compared to 2005 and the $2.5 million charge discussed above. Since the royalty rate on *Cardene* IV decreases as sales increase within a calendar year, as described below, our royalty obligations on sales of *Cardene* IV commenced at a lower rate in 2005, when we took over the product in late March 2005 subsequent to the acquisition of ESP Pharma, as compared to the initial rate in 2006.

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

Research and Development

Research and development expenses consist primarily of costs of personnel to support our research and development activities, milestone payments and technology licensing fees, costs of preclinical studies, costs of conducting our clinical trials, such as 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 accounted for under SFAS 123(R) as a component of personnel related costs. Total stock-based compensation expense recognized as research and development expenses, including amounts recognized under SFAS 123(R), was $3.5 million and $10.3 million, respectively, for the three and nine months ended September 30, 2006. The $21.4 million increase in research and development costs in the third quarter of 2006 compared to the corresponding quarter of 2005 was primarily due to increases in personnel related costs of $8.5 million related to the increase in headcount and the adoption of SFAS 123(R), $5.6 million incurred in connection with our acquisition in September 2006 of certain *Cardene*-related rights from Roche (see *Other Intangible Assets, Net* within Note 5 to the Condensed Consolidated Financial Statements), costs of $2.9 million related to consulting services and research grants, facility-related costs of $2.5 million, which is primarily attributable to the recognition of higher depreciation expense from our new Minnesota manufacturing facility, and licensing costs of $1.9 million. These increases were offset by a decrease in production materials costs of $2.5 million.

The $70.2 million increase in research and development costs for the nine months ended September 30, 2006 compared to the corresponding period of 2005 was primarily due to increases in personnel-related costs of $25.0 million, external clinical development expenses for our major research and development projects of $12.6 million,

facility-related costs of $11.9 million, costs of $8.9 million related to consulting services and research grants, $5.6 million incurred in connection with our acquisition in September 2006 of certain *Cardene*-related rights from Roche, research and development licensing costs of $5.2 million and information technology-related costs of $3.4 million. These increases were partially offset by a decrease in production materials costs of $5.1 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 Candidate	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Nine Months Ended September 30,	
					2006	2005
					(in thousands)	
Daclizumab					$ 41,023	$ 28,347
	Healthy Volunteer SC	Phase 1	Roche	2006		
	Asthma [1]	Phase 2a	—	Completed		
	Multiple Sclerosis Combination	Phase 2	Biogen Idec	2007		
Nuvion (visilizumab)					40,516	20,091
	IV steroid-refractory ulcerative colitis	Phase 2/3	—	2007		
	Crohn's Disease	Phase 2	—	2006		
Volociximab (M200)					17,782	20,286
	Solid tumors	Phase 2	Biogen Idec	2006		
Ularitide [2]					16,067	7,584
	Acute Decompensated Heart Failure	Phase 2	—	Completed		
HuZAF (fontolizumab) [3]					2,347	3,235
	Rheumatoid Arthritis	Phase 2	Biogen Idec	Program ceased		
Terlipressin [4]					736	2,098
	Type 1 Hepatorenal Syndrome	Phase 3	Orphan Therapeutics	—		
Other [5]	Multiple programs	See note below	—	N/A	76,792	43,439
Total Research and Development Expenses					$ 195,263	$ 125,080

(1) Our collaboration agreements with Roche had provided that Roche would jointly develop and commercialize daclizumab for the treatment of asthma and other respiratory diseases; however, in August 2006, following a portfolio review at Roche, Roche elected to discontinue its involvement in the development of daclizumab in treating asthma and other respiratory diseases.

(2) We acquired worldwide development and commercialization rights to this product pursuant to our acquisition of ESP Pharma in the first quarter of 2005. We have been planning to initiate a two-study, 3,300-patient Phase 3 trial in Europe; however, we have decided to delay the start of these trials pending a partnership for the ularitide program to better ensure the successful development of ularitide. This delay does not affect our planning and initiation of a Phase 1 trial in the United States.

(3) In July 2006, we and Biogen Idec jointly agreed to terminate further development of *HuZAF* in rheumatoid arthritis because *HuZAF* did not show positive results from the related Phase 2 trial that we conducted together with Biogen Idec. We and Biogen Idec do not currently have any plans for development of *HuZAF* in other indications. This Phase 2 trial is currently being completed.

(4) Orphan Therapeutics has development responsibility for this molecule; we have exclusive marketing rights in the United States and Canada. In August 2006, we announced that the Phase 3 study of terlipressin did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo. Orphan Therapeutics continues to analyze the study data, and we and Orphan Therapeutics plan to discuss the findings with the FDA to inform future decisions regarding the potential future development of terlipressin.

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

The information in the column labeled "Estimated Completion of Phase" is our current estimate of the timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates provided in the table. The clinical development portion of these programs may span as many as seven to 10 years 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses generally consist of costs of personnel, professional services, consulting and other expenses related to our selling and administrative functions and an allocation of facility costs. Beginning with the first quarter of 2006, selling, general and administrative costs also include stock-based compensation expense accounted for under SFAS 123(R) as a component of personnel related costs. Total stock-based compensation expense recognized as selling, general and administrative expenses, including amounts recognized under SFAS 123(R), was $2.5 million and $7.5 million, respectively, for the three and nine months ended September 30, 2006. Selling, general and administrative expenses for the three months ended September 30, 2006 decreased slightly to $26.7 million from $26.8 million during the comparable period in 2005. Despite this slight overall decrease, personnel-related expenses increased by $4.2 million due to the adoption of SFAS 123(R) and the growth of our sales force, operations and marketing teams in connection with marketing and supporting our commercial products, which was offset by decreases in costs of $2.7 million related to consulting services, information technology-related costs of $0.6 million as well as other miscellaneous expenses.

Selling, general and administrative expenses for the nine months ended September 30, 2006 increased 55% to $83.9 million from $54.3 million during the comparable period in 2005. This increase was primarily due to increases in personnel-related expenses of $22.0 million, a $4.1 million payment to Wyeth in the first quarter of 2006 in consideration of Wyeth's consent to our transfer of rights to the off-patent products, facility-related expenses of $2.8 million and costs of $2.8 million related to consulting services. These increases were partially offset by decreases in information technology-related costs of $3.4 million. The majority of the increase in personnel-related expenses was attributable to the addition of the sales force, sales management, operations and marketing teams in connection with the commencement of our selling and marketing commercial products subsequent to our acquisition of ESP Pharma and the rights to *Retavase* in late March 2005. We expect that selling, general and administrative expenses will continue to increase 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 recognized charges for acquired in-process research and development of $79.4 million in March 2005 and $37.8 million in April 2003 due to incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the respective acquisition dates.

In addition, during the fourth quarter of 2003, we recognized a charge to acquired in-process research and development totaling approximately $48.2 million in connection with the amendment to our collaboration agreement with Roche in October 2003, pursuant to which we 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.

Since the earliest acquisition date, we have incurred an additional $100.4 million in research and development expenditures related to completing the in-process projects as of September 30, 2006.

Other Acquisition-Related Charges

Other acquisition-related charges represent costs incurred that relate to ESP Pharma operations prior to our acquisition of the business and sales returns of *Retavase* from sales made prior to our acquisition of the rights to *Retavase* in March 2005. These costs primarily relate to product sales returns, but also include charges for uncollectible accounts receivable and other miscellaneous liabilities related to pre-acquisition ESP Pharma operations. As the product sales returns directly relate to operations prior to our acquisitions of ESP Pharma and the rights to *Retavase*, we recognize them as operating expenses rather than as a reduction to product sales. We recognize other acquisition-related charges under the specific identification method. We recognized a total of $2.6 million and $5.9 million in other acquisition-related charges in the three and nine months ended September 30, 2006, respectively, compared to $6.3 million and $9.5 million in the corresponding periods of 2005.

Asset Impairment Charges

In September 2006, we concluded that the carrying amount of our product rights related to the distribution of *Retavase* was impaired due to revised royalty revenue forecasts for the product. In accordance with SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” (SFAS 144), we prepared a cash flow analysis and compared the sum of the cash flows over the term of the agreement to the carrying value of the asset as of September 30, 2006. As the sum of the future cash flows was less than the carrying value of the asset, we calculated the net present value of the cash flows and recognized $1.5 million, the difference between the carrying value and the discounted cash flows, as an asset impairment charge during the third quarter of 2006. After recognizing the impairment charge, the book value of this intangible asset as of September 30, 2006 was approximately $0.2 million. Further, in connection with our acquisition of certain *Cardene* rights from Roche in September 2006, we wrote off $0.2 million, the fair value attributable to *Cardene* IR inventories, since we are not going to sell the *Cardene* IR product going forward. Accordingly, we recorded asset impairment charges totaling $1.7 million during the third quarter of 2006.

Asset impairment charges for the nine months ended September 30, 2006 were $2.6 million. In addition to the amount recorded in the third quarter of 2006, we recognized an asset impairment charge during the second quarter of 2006 totaling $0.9 million, which related to the abandonment of certain licensed research technology that we had acquired in the third quarter of 2004.

During the third quarter of 2005, we recognized an asset impairment charge of $15.2 million. In March 2005, we acquired both branded and off-patent branded products in connection with the acquisition of ESP Pharma. In June 2005, we engaged a financial advisor to help us divest our off-patent branded products. During the third quarter of 2005, we received inquiries from multiple potential buyers to acquire the off-patent branded products and the related inventory. Based on the indications of interest that we received, we concluded that the net carrying value of these product rights and related inventory was impaired at September 30, 2005 and recorded an impairment charge of $15.2 million to reduce the net carrying value of these product rights to $11.0 million. As of September 30, 2005, we also classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights. The sales of these products were completed in the first quarter of 2006.

Interest and Other Income, Net and Interest Expense

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	% Change	2006	2005	% Change
Interest and other income, net	$ 5,042	$ 2,027	149%	$12,436	$ 6,835	82%
Interest expense	(3,693)	(2,671)	38%	(9,465)	(7,522)	26%
Total interest and other income, net and interest expense	$ 1,349	$ (644)	* %	$ 2,971	$ (687)	* %

* Calculation is not meaningful.

Interest income for the three and nine months ended September 30, 2006 increased from the comparable periods 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 nine months ended September 30, 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 nine months of 2006, compared to the 2005 Notes being outstanding only for seven out of the first nine months of 2005 as the 2005 Notes were issued in mid-February 2005. In addition, interest expense increased in the three and nine months ended September 30, 2006 as compared to the prior year periods due to the absence of capitalized interest expense in the three months ended September 30, 2006, since we completed the construction of the Minnesota facility in the second quarter of 2006.

Income Taxes

We recognized income tax expense of $0.2 million and $1.7 million for the three months ended September 30, 2006 and 2005, respectively. We recognized income tax expense of $0.4 million and $1.8 million for the nine months ended September 30, 2006 and 2005, respectively. Income tax expense during the three and nine months ended September 30, 2006 was 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 and the lapsing of certain contingent tax liabilities of ESP Pharma for the tax year ended December 31, 2002. Income tax expense during the three months and nine months ended September 30, 2005 was primarily related to state income taxes on income earned by ESP Pharma, federal alternative minimum taxes on the consolidated income and foreign taxes on income earned by our foreign operations.

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 revenue, collaboration and other revenue under agreements with third parties, interest income on invested capital and, more recently, product sales. At September 30, 2006, we had cash, cash equivalents, marketable securities and restricted cash and investments in the aggregate of $422.3 million, compared to $333.9 million at December 31, 2005.

Net cash provided by operating activities for the nine months ended September 30, 2006 was $75.9 million, compared to $13.6 million in the corresponding period in 2005. The $75.9 million net cash provided by operating activities in the first nine 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 $76.8 million for the nine months ended September 30, 2006, compared to $295.5 million in the comparable period in 2005. The $76.8 million net cash used in investing activities in the first nine months of 2006 was primarily attributable to net purchases of approximately $61.0 million due to the timing differences of purchases and maturities of our available-for-sale marketable securities, $26.9 million in capital expenditures and $18.8 million related to the purchase of product rights. These net purchases were partially offset by the repayment of our $30.0 million note receivable from Exelixis. In the prior-year period, we acquired ESP Pharma and the rights to *Retavase* for approximately $432.5 million in cash, net of cash acquired.

Net cash provided by financing activities for the nine months ended September 30, 2006 was $22.7 million, compared to $372.3 million in the comparable period in 2005. The $22.7 million net cash provided by financing activities in the first nine months of 2006 was primarily due to the issuance of our common stock in connection with option exercises. In February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million to help fund our acquisitions of ESP Pharma and the rights to *Retavase* in March 2005.

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*, *Lucentis*, *Mylotarg*, *Raptiva*, *Synagis* and *Xolair*; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; interest income; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; investment in existing and new research and development programs; time required to gain regulatory approvals; significant resources we will devote to constructing and qualifying our Redwood City, California facility; significant resources we will need to expend to update or modify our manufacturing facilities as new products are introduced or manufacturing processes are revised; significant resources we will need to expend in the long term to refurbish or replace our manufacturing facilities due to obsolescence; our ability to obtain and retain funding from third parties under collaborative arrangements; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; successful integration of acquired businesses, including the transition to us of existing relationships with partners, distributors, third-party vendors, manufacturers, and customers of acquired companies; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. In order to develop and commercialize our potential products we may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders.

Our material contractual obligations under lease, debt, construction, contract manufacturing and other agreements as of September 30, 2006 are as follows:

(in thousands)	Payments Due by Period				
	Less Than 1 Year	1-3 Years	4-5 Years	More than 5 Years	Total
CONTRACTUAL OBLIGATIONS [1]					
Operating leases	$ 8,141	$15,129	$ 14,042	$ 109,022	$ 146,334
Long-term liabilities [2]	4,704	5,905	2,411	4,145	17,165
Convertible notes	11,875	23,750	266,873	252,500	554,998
Construction contracts	1,400	—	—	—	1,400
Milestone payment to Centocor [3]	15,000	—	—	—	15,000
Contract manufacturing	20,930	3,976	—	—	24,906
Total contractual obligations	$ 62,050	$48,760	$ 283,326	$ 365,667	$ 759,803

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

(2) Includes mortgage payments for the buildings we own in Fremont, California, post-retirement benefit obligations and the milestone payments related to our purchase of rights to *Cardene*.

(3) Represents payment due to Centocor under our agreement for their achievement of a milestone made in September 2006 related to *Retavase*. We capitalized this milestone payment as additional *Retavase* product rights.

In July 2006, we signed leases for office space in Redwood City, California, and we expect to incur approximately $85 million to $95 million in capital expenditures related to the build out and improvement of and relocation of our headquarters to this leased space. We expect that cash proceeds from the future sale of the land and buildings that we currently own in Fremont, California will partially offset these capital expenditures.

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 our revenues. As of September 30, 2006, we had an accumulated deficit of $480.4 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 sustain positive cash flow from operations as we previously projected. We may also incur additional acquisition-related charges related to our acquisitions of ESP Pharma and the rights to *Retavase*, which would adversely affect our operating results. The amount of net losses and the time required to reach sustained profitability from our proprietary products are highly uncertain.

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

- our earlier stage potential products move into later stage clinical development, which is generally a more expensive stage of development;
- additional potential products are selected as clinical candidates for further development;
- we pursue clinical development of our potential products in new indications;
- we invest in life cycle management initiatives for our products;
- we invest in staffing and operations to meet our manufacturing requirements;
- we expand our commercial infrastructure to market and sell our products;
- we defend or prosecute our patents and patent applications; 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 September 30, 2006, our product sales accounted for 37% of our 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 that we own or hold licenses to that cover *Cardene*, IV *Busulfex* and *Retavase* will expire between late 2009 and 2014. We are developing or may develop new dosage forms, formulations or manufacturing processes and we are identifying or may identify new indications for these products or otherwise develop new

intellectual property with respect to these products. As a result of these efforts, we may secure additional or extended patent or marketing or other nonpatent statutory exclusivity rights. If obtained, these additional rights may extend the life cycle of these products and permit us to maintain or expand our position in the marketplace and sustain our revenue stream from the sale of these products. If we do not succeed in our efforts to effectively extend the life cycle of any of these products, we likely would be exposed to significantly more competition from generic versions of these products upon expiration of the patents that cover these products. Competition from generic forms of any of our products likely would cause significant declines in the amount of 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 through 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 a rapid growth rate. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive and other related drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for *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 market that has recently declined and if our planned sales and promotional efforts do not increase or at least maintain market acceptance, our results of operations will suffer.**

We expect *Retavase* to continue to account for a significant portion of our operating income from product sales. *Retavase* is sold into a thrombolytic market that has recently declined 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 thrombolytic market will not decline significantly regardless of our efforts.

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

Retavase is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth RTP Inc. (Diosynth) and Roche. The manufacturing of this product for use as a therapeutic in compliance with regulatory requirements is complex, time-consuming and expensive and historically subject to periodic batch failure because of the complexity of the manufacturing process. Recently, however, one of our contract manufacturers has experienced higher than expected batch failure rates. As a result, we and that contract manufacturer have agreed to temporarily cease *Retavase* manufacturing and run three test batches under change order to extensively sample and analyze the process prior to making potential improvements. Although we currently have enough inventory of *Retavase* to satisfy our expected sales through mid-2008, our inability to reduce batch failure rates and timely and efficiently manufacture *Retavase* could result in the reduction or interruption of commercial sales and could impair our competitive position. In addition, our future cost of goods sold for *Retavase* as a percentage of product sales may increase in connection with an amended supply agreement that we are currently discussing with our contract manufacturer in connection with these higher than expected batch failure rates.

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 do not manufacture any of our marketed products. We have certain long-term agreements with various third parties to supply our marketed products under our label. If there are supply problems with our 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, future clinical trials or the potential commercialization of these products could be substantially delayed and our financial results would be adversely affected.

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

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

Achieving future profitability or revenue growth will depend in significant part upon the continuing growth of our currently marketed products.

We have incurred losses since inception. In order for us to achieve future profitability, we will need to sustain growth from our currently marketed drugs 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 product revenues may fluctuate from quarter to quarter based on the buying and return patterns of these wholesalers and distribution partners and our ability to estimate reserves for potential product returns.

We sell our products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the quarter ended September 30, 2006, revenues from the sales of our products to our three largest U.S. wholesalers totaled approximately 87% 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 September 30, 2006, these three U.S. wholesalers represented approximately 92% of our outstanding accounts receivable from product sales. We have received a significant number of returns of *Cardene* IV, *Retavase* and IV *Busulfex* product and off-patent branded products that were sold prior to our acquisitions of rights to these products in March 2005. The level of returns of these products sold prior to March 2005 exceeded our expectations at the time we acquired the rights to these products. We believe these unexpected returns resulted from overstocking of inventory by wholesalers in anticipation of future price increases that did not occur, and therefore affected the rate of returns. We continue to monitor current levels of inventory at the wholesalers consistent with our forecasts of end user demand and we continue to refine our trade practices and more effectively enforce trade policies including declining or holding orders to align selling patterns with our estimate of the end user demand for our products. We believe these efforts have led to inventory levels at wholesalers below prior levels, and this should reduce the level of returns. Nevertheless, there can be no assurance that our wholesalers and distribution partners will maintain inventory levels consistent with our forecast of end user demand. Due to enhanced inventory management and enforcement of our product return policy, we do not believe that we will experience the same level of returns for products we sold subsequent to March 2005, the date we acquired ESP Pharma and rights to *Retavase*. In accordance with our product returns reserve policy, we review the estimated rate for product sales returns on a quarterly basis. We review historical product returns, channel inventory levels and activities and other factors pursuant to this review. This review may result in an estimate that is higher or lower than our prior estimates for product sales returns to reflect the projected future level of returns. The effect of any change in estimate would affect product sales, net, during the quarter in which we revise our estimate. If returns exceed our expectations as they have in the past, revenues would be adversely affected. In addition, if any of these wholesalers fails to pay on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

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

At September 30, 2006, we had approximately $507.0 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 significantly affect our future operations because:

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

Our ability to make payments of principal and interest on our indebtedness depends upon our future performance, which will be subject to general economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which we cannot control. Our ability to generate sufficient cash flow from operations in the future to service our debt may require us to, among other things:

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

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

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

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

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

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

We face challenges inherent in efficiently managing a large number of employees over large geographic distances and across multiple functional disciplines, including the need to implement appropriate systems, policies, benefits

and compliance programs. The inability to manage successfully our large, geographically diverse organization and the inability to retain or replace key employees could have a material adverse effect on the operating results of our company and, as a result, on the market price of our common stock.

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

We have agreements with pharmaceutical and other companies to develop, manufacture and market certain of our potential products. In some cases, we rely on our partners to manufacture such products and essential components for those products, design and conduct clinical trials, compile and analyze the data received from these trials, obtain regulatory approvals and, if approved, market these licensed products. As a result, we may have 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 August 2005, Biogen Idec and we entered into a long-term agreement under which Biogen Idec became our partner on three of our antibody clinical programs, daclizumab in certain indications including MS and volociximab (M200) and *HuZAF* in all indications. We and Biogen Idec were conducting a proof of concept Phase 2 trial of HuZAF in severe rheumatoid arthritis, however, based on our preliminary evaluation of data from this open label study, we and Biogen Idec jointly agreed to discontinue development of HuZAF in severe rheumatoid arthritis. We and Biogen Idec do not currently have any plans for development of HuZAF in other indications. In October 2005, we expanded our existing relationship with Roche and our collaboration to include the co-development and commercialization of daclizumab for asthma and for organ transplant patients on longer-term maintenance therapy (transplant maintenance). Recently, however, Roche decided to discontinue its involvement in the co-development of daclizumab in treating asthma. Roche's decision has no effect on our ongoing collaboration with Roche to co-develop daclizumab in transplant maintenance, and we and Roche intend to proceed with planned Phase 2 studies for the transplant indication during 2007.

These collaboration agreements provide significant combined resources 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 depend in substantial part upon 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 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 obtain regulatory approval for or commercialize our product candidates. If any of the third parties upon whom we rely to conduct our clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, our clinical trials may be extended, delayed or terminated.

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

Our partners can terminate our collaborative agreements under certain conditions, and in some cases on short notice. A partner may terminate its agreement with us or separately pursue alternative products, therapeutic approaches or

technologies as a means of developing treatments for the diseases targeted by us, or our collaborative effort. For example, in August 2006, following a portfolio review at Roche, Roche elected to discontinue its involvement in the development of daclizumab in treating asthma and other respiratory diseases in accordance with the terms of our collaboration agreement with Roche. Even if a partner continues to contribute to the arrangement, it may nevertheless decide not to actively pursue the development or commercialization of any resulting products. In these circumstances, our ability to pursue potential products could be severely limited.

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

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

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

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

Pursuant to rules adopted under Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. The rules governing the standards that must be met for management to assess the effectiveness of our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal control over financial reporting successfully in 2004 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 continue to market and sell our products;
- the response of wholesalers to announced or anticipated price changes for our products;
- uncertainty resulting from the purchase practices of wholesalers and inventory levels at wholesalers;
- product returns, reimbursements and rebates which could differ from our estimates and accruals;
- the continued safety of approved products;
- the marketing and promotional efforts of our licensees from whom we receive royalty payments;
- the 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, collaboration 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, collaboration 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. 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 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, during the third quarter of 2006 we recognized $18.8 million of deferred revenue, or 17% of the total revenue for that quarter, related to Roche's election in August 2006 to discontinue its co-development of daclizumab in treating asthma and other respiratory diseases. In addition, 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).

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 under our patents. If our patents are successfully opposed 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 occur on April 23, 2007. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if the opponents are successful, our ability to collect royalties on European sales of antibodies humanized by others would depend on: (i) the scope and validity of our second European patent; and (ii) whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents and, if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to our related patents in other jurisdictions, including the United States. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents.

At an oral hearing in February 2005, the Opposition Division of the European Patent Office decided to revoke the claims in our second European antibody humanization patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We 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 succeeded in obtaining and maintaining such licensing arrangements, and in receiving royalties on product sales, from parties whose products may be covered by our patents. However, there can be no assurance that we will continue to succeed in our licensing efforts in the future. In the past, we have experienced challenges in our licensing efforts, such as the disagreement we had with Genentech in 2003 over whether its *Xolair* antibody product was covered under our humanization patents. Although we subsequently reached an amicable settlement with Genentech that is intended to resolve such disagreements, Genentech or other companies may, in the future terminate their licensing agreements with us, or seek to challenge our U.S. patents through litigation or patent office proceedings, such as re-examinations or interferences. If we experience difficulty in enforcing our patent rights through licenses, or if our licensees, or prospective licensees, challenge our antibody humanization patents, our revenues and financial condition could be adversely affected, and we could be required to undertake additional actions, including litigation, to enforce our rights. Such efforts would increase our expenses and could be unsuccessful.

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

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

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

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

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

Celltech Therapeutics Limited (Celltech), which has been acquired by UCB Group, for example, has been granted a European patent covering humanized antibodies, which we have opposed. At an oral hearing in September 2000, the Opposition Division of the European Patent Office decided to revoke this patent. Celltech appealed that decision, but the Technical Board of Appeal rejected the appeal. As a result, the decision revoking the patent is final; no further appeals are available. However, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. At an oral hearing in January 2005, the Opposition Division decided to revoke this patent. Celltech has filed an appeal. We cannot predict whether Celltech's appeal will be successful, or whether it will be able to obtain the grant of a patent from the pending divisional application with claims broad enough to generally cover humanized antibodies. Celltech has also been issued a corresponding U.S. patent that contains claims that may be considered broader in scope than its first European patent. In addition, Celltech was recently issued a second U.S. patent with claims that may be considered broader than its first U.S. patent. We have entered into an agreement with Celltech providing each company with the right to obtain nonexclusive 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 or efficacy data to obtain necessary regulatory approvals. For example, in August 2006, we announced that the Phase 3 study of terlipressin did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo although there appeared to be no significant differences in overall safety between the terlipressin and placebo arms of the study. 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 received fast track designation from the FDA for terlipressin for type 1 hepatorenal syndrome, 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.

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 addition, even if our licensees receive regulatory approval to sell a drug on which we would receive royalties, the marketing of such drug could be suspended or terminated either voluntarily by the licensee or by order of a regulatory agency or other governmental body as a result of safety or other events. For example, in February 2005, Biogen Idec and Elan announced that they had voluntarily suspended the marketing and commercial distribution of *Tysabri*, a drug approved to treat MS and which is licensed under our humanization patents, because Biogen Idec and Elan had

received reports of cases of progressive multifocal leukoencephalopathy (PML), a rare and frequently fatal, demyelinating disease of the central nervous system, in certain patients treated with *Tysabri*. In July 2006, Biogen Idec and Elan announced the reintroduction of *Tysabri*, however, *Tysabri's* label will include prominent warnings regarding *Tysabri's* risks and Biogen Idec and Elan implemented a risk management plan to inform physicians and patients of the benefits and risks of *Tysabri* treatment and to minimize the risk of PML potentially associated with *Tysabri* monotherapy. Notwithstanding the reintroduction of *Tysabri*, which occurred in July 2006, it is too early to determine whether we will receive significant royalties from future 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 believe we have been successful in hiring and retaining key personnel in the past; however, we face significant competition for experienced personnel. For example, our Senior Vice President and Chief Medical Officer resigned from his officer positions effective November 2, 2006 and we are actively recruiting for his successor.

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 new manufacturing facility in Brooklyn Park, Minnesota 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 use our new manufacturing plant 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.

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

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

With respect to our 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 *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. For example, one of our contract manufacturers recently had production issues and incurred additional production costs. As a result, we agreed to share the related costs even though we are only responsible for purchasing the inventory from successfully manufactured lots.

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

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

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

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 November 3, 2006, our common stock closed as high as $32.80 per share and as low as $16.51 per share. Additionally, the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The following are some of the factors that may have a significant effect on the market price of our common stock:

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

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

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

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

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

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

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

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

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

from our lenders at the time to repurchase the 2005 Notes. If we are unable to obtain their consent, we could attempt to refinance 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 our common stock.

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

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

The acquisitions of ESP Pharma and certain rights to *Retavase* required net cash payments of approximately $432.5 million. While we believe we have sufficient funds for our anticipated operations, we will need to generate significantly greater revenues to achieve and then maintain profitability on an annual basis. The product development, including clinical trials, manufacturing and regulatory approvals of product candidates currently in development, and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future funding requirements, which may be significantly greater than we expect, depend upon many factors, including:

- the extent to which *Cardene* is commercially successful;
- the extent to which we can maintain or increase *Retavase* sales 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 may face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of our products. In addition, competitors may succeed in developing products and technologies that are more effective or less costly than our products, or that would render our products obsolete or noncompetitive.

Our ability to generate future 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 which we do business are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

ITEM 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. 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 September 30, 2006, there has been no material change in our interest rate exposure from that described in our 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 and nine months ended September 30, 2006 and 2005, there was no material foreign currency exchange impact on our Condensed Consolidated Statements of Operations from our intercompany transactions. As of September 30, 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 and Chief Financial 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 and Chief Financial Officer concluded that our disclosure controls and procedures are effective in reaching a reasonable level of assurance that information required to be disclosed by us in the reports that we file or submit under the 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 September 30, 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 year ended December 31, 2005 (Annual Report). As reported in our Annual Report, we are involved in administrative opposition proceedings being conducted by the European Patent Office with respect to our first European patent relating to humanized antibodies. In February 2006, we received a summons to attend oral proceedings before the Opposition Division of the European Patent Office which

were then scheduled to take place in July 2006. Due to a schedule conflict, we petitioned to have the oral proceeding rescheduled to a more convenient time. The Opposition Division accepted our petition. A rescheduled date for these oral proceedings is now set to occur on April 23, 2007 before the Opposition Division.

ITEM 1A. RISK FACTORS

Other than with respect to the new risk factor regarding the life cycle or our product portfolio and the revisions to the following risk factors 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 September 30, 2006, our product sales accounted for 37% of our 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 *Busulfex* and *Retavase* will expire between 2009 and 2014. We are developing or may develop new dosage forms, formulations or manufacturing processes and we are identifying or may identify new indications for these products or otherwise develop new intellectual property with respect to these products. As a result of these efforts, we may secure additional or extended patent or marketing or other nonpatent statutory exclusivity rights. If obtained, these additional rights may extend the life cycle of these products and permit us to maintain or expand our position in the marketplace and sustain our revenue stream from the sale of these products. If we do not succeed in our efforts to effectively extend the life cycle of any of these products, we likely would be exposed to significantly more competition from generic versions of these products upon expiration of the patents that cover these products. Competition from generic forms of any of our products likely would cause significant declines in the amount of revenue and profit margins we recognize from the sale of that product.

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

Retavase is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth RTP Inc. (Diosynth) and Roche. The manufacturing of this product for use as a therapeutic in compliance with regulatory requirements is complex, time-consuming and expensive and historically subject to periodic batch failure because of the complexity of the manufacturing process. Recently, however, one of our contract manufacturers has experienced higher than expected batch failure rates. As a result, we and that contract manufacturer have agreed to temporarily cease *Retavase* manufacturing and run three test batches under change order to extensively sample and analyze the process prior to making potential improvements. Although we currently have enough inventory of *Retavase* to satisfy our expected sales through mid-2008, our inability to reduce batch failure rates and timely and efficiently manufacture *Retavase* could result in the reduction or interruption of commercial sales and could impair our competitive position. In addition, our future cost of goods sold for *Retavase* as a percentage of product sales may increase in connection with an amended supply agreement that we are currently discussing with our contract manufacturer in connection with these higher than expected batch failure rates.

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

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

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

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

We sell our products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the quarter ended September 30, 2006, revenues from the sales of our products to our three largest U.S. wholesalers totaled approximately 87% 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 September 30, 2006, these three U.S. wholesalers represented approximately 92% of our outstanding accounts receivable from product sales. We have received a significant number of returns of *Cardene* IV, *Retavase* and IV *Busulfex* product and off-patent branded products that were sold prior to our acquisitions of rights to these products in March 2005. The level of returns of these products sold prior to March 2005 exceeded our expectations at the time we acquired the rights to these products. 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 affected the rate of returns. We continue to monitor current levels of inventory at the wholesalers consistent with our forecasts of end user demand and we continue to refine our trade practices and more effectively enforce trade policies including declining or holding orders to align selling patterns with our estimate of the end user demand for our products. We believe these efforts have led to inventory levels at wholesalers below prior levels, and this should reduce the level of returns. Nevertheless, there can be no assurance that our wholesalers and distribution partners will maintain inventory levels consistent with our forecast of end user demand. Due to enhanced inventory management and enforcement of our product return policy, we do not believe that we will experience the same level of returns for products we sold subsequent to March 2005, the date we acquired ESP Pharma and the rights to *Retavase*. In accordance with our product returns reserve policy, we review the estimated rate for product sales returns on a quarterly basis. We review historical product returns, channel inventory levels and activities and other factors pursuant to this review. This review may result in an estimate that is higher or lower than our prior estimates for product sales returns to reflect the projected future level of returns. The effect of any change in estimate would affect product sales, net, during the quarter in which we revise our estimate. If returns exceed our expectations as they have in the past, revenues would be adversely affected. In addition, if any of these wholesalers fails to pay on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

ITEM 6. EXHIBITS

4.1	Rights Agreement, effective as of August 25, 2006, between the Company and Mellon Investor Services LLC (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed August 29, 2006)
10.1	Sublease, effective July 6, 2006, between Openwave Systems Inc. and the Company (for building located at 1400 Seaport Boulevard, Redwood City, California) (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed July 6, 2006).
10.2	Triple Net Lease, effective July 6, 2006, between Pacific Shores Investors, LLC and the Company (for building located at 1400 Seaport Boulevard, Redwood City, California) (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed July 6, 2006).
10.3	Triple Net Lease, effective July 6, 2006, between the Pacific Shores Investors, LLC and the Company (for building located at 1500 Seaport Boulevard, Redwood City, California) (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed July 6, 2006).
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).

Table of Contents

SIGNATURES

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

Dated: November 7, 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 and Accounting Officer)

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 officer 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: November 7, 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 officer 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: November 7, 2006

/s/ Andrew L. Guggenhime

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

EXHIBIT 32.1

CERTIFICATION

Mark McDade, Chief Executive Officer, and Andrew L. Guggenhime, Senior Vice President and Chief Financial Officer, of PDL BioPharma, Inc. (the "Registrant"), each hereby certifies 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 September 30, 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 will be provided to the Securities and Exchange Commission or its staff upon request.

Dated: November 7, 2006

/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 and Accounting Officer)