PDL BIOPHARMA, INC.
Form 10-Q
May 10, 2007
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2007

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 x 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 x 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 x

As of May 2, 2007, there were 116,603,643 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 March 31,	
	2007	2006
Revenues:		
Product sales, net	$ 49,127	$ 37,547
Royalties	48,595	43,970
License, collaboration and other	10,261	9,695
Total revenues	107,983	91,212
Costs and expenses:		
Cost of product sales	24,998	22,959
Research and development	55,625	58,586
Selling, general and administrative	37,941	35,344
Other acquisition-related charges	1,436	1,118
Total costs and expenses	120,000	118,007
Operating loss	(12,017)	(26,795)
Interest and other income, net	5,032	3,330
Interest expense	(3,557)	(2,650)
Loss before income taxes	(10,542)	(26,115)
Income tax expense	64	115
Net loss	$ (10,606)	$ (26,230)
Net loss per basic and diluted share	$ (0.09)	$ (0.23)
Shares used in computation of net loss per basic and diluted share	115,104	112,472

See accompanying notes.

Table of Contents

PDL BIOPHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	March 31, 2007 (unaudited)	December 31, 2006 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 142,544	$ 179,009
Restricted cash	25,005	
Marketable securities	158,501	154,115
Accounts receivable, net of allowances of $12,649 and $13,709 at March 31, 2007 and December 31, 2006, respectively	14,338	18,780
Inventories	20,483	19,663
Prepaid and other current assets	11,557	7,929
Total current assets	372,428	379,496
Long-term marketable securities	75,000	74,892
Long-term restricted cash	3,269	18,269
Land, property and equipment, net	305,889	296,529
Goodwill	70,363	69,954
Other intangible assets, net	276,930	285,713
Other assets	16,802	17,040
Total assets	$ 1,120,681	$ 1,141,893
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 5,383	$ 13,478
Accrued compensation	16,177	21,123
Royalties payable	9,929	4,780
Other accrued liabilities	42,111	52,000
Deferred revenue	10,024	13,443
Current portion of other long-term liabilities	646	635
Total current liabilities	84,270	105,459
Convertible notes payable	499,998	499,998
Long-term deferred revenue	33,329	31,366
Other long-term liabilities	36,374	37,529
Total liabilities	653,971	674,352
Stockholders equity:		
Common stock, par value $0.01 per share, 250,000 shares authorized; 115,426 and 115,006 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	1,154	1,150
Additional paid-in capital	1,047,512	1,037,846
Accumulated deficit	(580,890)	(570,129)
Accumulated other comprehensive loss	(1,066)	(1,326)
Total stockholders equity	466,710	467,541
Total liabilities and stockholders equity	$ 1,120,681	$ 1,141,893

See accompanying notes.

Table of Contents

PDL BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31, 2007	2006
Cash flows from operating activities:		
Net loss	$ (10,606)	$ (26,230)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	7,377	7,605
Amortization of convertible notes offering costs	585	587
Amortization of intangible assets	8,783	11,052
Stock-based compensation expense	5,209	6,146
Loss on disposal of equipment	31	
Tax benefit from employee stock options		138
Changes in assets and liabilities:		
Accounts receivable, net	4,442	(2,133)
Interest receivable	(868)	(563)
Inventories	(787)	(2,584)
Other current assets	(3,628)	1,907
Other assets	(347)	239
Accounts payable	(8,095)	6,075
Accrued liabilities	(9,841)	(2,896)
Other long-term liabilities	85	106
Deferred revenue	(1,456)	2,930
Total adjustments	1,490	28,609
Net cash provided by (used in) operating activities	(9,116)	2,379
Cash flows from investing activities:		
Purchases of marketable securities	(19,434)	(98,851)
Maturities of marketable securities	16,047	24,949
Maturities of restricted securities		3,414
Sale of intangible assets		2,750
Purchase of property and equipment	(16,768)	(9,449)
Transfer to restricted cash	(10,005)	
Net cash used in investing activities	(30,160)	(77,187)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of cancellations	4,019	15,803
Payments on other long-term debt	(1,208)	(169)
Net cash provided by financing activities	2,811	15,634
Net decrease in cash and cash equivalents	(36,465)	(59,174)
Cash and cash equivalents at beginning of the period	179,009	183,377

Cash and cash equivalents at end of the period	$ 142,544	$ 124,203

See accompanying notes.

Table of Contents

PDL BIOPHARMA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(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 currently market and sell products in the acute-care hospital setting in the United States and Canada. We also receive royalties and other revenues through licensing agreements with numerous biotechnology and pharmaceutical companies based on our proprietary antibody humanization technology platform. These licensing agreements have contributed to the development by our licensees of nine marketed products. We currently have several investigational compounds in clinical development for severe or life-threatening diseases, and 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 (GAAP) 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, 2006 filed with the Securities and Exchange Commission. The Condensed Consolidated Balance Sheet as of December 31, 2006 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.

Additionally, our master patent license agreement with Genentech, Inc. (Genentech) provides for a tiered royalty structure under which the royalty rate Genentech must pay on royalty-bearing products sold in the United States or manufactured in the United States and sold anywhere (U.S.-based Sales) in a given calendar year decreases during that year on incremental U.S.-based Sales above several net sales thresholds. As a result, Genentech s average annual royalty rate during a year will decline as Genentech s aggregate U.S.-based Sales increase during that year. Because we receive royalties in arrears, the average royalty rate for the payments we receive from Genentech in the second calendar quarter which would be for Genentech s sales from the first calendar quarter will be higher than the average royalty rate for following quarters and will be lowest in the first calendar quarter, which would be for Genentech s sales from the fourth calendar quarter, when more of Genentech s U.S.-based Sales bear royalties at lower royalty rates.

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

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

Table of Contents

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 $0.8 million for the three-month period ended March 31, 2006.

In addition, we reclassified certain costs previously included in research and development expenses to selling, general and administrative expenses. Such amounts primarily relate to certain of our clinical affairs costs that are more appropriately classified as general and administrative costs within selling, general and administrative expenses. The impact of this reclassification decreased research and development expenses and correspondingly increased selling, general and administrative expenses by approximately $3.2 million for the three-month period ended March 31, 2006. Such reclassification had no impact on our total operating expenses or our net loss during the three-month period ended March 31, 2006.

Management Estimates

The preparation of financial statements in conformity with GAAP 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.

Concentrations Disclosure

The following table summarizes revenues from our customers and licensees who individually accounted for 10% or more of our total revenues for the three months ended March 31, 2007 and 2006 (as a percentage of total revenues):

	Three Months Ended March 31,	
	2007	2006
Customers		
Cardinal Health, Inc.	18%	21%
AmerisourceBergen Corp.	16%	12%
McKesson Corp.	13%	12%
Licensees		
Genentech	31%	31%
MedImmune	13%	16%

2. Stock-Based Compensation

Stock-based compensation expense recognized under SFAS No. 123, Share-Based Payment (Revised 2004) (SFAS 123(R)) for employees and directors and the impact on our Condensed Consolidated Statements of Operations were as follows:

	Three Months Ended March 31,	
(in thousands, except per share amounts)	**2007**	**2006**
Research and development	$ 2,862	$ 3,358
Selling, general and administrative	2,328	2,644
Total stock-based compensation expense	$ 5,190	$ 6,002

Stock-based compensation expense related to stock options granted to non-employees was approximately $0.0 million and $0.1 million for the three-month periods ended March 31, 2007 and 2006, respectively.

Table of Contents

Stock Option Activity

A summary of our stock option activity since December 31, 2006 is presented below:

Options (in thousands, except per share data)	Total Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2006	14,313	$ 18.79
Granted	699	19.82
Forfeited	(215)	19.65
Exercised	(393)	10.22
Expired	(45)	27.60
Outstanding as of March 31, 2007	14,359	$ 19.04
Exercisable as of March 31, 2007	8,532	$ 18.58

As required by SFAS 123(R), management has made an estimate of expected forfeitures and is recognizing compensation costs only for those equity awards expected to vest. Total unrecognized compensation cost related to unvested stock options outstanding as of March 31, 2007 was $41.2 million, excluding forfeitures, which we expect to recognize over a weighted-average period of 2.8 years.

Restricted Stock

A summary of our restricted stock activity since December 31, 2006 is presented below:

	Restricted Stock	
	Number of shares	Weighted-average grant-date fair value
Unvested at December 31, 2006	136,900	$ 20.67
Awards granted	7,500	19.14
Unvested at March 31, 2007	144,400	$ 20.59

Total unrecognized compensation cost related to unvested restricted stock outstanding as of March 31, 2007 was $2.4 million, excluding forfeitures, which we expect to recognize over a weighted-average period of 2.7 years. No shares of restricted stock vested during the three months ended March 31, 2007.

Employee Stock Purchase Plan (ESPP)

The stock-based compensation expense in connection with our ESPP was $0.4 million for both of the three-month periods ended March 31, 2007 and 2006.

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, less the weighted-average number of shares of restricted stock that is subject to repurchase. 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 outstanding common equivalent shares 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:

	Three Months Ended March 31,	
(in thousands)	**2007**	**2006**
Stock options	14,249	13,951
Common stock in escrow	845	1,227
Restricted stock	140	103
ESPP	166	88
Convertible notes	22,970	22,970
Total	38,370	38,339

Table of Contents

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 unrealized gains and losses are excluded from our net loss. In the first quarter of 2007, other comprehensive loss also included the liability that has not yet been recognized as net periodic benefit cost for our postretirement benefit plan due to our adoption of SFAS No. 158, Employers Accounting for Defined Benefit Pension and Other Postretirement Plans an amendment of FASB Statements No. 87, 88, 106, and 132(R) (SFAS 158) during the fourth quarter of 2006. The following table presents the calculation of our comprehensive loss:

	Three Months Ended March 31,	
(in thousands)	**2007**	**2006**
Net loss	$ (10,606)	$ (26,230)
Other comprehensive loss:		
Change in unrealized gains and losses on marketable securities, net of taxes	239	265
Change in postretirement benefit liability not yet recognized in net periodic benefit expense	21	
Total comprehensive loss	$ (10,346)	$ (25,965)

5. Balance Sheet Information

Restricted Cash

As of March 31, 2007 and December 31, 2006, we had a total of $28.3 million and $18.3 million of restricted cash, respectively. As of March 31, 2007 and December 31, 2006, $25.0 and $15.0 million of the restricted cash, respectively, supported letters of credit on which our landlord and construction contractor can draw if we do not fulfill our obligations with respect to the construction of our leasehold improvements to our Redwood City, California, facility. The remaining $3.3 million of long-term restricted cash supports letters of credit serving as a security deposit for obligations under our Redwood City leases.

Inventories

Inventories consisted of the following:

(in thousands)	**March 31, 2007**	**December 31, 2006**
Raw materials	$ 12,813	$ 9,689
Work-in-process	4,716	5,286
Finished goods	2,954	4,688
Total	$ 20,483	$ 19,663

Table of Contents

Other Intangible Assets, Net

Other intangible assets, net consisted of the following:

	March 31, 2007			December 31, 2006		
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Product rights	$ 328,876	$ (62,236)	$ 266,640	$ 328,876	$ (53,865)	$ 275,011
Core technology	16,053	(5,763)	10,290	16,053	(5,351)	10,702
Net intangible assets	$ 344,929	$ (67,999)	$ 276,930	$ 344,929	$ (59,216)	$ 285,713

Amortization expense for our intangible assets was recorded in cost of product sales and research and development expense during the three months ended March 31, 2007 and 2006 as set forth below:

	Three Months Ended March 31,	
(in thousands)	2007	2006
Cost of product sales	$ 8,371	$ 10,565
Research and development	412	487
Total amortization expense	$ 8,783	$ 11,052

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(in thousands)	March 31, 2007	December 31, 2006
Consulting and services	$ 8,704	$ 12,105
Accrued clinical and pre-clinical trial costs	2,827	14,302
Accrued interest	1,484	4,453
Construction-in-process	6,960	3,294
Milestone payment related to purchase of rights to *Cardene*	3,500	3,500
Deferred tax liability	6,075	6,075
Other	12,561	8,271
Total	$ 42,111	$ 52,000

6. Income Taxes

In July 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, (FIN 48) 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 adopted FIN 48 on January 1, 2007. As a result of the adoption of FIN 48, we recorded a $0.1 million increase related to our liability for unrecognized tax benefits, which was accounted for as an increase to our accumulated deficit. Subsequent to our adoption of FIN 48, we have unrecognized tax benefits totaling approximately $10.0 million.

The future impact of the unrecognized tax benefit of $10.0 million, if recognized, is as follows: approximately $0.1 million would affect the effective tax rate; approximately $1.4 million would result in a reduction in goodwill associated with the acquisition of ESP Pharma; and approximately $8.5 million would result in adjustments to deferred tax assets and corresponding adjustment to the valuation allowance.

Estimated interest and penalties related to the underpayment of income taxes are classified as a component of tax expense in the Condensed Consolidated Statement of Operations and totaled approximately $0.1 million for the quarter ended March 31, 2007. Accrued interest and penalties were approximately $0.6 million and $0.7 million as of December 31, 2006 and March 31, 2007, respectively.

Table of Contents

In general, our income tax returns are subject to examination by U.S. federal, state and local tax authorities for tax years 1992 forward. Our French subsidiary s income tax returns for 2004 and 2005 are currently under examination by the French tax authorities. We do not anticipate any additional unrecognized benefits in the next twelve months that would result in a material change to our financial position.

Income tax expense during the three months ended March 31, 2007 was primarily related to state taxes and foreign taxes on income earned by our foreign operations. Taxes during the three months ended March 31, 2006 are primarily related to federal alternative minimum 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.

7. Subsequent Event Settlement of Escrow Shares Related to ESP Pharma Acquisition

In connection with our acquisition of ESP Pharma in March 2005, and pursuant to the terms of an Escrow Agreement, we deposited 2,523,588 shares of common stock, with a deemed value of $49.8 million, into a one-year escrow account, against which we could make claims for indemnification against certain former ESP Pharma stockholders. During the fourth quarter of 2005 and the first quarter of 2006, we delivered several indemnification claims totaling $18.5 million against this escrow. The former ESP Pharma stockholders disputed all of the claims we made.

Prior to March 31, 2007, we released our claim to $1.9 million of the $18.5 million we originally claimed, and 841,544 shares of common stock remained in escrow at March 31, 2007. In July 2006, we filed a demand for arbitration with Judicial Arbitration and Mediation Services to resolve the disputed claims against the shares of common stock then in escrow and, as of March 31, 2007, an initial arbitration session had been scheduled to occur in June 2007. In April 2007, however, we settled our claims with the former ESP Pharma stockholders and, as a result, 486,808 of the shares of common stock in escrow were released to the former ESP Pharma stockholders and the remaining 354,736 shares were transferred to us. Accordingly, we expect to increase goodwill and stockholders equity in the second quarter of 2007 by approximately $12.2 million, the fair value of the 486,808 shares of common stock released to the former ESP Pharma stockholders as of the release date.

Table of Contents

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 products in the acute-care hospital setting in the United States and Canada. We also receive royalties and other revenues through licensing agreements with numerous biotechnology and pharmaceutical companies based on our proprietary antibody humanization technology platform. These licensing agreements have contributed to the development by our licensees of nine marketed products. We currently have several investigational compounds in clinical development for severe or life-threatening diseases, and 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.

We continue to evolve from a company dependent on licensing activities, development arrangements, humanization services and royalties as the primary sources of revenues to a commercial enterprise that ultimately derives the majority of its revenues from sales of proprietary products. The key elements of our strategy include continuing to build our acute-care, hospital-focused commercial organization and developing novel, proprietary products by leveraging our antibody humanization platform, while pursuing corporate development activities that may enable expansion or acceleration of our product portfolio prior to the launch of products from our current proprietary pipeline:

Acute-care focused commercial organization. Our hospital sales force specializes in the acute-care setting and currently markets our *Cardene* IV, *Retavase* and IV *Busulfex* products to nearly 1,800 hospitals in the United States. In the hospital setting, our sales force focuses its efforts in the cardiac, neurological and intensive care units as well as in emergency departments.

Development of proprietary drugs. Our aim is to develop antibody- or other protein-based products through our own research and development efforts, as well as to selectively and opportunistically license proprietary therapeutic candidates from other companies. Our current stated aim is to submit to the U.S. Food and Drug Administration (FDA), on average, one investigational new drug application (IND) per calendar year, and augment this pipeline generation through additional in-licensing at various stages of development. Our internal research and development efforts are focused primarily on novel antibodies for the treatment of cancer and autoimmune diseases. Our goal is to market our hospital-focused products in North America. However, certain of our products in development address indications that require specific expertise or large development and marketing efforts, such as heart failure, multiple sclerosis (MS), respiratory diseases and some oncology indications, and our strategy for those products is to seek appropriate partners with global development, manufacturing and commercialization capabilities.

Table of Contents

Research and Development Programs

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. These potential products include both antibodies and small molecule therapeutics in oncology, autoimmune disease and cardiovascular indications. The table below lists various investigational compounds for which we are pursuing clinical development activities either on our own or in collaboration. Not all clinical trials for each product candidate are listed below. The development and commercialization of our product candidates are subject to numerous risks and uncertainties, as noted in our Risk Factors of this Quarterly Report.

Product Candidate	Indication/Description	Program Status	Collaborator
Nuvion® (visilizumab)	IV steroid-refractory ulcerative colitis	Phase 2/3 program ongoing	
	Crohn s disease	Phase 2 program being evaluated	
Ularitide (synthetic peptide)	Acute decompensated heart failure	Phase 1 (US) program initiated	
		Phase 3 (Europe) program pending partnership	
Daclizumab	Asthma	Phase 2 program advancement pending partnership	
	Multiple sclerosis	Phase 2 program in ongoing partnership	Biogen Idec
	Transplant maintenance	Phase 2 program advancement pending partnership	
Volociximab (M200)	Solid tumors	Phase 2 program ongoing in partnership	Biogen Idec
HuLuc63	Multiple myeloma	Phase 1 program ongoing	
PDL192	Solid Tumors	Pre-IND	
Cardene	Product Life Cycle Management	Marketed; Phase 2	

Nuvion (visilizumab). Our *Nuvion* antibody 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. We hold all worldwide rights to the development, manufacturing and sales of the *Nuvion* antibody.

The *Nuvion* antibody is currently being tested in a registrational program in patients with intravenous steroid-refractory ulcerative colitis (IVSR-UC). Our Phase 2/3 pivotal trial of the *Nuvion* antibody in patients with IVSR-UC, a study we refer to as RESTORE 1, continues to enroll patients. In April 2007, an independent Data Monitoring Committee (DMC), reviewed data from the first 60 patients in the RESTORE 1 study and recommended moving forward with a second pivotal Phase 3 study called RESTORE 2. The primary endpoint of both the RESTORE 1 and RESTORE 2 studies is patient response at day 45 using standard clinical assessments of disease symptoms. Each study is expected to enroll up to 150 patients. Additional supportive trials of Nuvion in this patient population are ongoing.

While our near-term focus continues to be in the area of severe ulcerative colitis, the *Nuvion* antibody has shown potential as a treatment for severe Crohn s disease and may also be useful as a treatment for certain other autoimmune diseases, such as multiple sclerosis.

Table of Contents

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. We hold worldwide rights under an exclusive license from CardioPep Pharma GmbH to develop, manufacture and sell ularitide.

In April 2007, we initiated a dose-ranging Phase 1 trial of ularitide in patients with acute decompensated heart failure (ADHF) in the U.S. In parallel, we are pursuing a partnership prior to advancing the European-focused Phase 3 trials of ularitide in this patient population.

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. Daclizumab is the active component of the approved drug marketed worldwide by Roche as *Zenapax*, which is indicated for the prevention of acute organ transplant rejection following transplant surgery.

We and our partner, Biogen Idec, are currently testing daclizumab in a Phase 2 study in patients with multiple sclerosis. In March 2007, we and Biogen Idec announced that the ongoing CHOICE trial, a Phase 2, randomized, double-blind, placebo-controlled trial of daclizumab, met its primary endpoint in relapsing multiple sclerosis (MS) patients being treated with interferon beta. We now plan to initiate a Phase 2 monotherapy trial of daclizumab, and to advance the overall clinical development program in relapsing MS.

Since Roche s election to terminate its co-development of daclizumab in treating asthma and transplant maintenance with us, we are evaluating opportunities to establish a new collaboration for these indications. Refer to the Collaboration and Strategic Agreements section of Part 1, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2006 filed with the SEC for further details regarding our collaboration agreement with Roche.

Volociximab (M200). Volociximab is a chimeric monoclonal antibody that inhibits the functional activity of α5ß1 integrin, a protein found on activated endothelial cells. Blocking the activity of α5ß1 integrin has been found to prevent angiogenesis, which is the formation of new blood vessels that feed tumors and allow them to grow and metastasize.

We and our partner, Biogen Idec, are currently investigating volociximab in various Phase 2, open-label clinical trials in patients with advanced solid tumors. We expect to broaden the scope of this program during 2007 to include clinical trials in additional tumor types, including non-small cell lung cancer (NSCLC) and ovarian cancer. Additional trials in renal cell carcinoma (RCC), melanoma and pancreatic cancer may also be pursued pending results of the ongoing open-label studies. The design and size of these trials will vary by indication.

HuLuc63. HuLuc63 is a humanized monoclonal antibody that binds to CS1, a cell surface glycoprotein that is highly expressed on myeloma cells but minimally expressed on normal cells. HuLuc63 may induce anti-tumor effects through antibody-dependent cellular cytotoxicity activity on myeloma cells. The Phase 1 trial of HuLuc63 in patients with advanced multiple myeloma is currently enrolling patients.

PDL192. PDL192 is a novel humanized monoclonal antibody in pre-clinical development. We intend to file an IND, upon successful completion of certain remaining pre-clinical studies, in late 2007 for solid tumor applications.

Cardene. We have initiated a lifecycle management program, within our development groups, for our marketed drug *Cardene*. Within the scope of this plan are efforts on new formulations and presentation of the product, as well as clinical trial work in pediatric populations.

Commercial Products

We market our *Cardene* IV, *Retavase* and IV *Busulfex* products through our hospital-focused sales force, which focuses on the emergency, cardiac, neurological and intensive care units of hospitals. Our commercial products are summarized below:

Cardene. We sell our *Cardene* product in two formulations, *Cardene* IV and *Cardene* SR. The *Cardene* IV product is the only branded, U.S.-approved pharmaceutical in its specific chemical category delivered intravenously that is indicated for short-term treatment of hypertension when oral therapy is not feasible or desirable. The *Cardene* SR product is a patented, sustained-release formulation, which is sold in capsule form for oral administration. Our *Cardene* SR product is indicated for the treatment of hypertension and may be used alone or in combination with other antihypertensive drugs.

Table of Contents

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 the *Cardene* IV product 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 our *Cardene* IV product will be the most significant contributor to our product sales in the next several years. Our patent protection in the United States on our *Cardene* IV product and on our *Cardene* SR product expires in November 2009 and March 2010, respectively. We are working on lifecycle management initiatives, including a study in pediatric patients beginning in 2007, to extend the life of our *Cardene* brand franchise in the United States.

Retavase. Our *Retavase* product 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 the *Retavase* product competes has declined since we acquired the rights to the *Retavase* product in March 2005 due to physicians increased use of emergency surgical procedures to treat AMI, and, although we believe the decline in the thrombolytics market may have recently subsided, this market could decline further in the 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 our *Retavase* product expires in March 2014.

IV *Busulfex.* Our IV *Busulfex* product, 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. Our IV *Busulfex* product is our first global product and is sold outside the United States through our distributors, including Pierre Fabre Medicament S.A. in Europe and Kirin Brewery Company, Limited in several Asian countries. 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 the IV *Busulfex* product expires in September 2013 while regulatory extensions in the United States for the IV *Busulfex* product will expire in March 2014. Patent protection for the IV *Busulfex* product in the European Union (EU), Japan and certain other foreign countries will expire in August 2014. We also have been granted marketing exclusivity in Japan that begins upon the expiration of our Japanese patent and ends in July 2016. We have filed for similar regulatory and marketing exclusivity in other jurisdictions. In April 2007, PDL received its first-ever FDA approval for a new vial configuration of our IV *Busulfex* product, which we believe will enhance ease of use of this product.

Technology Outlicense Agreements

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.

Table of Contents

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

(1) 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.

Collaborative and Strategic Agreement

We have a collaboration agreement with Biogen Idec for the joint development, manufacture and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and for shared development and commercialization of volociximab (M200) in all indications. Under our collaboration agreement with Biogen Idec, we share equally the costs of all development activities. This agreement requires 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 this collaboration.

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

Summary of the First Quarter of 2007

In the first quarter of 2007, our total revenues were $108.0 million, an 18% increase from $91.2 million in the comparable period in 2006. This revenue growth was driven primarily by the growth in sales of our marketed products and an increase in royalties from our licensees. Of the total revenues we generated in the first quarter of 2007, approximately 45% were from net product sales, 45% were from royalties and 10% were from license, collaboration and other revenue, compared to 41%, 48%, and 11%, respectively, in the corresponding period of 2006.

Our total costs and expenses in the first quarter of 2007 were $120.0 million, an increase of $2.0 million from the first quarter of 2006. Our net loss for the first quarter of 2007 was $10.6 million, compared to $26.2 million in the prior-year comparable period. In the first three months of 2007, net cash used in operating activities was $9.1 million, a decrease from $2.4 million provided by operating activities in the comparable period in 2006. At March 31, 2007, we had cash, cash equivalents, marketable securities and restricted cash of $404.3 million, compared to $426.3 million at December 31, 2006. As of March 31, 2007, we had $531.8 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.

During the preparation of our financial statements for the quarter ended March 31, 2007, and subsequent to our May 2, 2007 announcement of our financial results for the first quarter of 2007 (the Earnings Announcement), we recorded an adjustment to reclassify certain costs previously included in research and development expenses to selling, general and administrative expenses. Such amounts primarily relate to certain of our clinical affairs costs that are more appropriately classified as general and administrative costs within selling, general and administrative expenses. As compared to the financial information presented in the Earnings Announcement, these reclassifications decreased research and development expenses and correspondingly increased selling, general and administrative expenses by approximately $4.6 million and $3.2 million for the three-month periods ended March 31, 2007 and March 31, 2006, respectively. These reclassifications had no impact on our total operating expenses or our net loss for either of these periods.

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

Table of Contents

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 revenues 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.

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 of dollars 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 assert and defend our intellectual property rights are expensive, can, and have, continued over many 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. We face significant competition for experienced personnel and continue to focus on hiring and retaining key personnel.

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 (GAAP) 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. For a

17

Table of Contents

description of the critical accounting policies that affect our more significant judgments and estimates used in the preparation of our condensed consolidated financial statements, refer to our Annual Report on Form 10-K for the year ended December 31, 2006, filed with the SEC. Except as noted below, there have been no changes to our critical accounting policies since December 31, 2006.

Sales Allowances and Rebate Accruals

We record reductions to product sales for estimated returns of products sold by us for chargebacks, wholesaler rebates, government rebate programs, such as Medicaid reimbursements, and for 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 rebates 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 our products 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 the sell-through of our products. Further, we monitor the activities and clinical trials of our key competitors to assess the potential impact on our future sales and return expectations. Accounts receivable allowances for chargebacks, wholesaler rebates and product returns, as well as rebate accruals, require substantial judgment. Actual results may differ in the future from our estimates and could impact our earnings in any period during which an adjustment is made.

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 or increase of revenues at the time the return estimate is changed or new incentives are offered. For example, during the first quarter of 2007, we refined our estimates with respect to future product returns of two of our currently marketed products based on recent historical return patterns. For one product, we slightly increased the rate at which we are accruing for product returns and, for the other, we slightly decreased such rate. As of March 31, 2007, the returns reserves for one of these products is at the lower end of our estimated range for expected future returns and the returns reserve for the other product is at the higher end of our estimated range. While we believe that the returns reserves for each of these products at the end of the first quarter of 2007 are within a reasonable range based on our expectations for future product returns, we may experience actual returns that differ from these estimates. A material deviation from expected returns could either result in an increase or decrease in our net product sales in future periods.

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, 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.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2007 and 2006

Revenues

	Three Months Ended March 31,		
(in thousands)	**2007**	**2006**	**% Change**
Product sales, net	$ 49,127	$ 37,547	31%
Royalties	48,595	43,970	11%
License, collaboration and other	10,261	9,695	6%
Total revenues	$ 107,983	$ 91,212	18%

Table of Contents

Our total revenues increased by $16.8 million, or 18%, in the three months ended March 31, 2007 from the comparable period in 2006 for reasons discussed below.

Product sales, net

	Three Months Ended March 31,		
(in thousands)	2007	2006	% Change
Cardene	$ 34,549	$ 24,761	40%
Retavase	6,865	6,505	6%
IV *Busulfex*	7,713	5,164	49%
Total marketed products	49,127	36,430	35%
Off-patent branded products		1,117	(100)%
Total product sales, net	$ 49,127	$ 37,547	31%

For the three months ended March 31, 2007, net product sales increased 31%, or $11.6 million, from the comparable period in 2006, principally due to increased sales of our *Cardene* product. Since we divested the rights to our off-patent branded products in the first quarter of 2006, product sales in the first quarter of 2007 consisted only of our *Cardene*, *Retavase* and IV *Busulfex* products, sales of which increased by 35% from the comparable period in 2006.

Cardene

Net product sales of our *Cardene* product increased by $9.8 million, or 40%, in the three months ended March 31, 2007 from the comparable period in 2006. This increase was primarily driven by higher sales volumes of our *Cardene* IV product and, to a lesser extent, an increase in *Cardene* IV product prices in January 2007. We expect our *Cardene* net product sales to continue to increase due to expected growth in sales volumes of our *Cardene* IV product in the foreseeable future.

Retavase

Net product sales of our *Retavase* product increased by $0.4 million, or 6%, in the three months ended March 31, 2007 from the comparable period in 2006 due to a slight increase in sales volumes. We continue to maintain our *Retavase* product market share in the thrombolytics market, and we believe that opportunities exist for us to expand our market share through focused sales and promotional efforts. We did not institute price increases for our *Retavase* product in 2006 or the first quarter of 2007, and the competitiveness of the market for thrombolytics may limit our ability to obtain price increases in the future.

IV Busulfex

Net product sales of our IV *Busulfex* product increased by $2.5 million, or 49%, in the three months ended March 31, 2007 from the comparable period in 2006. This increase was primarily due to higher sales volumes with respect to the continued growth of our international sales and, to a lesser extent, a price increase that was effective in January 2007. We expect IV *Busulfex* product sales volumes to continue to increase in the future primarily as a result of international sales expansion.

Off-Patent Products

Sales of our off-patent products in 2006 consisted of net product sales of *Sectral*, *Ismo* and *Tenex* products. We divested all of our off-patent products in the first quarter of 2006.

Royalties

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

		Three Months Ended March 31,	
Licensee	**Product Name**	**2007**	**2006**
Genentech	*Herceptin*	39%	34%
	Avastin	19%	24%
MedImmune	*Synagis*	30%	32%

Table of Contents

Royalty revenues increased by $4.6 million, or 11%, in the three months ended March 31, 2007 from the comparable period in 2006. This increase was primarily due to higher reported sales of *Herceptin* and *Avastin* products, which are marketed by Genentech, as well as royalties on sales of the *Lucentis* product, which Genentech launched during the second quarter of 2006. These increases were partially offset by a lower effective royalty rate for Genentech product sales when compared to the first quarter of 2006, because, due to the tiered royalty structure under our master patent license agreement with Genentech, a significant portion of the royalties Genentech paid us in the first quarter of 2007 were paid at the fourth and lowest tiered royalty rate whereas none of the royalties paid to us in the first quarter of 2006 were at this lowest rate.

Under most of the agreements for the license of rights under our Queen patents, we receive a flat-rate royalty based upon our licensees net sales of covered products. Royalty payments are generally due one quarter in arrears; that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. As noted above, however, our master patent license agreement with Genentech provides for a tiered royalty structure under which the royalty rate Genentech must pay on royalty-bearing products sold in the United States or manufactured in the United States and sold anywhere (U.S.-based Sales) in a given calendar year decreases during that year on incremental U.S.-based Sales above several net sales thresholds. As a result, Genentech s average annual royalty rate during a year declines as Genentech s aggregate U.S.-based Sales increase during that year. Because we receive royalties in arrears, the average royalty rate for the payments we receive from Genentech in the second calendar quarter which would be for Genentech s sales from the first calendar quarter is higher than the average royalty rate for following quarters and is lowest in the first calendar quarter, which would be for Genentech s sales from the fourth calendar quarter, when more of Genentech s U.S.-based Sales bear royalties at lower royalty rates.

We expect that in 2007, we will continue to experience aggregate royalty revenue growth based on the assumed continued growth in aggregate product sales underlying our royalty revenues. Further, we expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of the *Synagis* antibody, 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, and the tiered royalty structure under our agreement with Genentech.

License, Collaboration and Other

	Three Months Ended March 31,		
(in thousands)	**2007**	**2006**	**% Change**
License and milestone from collaborations	$ 5,868	$ 2,071	183%
R&D services from collaborations	3,993	6,874	(42)%
License and other	400	750	(47)%
Total revenues from license, collaboration and other	$ 10,261	$ 9,695	6%

License, collaboration and other revenues recognized during the three months ended March 31, 2007 and 2006 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 $0.6 million, or 6% in the three months ended March 31, 2007 from the comparable period in 2006 primarily due to the accelerated recognition of deferred revenue resulting from the termination of our agreement with Roche, effective May 2007, to co-develop daclizumab for transplant indications. This increase was partially offset by a decrease in revenue recognized under our collaboration agreement with Biogen Idec and the absence of revenues in the first quarter of 2007, when compared to the first quarter of 2006, due to the termination in the third quarter of 2006 of our collaboration agreement with Roche to co-develop daclizumab for the treatment of asthma and other respiratory diseases.

Table of Contents

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 likely would increase.

Costs and Expenses

	Three Months Ended March 31,		
(in thousands)	**2007**	**2006**	**% Change**
Cost of product sales	$ 24,998	$ 22,959	9%
Research and development	55,625	58,586	(5)%
Selling, general and administrative	37,941	35,344	7%
Other acquisition-related charges	1,436	1,118	28%
Total costs and expenses	$ 120,000	$ 118,007	2%

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. The following table summarizes COS by component, as a percentage of products sales:

	Three Months Ended March 31,	
	2007	**2006**
Cost of goods sold	14%	12%
Royalty expense	20%	21%
Amortization of product rights	17%	28%
Cost of product sales	51%	61%

COS increased 9% in the three months ended March 31, 2007 as compared to the same period in the prior year primarily as a result of the increase in product sales. This increase was offset by lower amortization of product rights as a result of the $72.1 million impairment charge we recognized related to our Retavase intangible asset during the fourth quarter of 2006, which reduced amortization charges that otherwise would have been recognized in the first quarter of 2007 and future periods.

For the three months ended March 31, 2007, COS, excluding amortization of product rights, as a percentage of product sales was relatively flat as compared to the same period in the prior year.

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 our *Cardene* IV product, 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 our *Retavase* product, we expect our future cost of goods sold as a percentage of product sales to increase, beginning in 2009, in connection with increased manufacturing costs under an amended supply agreement with our contract manufacturer for our *Retavase* product.

Table of Contents

Research and Development Expenses

Our research and development activities include research, process development, pre-clinical development, manufacturing, clinical, regulatory, biometry, quality and program management. Research and development expenses consist primarily of costs of personnel to support these research and development activities, as well as milestone payments and technology licensing fees, costs of preclinical studies, costs of conducting our clinical trials, such as fees to clinical research organizations and clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties, an allocation of facility and overhead costs and stock-based compensation expense accounted for under SFAS 123(R) as a component of personnel related costs.

The $3.0 million decrease in research and development costs in the first quarter of 2007 compared to the corresponding quarter of 2006 was primarily due to decreases of $4.6 million in external clinical development expenses for certain of our research and development projects and $0.6 million in contract manufacturing and production costs, which were partially offset by increases in personnel related costs of $0.6 million, information technology-related costs of $0.5 million, facility-related costs of $0.5 million, consulting services and research grant costs of $0.4 million, and licensing costs of $0.2 million. Total stock-based compensation expense recognized as research and development expenses, including amounts recognized under SFAS 123(R), was $2.9 million and $3.4 million for the three months ended March 31, 2007 and 2006, respectively.

We expect our research and development expenses 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 research and developments costs, including research, process development, pre-clinical development, manufacturing, clinical, regulatory, biometry, quality and program management, for those programs or products that comprised more than 5% of total research and development expenses for either period presented. The stage of development for each of our products in clinical development is also indicated.

Program/Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Three Months Ended March 31, 2007	2006
					(in thousands)	
Nuvion (visilizumab)					$ 11,657	$ 9,795
	IV steroid-refractory ulcerative colitis	Phase 2/3		Not yet disclosed		
	Crohn s Disease	Phase 2		Not yet disclosed		
Daclizumab[1]					7,261	12,007
	Healthy Volunteer SC	Phase 1		Completed		
	Asthma	Phase 2a		Completed		
	Multiple Sclerosis	Phase 2	Biogen Idec	2007		
PDL192	Solid tumors	Pre-IND		2007	5,451	11
Volociximab (M200)	Solid tumors	Phase 2	Biogen Idec	2008	4,276	5,331
HuLuc63	Multiple myeloma	Phase 1		2007/2008	3,817	6,554
Ularitide [2]	Acute Decompensated Heart Failure	Phase 2		Completed	3,319	3,583
Cardene[3]	Product Life Cycle Management	Marketed; Phase 2		Not yet disclosed	3,090	796
Other Program-Related Costs [4]	Multiple programs and products				1,539	2,936
Non-Program-Related Costs[5]					15,215	17,573
Total Research and Development Expenses					$ 55,625	$ 58,586

(1) The Roche Amended and Restated Co-Development and Commercialization Agreement provided that Roche would jointly develop and commercialize daclizumab for the treatment of asthma and transplant indications; however, in August 2006, Roche decided to first discontinue its involvement in the development of daclizumab in treating asthma and then later, in November 2006, elected to discontinue its co-development of daclizumab in transplant indications and terminate the Roche Co-Development Agreement effective in May 2007.

Table of Contents

(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 had been planning to initiate a two-study, 3,300-patient Phase 3 trial in Europe; however, we had decided to delay the start of these trials pending a partnership for the ularitide program to contribute to the successful development of ularitide. This delay does not affect our planning and initiation of a Phase 1 trial in the United States.

(3) We have initiated a lifecycle management program, within our development groups, for our marketed drug *Cardene*. Within the scope of this plan are efforts on new formulations and presentation of the product, as well as clinical trial work in pediatric populations.

(4) Other Program-Related Costs consist of the aggregate research and development costs for those distinct programs or products that do not individually constitute more than 5% of the total research and development expenses for the periods presented.

(5) Non-Program-Related Costs consist of the aggregate research and development costs that are not associated with any particular program or product, but rather, support our broad research and development efforts. Such costs primarily include those related to discovery of new antibody candidates and manufacturing and quality activities in support of product development activities.

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, clinical affairs, an allocation of facility and overhead costs and stock-based compensation expense accounted for under SFAS 123(R) as a component of personnel related costs. Of total selling, general and administrative expenses for the three months ended March 31, 2007, 56%, or $21.3 million, related to sales and marketing expenses, compared to 48%, or $16.9 million, for the comparable period in 2006. Total stock-based compensation expense recognized as selling, general and administrative expenses, including amounts recognized under SFAS 123(R), was $2.3 million and $2.7 million for the three months ended March 31, 2007 and 2006, respectively.

Selling, general and administrative expenses for the three months ended March 31, 2007 increased to $37.9 million from $35.3 million during the comparable period in 2006. This increase was primarily due to increases in facilities-related expenses of $1.9 million and consulting and outside services of $1.6 million, which were partially offset by decreases in information technology-related costs of $0.5 million and other miscellaneous expenses of $0.4 million.

Additionally, selling, general and administrative expenses for the three months ended March 31, 2007 included approximately $1.4 million of costs related to our Brooklyn Park manufacturing facility. Our Brooklyn Park facility, which was placed into service in July 2006, is qualified to manufacture clinical development products. Currently, this facility has capacity greater than our current manufacturing demands, and therefore, we had idle manufacturing capacity during the first quarter of 2007, the costs of which we recorded as selling, general and administrative expenses.

Table of Contents

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 our *Retavase* product from sales made prior to the acquisition of our rights to the *Retavase* product 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 the *Retavase* product, 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 $1.4 million and $1.1 million in other acquisition-related charges in the three months ended March 31, 2007 and 2006, respectively.

Interest and Other Income, Net and Interest Expense

	Three Months Ended March 31,		
(in thousands)	**2007**	**2006**	**% Change**
Interest and other income, net	$ 5,032	$ 3,330	51 %
Interest expense	(3,557)	(2,650)	34 %
Total interest and other income, net and interest expense	$ 1,475	$ 680	117 %

Interest income for the three months ended March 31, 2007 increased from the comparable period in 2006 due to the increased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of higher interest rates.

Interest expense for the three months ended March 31, 2007 increased from the comparable period in 2006 primarily as a result of lower capitalized interest expense in the three months ended March 31, 2007, since we completed the construction of the Minnesota facility in the second quarter of 2006.

Income Taxes

In July 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, (FIN 48) 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 adopted FIN 48 on January 1, 2007. As a result of the adoption of FIN 48, we recorded a $0.1 million increase related to our liability for unrecognized tax benefits, which was accounted for as an increase to our accumulated deficit. Subsequent to our adoption of FIN 48, we have unrecognized tax benefits totaling approximately $10.0 million.

The future impact of the unrecognized tax benefit of $10.0 million, if recognized, is as follows: approximately $0.1 million would affect the effective tax rate; approximately $1.4 million would result in a reduction in goodwill associated with the acquisition of ESP Pharma; and approximately $8.5 million would result in adjustments to deferred tax assets and corresponding adjustment to the valuation allowance.

Estimated interest and penalties related to the underpayment of income taxes are classified as a component of tax expense in the Condensed Consolidated Statement of Operations and totaled approximately $0.1 million for the quarter ended March 31, 2007. Accrued interest and penalties were approximately $0.6 million and $0.7 million as of December 31, 2006 and March 31, 2007, respectively.

Table of Contents

In general, our income tax returns are subject to examination by U.S. federal, state and local tax authorities for tax years 1992 forward. Our French subsidiary s income tax returns for 2004 and 2005 are currently under examination by the French tax authorities. We do not anticipate any additional unrecognized benefits in the next 12 months that would result in a material change to our financial position.

Income tax expense during the three months ended March 31, 2007 was primarily related to state taxes and foreign taxes on income earned by our foreign operations. Taxes during the three months ended March 31, 2006 are primarily related to federal alternative minimum 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.

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 revenues under agreements with third parties, interest income on invested capital and, more recently, product sales. At March 31, 2007, we had cash, cash equivalents, marketable securities and restricted cash in the aggregate of $404.3 million, compared to $426.3 million at December 31, 2006.

Net cash used in operating activities for the three months ended March 31, 2007 was $9.1 million, compared to $2.4 million of cash provided by operating activities in the corresponding period in 2006. The $9.1 million net cash used in operating activities in the first three months of 2007 was primarily attributable to our net loss, less non-cash expenses such as depreciation and amortization expenses and stock-based compensation, and adjusted for the timing of payments related to our clinical operations and the manufacture of our commercial products. The increase in cash used in operations in the first quarter of 2007 compared to the prior-year period was primarily related to the timing of payments in connection with our clinical operations and the manufacture of our commercial products, partially offset by higher cash receipts in the first quarter of 2007 related to our product sales and royalties. In addition, during the first quarter of 2006, we received a $5.0 million milestone payment under the terms of our collaboration agreement with Biogen Idec, and we received no upfront fees or milestone payments during the first quarter of 2007.

Net cash used in investing activities was $30.2 million for the three months ended March 31, 2007, compared to $77.2 million in the comparable period in 2006. The $30.2 million net cash used in investing activities in the first three months of 2007 was primarily attributable to capital expenditures of $16.8 million, the transfer of $10.0 million to restricted cash to support an additional letter of credit related to our obligations with respect to the construction of our leasehold improvements to our Redwood City, California facility, and net purchases of approximately $3.4 million of our available-for-sale marketable securities. The decrease in cash used in investing activities when compared to the first quarter of 2006 was due principally to the timing of purchases of marketable securities.

Net cash provided by financing activities for the three months ended March 31, 2007 was $2.8 million, compared to $15.6 million in the comparable period in 2006. The $2.8 million net cash provided by financing activities in the first three months of 2007 was primarily due to the issuance of our common stock in connection with option exercises. In the prior year, net cash provided by financing activities was higher when compared to the current period due to a greater volume of employee stock option exercises.

We estimate that our existing capital resources will be sufficient to fund our operations through 2007 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, Tysabri* 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

Table of Contents

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 March 31, 2007 are as follows:

	Payments Due by Period				
(in thousands)	Less Than 1 Year	1-3 Years	4-5 Years	More than 5 Years	Total
CONTRACTUAL OBLIGATIONS [1]					
Operating leases	$ 6,881	$ 7,237	$ 6,883	$ 65,862	$ 86,863
Long-term liabilities [2]	8,009	12,892	9,868	46,158	76,927
Convertible notes	11,875	23,750	513,435		549,060
Construction contracts and equipment	70,823				70,823
Contract manufacturing	33,194	11,966			45,160
Total contractual obligations	$ 130,782	$ 55,845	$ 530,186	$ 112,020	$ 828,833

(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 lease payments related to our Lab Building in Redwood City, California, mortgage payments for the buildings we own in Fremont, California, post-retirement benefit obligations and the milestone payments related to our purchase of product-related rights to *Cardene*.

RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Quarterly Report, 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 shares of our common stock. Additional risks not currently known to us may also harm our business.

Keep these risk factors in mind when you read forward-looking statements contained in this Quarterly Report and the documents incorporated by reference in this Quarterly Report. 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, pre 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 March 31, 2007, we had an accumulated deficit of $580.9 million. We expect our expenses to increase primarily because of the extensive resource commitments

Table of Contents

required to achieve regulatory approval of potential products and commercial success for our portfolio of existing products and any other products we add to our product development portfolio through our development or in-licensing activities. 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 or with appropriate quality, or successfully market such products with desired margins, we may not sustain positive cash flow from operations as we have projected. We may also incur additional acquisition-related or impairment charges related to our acquisitions of ESP Pharma and the rights to the *Retavase* product, 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 pre-clinical product candidates are selected for further clinical 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 increase the number of patents we are prosecuting;
- we expend additional resources to defend our patents;
- we invest in research or acquire additional technologies, product candidates or businesses; and
- we increase our capital expenditures as we improve our research, development and other facilities and as a result also record higher depreciation expenses.

In the absence of substantial revenues from additional sales of existing or newly approved or acquired products, new agreements with third-party collaborators, significant royalties on sales of products licensed under our intellectual property rights or other sources of revenues, 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 cycles of our portfolio products, our results of operations will suffer.

In the quarter ended March 31, 2007, our product sales accounted for 45% of our total revenues. We expect that revenues from our product portfolio will continue to represent a significant and possibly growing portion of our total revenues. The patents that we own or hold licenses to

that cover our *Cardene*, IV *Busulfex* and *Retavase* products, our marketed products, 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 revenues and profit margins we recognize from the sale of that product.

Table of Contents

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

Sales of our *Cardene* IV product have accounted for a significant portion of our total revenues and growth in our sales since we acquired rights to it through our acquisition of ESP Pharma in March 2005. For example, our *Cardene* product sales, net, accounted for 22% of total revenues in 2005 and 26% of total revenues in 2006. However, our *Cardene* IV product faces competition from branded and generic intravenous anti-hypertensive products marketed in the United States and it may be harder to continue to penetrate this market and continue to grow *Cardene* IV product sales especially at the recent rate. While we have recently increased committed sales and marketing resources and expect to sustain this increased commitment of resources in an effort to ensure the continued growth of our *Cardene* IV product sales, there can be no assurance that we can continue a significant 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 the *Cardene* IV product to continue its success, we will have to maintain and expand its position in the marketplace against these competitors drugs.

In March 2007, we received a letter from Sun Pharmaceutical Industries Ltd. (Sun) purporting to be a Notice of Certification (the Paragraph IV Certification) with respect to an Abbreviated New Drug Application (ANDA) Sun filed with the FDA seeking approval to sell in the United States a generic version of injectable nicardipine hydrochloride, which, if approved, would likely compete with our *Cardene* IV product. Sun claimed in the Paragraph IV Certification that neither the manufacture, use nor sale of Sun s ANDA product would infringe our United States Patent Number 5,164,405, titled Nicardipine pharmaceutical composition for parenteral administration (the 405 Patent). In April 2007, we filed a patent infringement lawsuit against Sun seeking, among other things, to enjoin Sun s infringement of our 405 Patent and to stay any sale of Sun s ANDA product until at least the expiration of our 405 Patent. Although we intend to vigorously defend our rights under the 405 Patent, we may not prevail. If the outcome of this case were to be unfavorable for us, we believe we would face significant competition from Sun s ANDA product, which likely would cause significant declines in the amount of revenues and profit margins we recognize from the sale of our *Cardene* IV product.

Our *Retavase* product is sold in a market that has declined since we acquired the rights to the *Retavase* product in March 2005 and if our continued sales and promotional efforts do not increase sales, our results of operations will suffer.

We expect our *Retavase* product to continue to account for a significant portion of our total revenues and product sales, net. However, our *Retavase* product is sold into a thrombolytic market that has declined due to the more widespread use of stents and gpIIb/IIIa inhibitor products. Moreover, our *Retavase* product competes for use in the management of acute myocardial infarction with the TNKase and *Activase®* products from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we possess. While we continue to invest in promotional efforts for our *Retavase* product, there can be no assurance that we can increase the market share of our *Retavase* product, or that even if we are able to increase our market share, that the thrombolytic market will not continue to decline regardless of our efforts.

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

Our *Retavase* product 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 relatively frequent batch failures because of the complexity of the manufacturing process. For example in 2006, one of our contract manufacturers experienced higher than expected batch failure rates. As a result, we and that contract manufacturer agreed to temporarily cease *Retavase* product manufacturing and run three test batches to extensively sample and analyze the process prior to making potential improvements. Although we believe we will be able to improve the manufacturing process to reduce batch failure rates, there can be no assurance that we will not experience subsequent manufacturing issues or batch failures that 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 our *Retavase* product will increase under our amended supply agreement with our contract manufacturer. This new supply agreement requires higher per gram fee payments as well as charges for additional testing during the manufacturing process.

Because we do not have the capability to manufacture our commercial products or our ularitide development product, we rely on third-party contract manufacturers to manufacture these products. If we are unable to continue those manufacturing arrangements successfully or at a reasonable cost, our operations and future results could suffer.

We do not have the capability to manufacture any of our marketed products or our ularitide development product. We have entered into manufacturing agreements with various third parties to manufacture and supply these products under our label. Each of our products is manufactured by a single manufacturer. If there are supply problems with any third-party manufacturer, there may not be sufficient supplies of the product which that manufacturer produces for us to meet commercial or clinical trial demand, in which case our operations and results could

suffer.

For example, earlier in 2006, we encountered manufacturing challenges for our *Retavase* product and temporarily ceased manufacturing of the *Retavase* product to run test batches to analyze and improve the manufacturing process. In connection with these efforts, we also negotiated an amended supply agreement with our contract manufacturer

Table of Contents

pursuant to which our expected manufacturing costs will increase. These cost increases prompted us to conduct an asset impairment analysis and, in the fourth quarter of 2006, we recognized a $72.1 million asset impairment charge to our *Retavase* product rights intangible assets.

Our products must be manufactured in facilities approved by the FDA and the process for qualifying and obtaining approval for a manufacturing facility is a time-consuming process. If our relationship with any of our manufacturers were to terminate unexpectedly or on short notice or expire without being renewed, our ability to meet commercial or clinical trial demand for the product manufactured by that single manufacturer could be adversely affected while we qualify a new manufacturer for that product and our operations and future results could suffer.

We also engage third parties for product filling, labeling and packaging. If any filling, labeling or 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, we must rely on our third-party manufacturers and suppliers for regulatory compliance and adhering to the FDA s current Good Manufacturing Practices (cGMP) requirements. If these manufacturers or suppliers fail to comply with applicable regulations, including FDA pre-or post-approval inspections and cGMP requirements, then the FDA could sanction 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 or criminal prosecutions, any of which could significantly and adversely affect our business.

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 March 31, 2007, 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 March 31, 2006, these three U.S. wholesalers represented approximately 83% of our outstanding accounts receivable from product sales.

Since our acquisition in March 2005 of rights to our *Cardene* IV, *Retavase* and IV *Busulfex* products and certain off-patent products, which we have since divested, we received and continued to receive through 2006 a significant number of returns of these products that were sold prior to our acquisition of these rights. The level of these returns 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. The level of returns of products sold prior to our March 2005 acquisition have declined from the rates we experienced in 2006 and we believe these return rates will continue to decline as our product channel is cleared of these products.

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 rights to our *Cardene* IV, *Retavase* and IV *Busulfex* products. 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. For example, in the second quarter of fiscal 2006 we increased our estimate of the rate of product returns and the effect of this change was to reduce product sales, net, in that quarter by approximately $5.6 million. 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.

Table of Contents

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

At March 31, 2007, we had approximately $654.0 million in total liabilities outstanding, including $250.0 million in principal that remains outstanding under our 2.00% Convertible Senior Notes due February 15, 2012 (the 2005 Notes) and $250.0 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2023 (the 2003 Notes). The 2003 and 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 acquisitions of ESP Pharma and rights to the *Retavase* product 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 have encountered and may encounter further 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.

Table of Contents

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 or are terminated by our partners, 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 limited 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 arrangement with Biogen Idec is particularly important to us. In September 2005, we entered into an agreement with Biogen Idec under which Biogen Idec became our partner on the development of daclizumab in certain indications, including MS, and volociximab (M200) in all indications. Our collaboration agreement with Biogen Idec also covers the development of *HuZAF* (fontilizumab), which we and Biogen Idec were developing in severe rheumatoid arthritis. However, we and Biogen Idec agreed to discontinue development of the *HuZAF* antibody and do not currently have any plans for further development of the *HuZAF* antibody.

Our collaboration agreement with Biogen Idec provides significant combined resources for the development, manufacture and potential commercialization of covered products. We and Biogen Idec each assume certain responsibilities and share expenses. Because of the broad scope of the collaborations, we are particularly dependent upon the performance by Biogen Idec of their obligations under the agreement. The failure of Biogen Idec to perform their obligations, our failure to perform our obligations, our failure to effectively manage the relationship, or a material contractual dispute between us and Biogen Idec 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 collaboration will vary depending on the work performed by us and Biogen Idec in any particular reporting period.

The arrangement with Roche pursuant to which were co-developing daclizumab for asthma and transplant maintenance was also particularly important to us. In 2006, however, Roche decided to first discontinue its involvement in the co-development of daclizumab in treating asthma and then later to discontinue its co-development of daclizumab in transplant maintenance and terminate the Roche Co-Development Agreement effective in May 2007.

We rely on other collaborators, 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.

Table of Contents

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 the collaboration agreement we had with Roche, and in November 2006, Roche elected to terminate the entire collaboration agreement. 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. Although we reviewed, documented and tested our internal control over financial reporting successfully in 2004, 2005 and 2006, our inability to do so in the future could adversely affect our stock price.

The Section 404 compliance process has also resulted in increased expenses and the devotion of significant management resources and we expect that the expenses for this process will continue to increase modestly.

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;

Table of Contents

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 occurrence of key events under collaborative arrangements, including milestones, development decisions or program or collaboration terminations;

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;

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; and

the structure of out-licensing, collaboration and royalty 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 in our revenues from quarter to quarter.

Additionally, our master patent license agreement with Genentech provides for a tiered royalty structure under which the royalty rate Genentech must pay on royalty-bearing products sold in the United States or manufactured in the United States and sold anywhere (U.S.-based Sales) in a given calendar year decreases on incremental U.S.-based Sales above several net sales thresholds. As a result, Genentech s average annual royalty rate declines as Genentech s U.S.-based Sales increase. Because we receive royalties in arrears, the average royalty rate for the payments we receive from Genentech in the second calendar quarter which would be for Genentech s sales from the first calendar quarter is higher than the average royalty rate for following quarters and is lowest in the first calendar quarter when more of Genentech s U.S.-based Sales bear royalties at lower royalty rates.

License, collaboration and other revenues 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 revenues 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 revenues 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 revenues would be accelerated and recognized in the period in which the termination occurred. In such a case, it may cause our revenues 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 revenues 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, revenues historically recognized under our prior agreements may not be an indicator of revenues 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

Table of Contents

in which such expenses are reported to us or to our partners and agreed to by us or our partners. Moreover, the underlying terms of in-licensing and royalty arrangements, especially those with tiered payment structures, will impact the timing of costs and expenses recognized during any particular quarter. 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 operating 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 Queen patents are of significant value to us. In 2006, we received royalty revenues under license agreements covering our Queen patents which represented approximately 44% of our total revenues in 2006. We expect that in 2007, we will continue to experience aggregate royalty revenue growth based on the assumed continued growth in aggregate product sales underlying our royalty revenues and that these royalty revenues will continue to represent a significant portion of our total revenues.

Two of our Queen patents were issued to us by the European Patent Office, European Patent No. 0 451 216 (the 216 Patent) and European Patent No. 0 682 040 (the 040 Patent). Eighteen notices of opposition to our 216 Patent and eight notices of opposition to our 040 Patent were filed by major pharmaceutical and biotechnology companies, among others, and we are currently in two separate opposition proceedings with respect to these two patents. Although six opponents, including Genentech, have withdrawn from the opposition proceedings with respect to the opposition to our 216 Patent, 12 opponents to this patent remain. In addition, although the Opposition Division upheld claims in our 216 Patent in April 2007 that are virtually identical to the claims remitted by the Technical Board of Appeal to the Opposition Division, the opponents in this opposition have the right to appeal the Opposition Division s recent decision and this proceeding has not yet concluded. A description of both opposition proceedings is included under the heading Legal Proceedings in Part II, Item 1 of this Quarterly Report. If our patents are successfully opposed in either of these two proceedings or third parties decline to take licenses to our Queen patents, our future revenues would be adversely affected. For example, if the opponents in the proceeding regarding our 216 Patent 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 040 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.

In addition, until the opposition proceedings are resolved, we may be limited in our ability to collect royalties or to negotiate future license agreements based on our Queen patents. An adverse decision by the Opposition Division could encourage challenges to our related Queen patents in other jurisdictions, including the United States. Such a 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 proceedings to enforce our rights under our Queen 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 216 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. patents.

Although we intend to vigorously defend the European patents in these two proceedings, we may not prevail in either of these opposition proceedings or any litigation contesting the validity of these patents. For example, our Japanese humanization patent, which was issued in September 1998, was opposed and eventually revoked by the Japanese Patent Office in March 2001. Although we appealed the Japanese Patent Office s revocation of this patent,

Table of Contents

the Tokyo High Court upheld the revocation of the patent and, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court s decision. The decision by the Japanese Supreme Court concluded the proceedings in the matter and the Japanese Patent Office s decision to revoke our patent is final and nonappealable.

If the outcome of either 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.

Our ability to maintain and increase our revenues from licensing our Queen patents 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 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.

Table of Contents

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 a Celltech U.S. patent application conflicts 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 progress 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 higher number of potential targets than we expect to be able to progress through clinical development. 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;

Table of Contents

- 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, a drug to which we had commercialization rights at the time, did not meet its primary endpoint of reversing type 1 hepatorenal syndrome compared to placebo. 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 reaching 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 development generally takes 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 regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA s or EMEA 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 or EMEA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

37

Table of Contents

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

Table of Contents

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 our *Nuvion* antibody for the treatment of intravenous steroid-refractory ulcerative colitis, 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 our *Nuvion* antibody will receive regulatory approval.

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 the *Nuvion* antibody are dependent on our ability to timely enroll a worldwide clinical program.

Our royalty revenues from technologies we license to others depend on, among other things, 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, in part, 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 a licensee will be affected by competitive products, including potential competing therapies, that may be marketed by the licensee or others. In addition, even if a licensee receives 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 the *Tysabri* antibody, 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* antibody. In July 2006, Biogen Idec and Elan reintroduced the *Tysabri* antibody, however, the *Tysabri* antibody s label now includes prominent warnings regarding the *Tysabri* antibody s risks and Biogen Idec and Elan implemented a risk management plan to inform physicians and patients of the benefits and risks of *Tysabri* antibody treatment and to minimize the risk of PML potentially associated with *Tysabri* antibody monotherapy.

Table of Contents

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 continue to seek to hire and retain key personnel; however, we face significant competition for experienced personnel. We also believe that the move of our corporate headquarters from Fremont, California, to Redwood City, California, in the second half of 2007, may before and for a period after the move cause employee turnover to increase and make retaining key employees more difficult because our new headquarters is 12 miles away from our current headquarters and on the other side of the San Francisco Bay, which will increase the commute time of the many employees that reside in and around Fremont, California, and the greater East Bay Area of the San Francisco Bay Area.

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

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

We intend to continue to manufacture potential products for use in preclinical and clinical trials using our manufacturing facility in Brooklyn Park, Minnesota in accordance with standard procedures that comply with appropriate regulatory standards. The manufacture of sufficient quantities of antibodies that comply with these standards is an expensive, time-consuming and complex process and subject to a number of risks that could result in delays 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 ourselves at an acceptable cost, we will need to improve and significantly expand our manufacturing capabilities. Our current plans are to use our new manufacturing plant in order to manufacture initial commercial supplies of the *Nuvion* product 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;

Table of Contents

- 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 collaboration with 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.

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.

Competition and rapid technological change may adversely affect our revenues.

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 development products 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

41

Table of Contents

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 and the Department of Health and Human Services, among others, 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

42

Table of Contents

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. The FDA prohibits the marketing of any pharmaceutical or biologic products for off-label uses. If our advertising or promotional activities fail to comply with applicable regulations or guidelines, including with respect to off-label use, we may be subject to warnings, fines, sanctions or other enforcement action.

Further, regulatory approvals may be withdrawn if we do not comply with regulatory standards or if problems with our marketed products occur. 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 candidates 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 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 product candidates, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our 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

Table of Contents

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 product candidates 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

Table of Contents

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, 2007 to May 3, 2007, our common stock closed as high as $25.76 per share and as low as $18.26 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.

Table of Contents

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 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, 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 operating expenses are significantly higher than prior to the adoption of SFAS 123(R).

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

Table of Contents

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 as a result of amortization or impairment 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 the *Retavase* product 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 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. For example, during the fourth quarter of 2006, we recognized a $72.1 million impairment charge related to our *Retavase* product-related intangible assets.

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 the *Retavase* product 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 our *Cardene* products are commercially successful;
- the extent to which we can maintain our *Retavase* product sales relative to 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* antibody, ularitide and volociximab;
- the cost and outcomes of regulatory submissions and reviews;

47

Table of Contents

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 revenues 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;

Table of Contents

the federal Foreign Corrupt Practices Act, which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity; 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

As of March 31, 2007, there has been no material change in our market risk exposure from that described in our Annual Report on Form 10-K for the year ended December 31, 2006.

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 March 31, 2007 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

European Patent Oppositions

Two humanization patents based on the Queen technology were issued to us by the European Patent Office, European Patent No. 0 451 216 (the 216 Patent) and European Patent No. 0 682 040 (the 040 Patent). Eighteen notices of opposition to our 216 Patent and eight notices of opposition to our 040 Patent were filed by major pharmaceutical and biotechnology companies, among others, and we are currently in two separate opposition proceedings with respect to these two patents. Six opponents, including Genentech, have withdrawn from the opposition proceedings with respect to the opposition to our 216 Patent leaving 12 remaining opponents. A description of these two proceedings is set forth below.

Table of Contents

Opposition to 216 Patent

In November 2003, in an appeal proceeding of a prior action of the Opposition Division of the European Patent Office, the Technical Board of Appeal of the European Patent Office ordered that certain claims in our 216 Patent 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 cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. On April 24, 2007, at an oral proceeding the Opposition Division upheld claims that are virtually identical to the claims remitted by the Technical Board of Appeal to the Opposition Division. The opponents in this opposition have the right to appeal the Opposition Divisions recent decision. If any of the opponents appeal the decision to the Technical Board of Appeal, the 216 Patent would continue to be enforceable during the appeal process.

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 opposition is eventually successful, our ability to collect royalties on European sales of antibodies humanized by others would depend on the scope and validity of our 040 Patent, which is also being opposed, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, if the Opposition Division rules against us, that decision could encourage challenges of our related patents in other jurisdictions, including the United States. Such a decision may also 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 216 Patent, if we were to commence an infringement action 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.

Opposition to 040 Patent

At an oral hearing in February 2005, the Opposition Division also decided to revoke the claims in our 040 Patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We appealed the decision to the Technical Board of Appeal. The appeal suspended the legal effect of the decision of the Opposition Division during the appeal process. The Technical Board of Appeal has not scheduled a date for the appeal hearing with respect to the 040 Patent.

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

Patent Infringement Suit Against Alexion

In March 2007, after the FDA s market approval of Alexion Pharmaceuticals, Inc. s (Alexion) Soliris (eculizumab) humanized antibody product, we filed a lawsuit against Alexion seeking monetary damages for infringement of certain of our antibody humanization patents, commonly referred to as the Queen patents, in order to protect our intellectual property rights. On April 23, 2007, we served Alexion with our complaint. Alexion has not yet responded to our complaint. We intend to vigorously defend our rights under the Queen patents.

Table of Contents

Patent Infringement Suit Against Sun Pharmaceutical

In March 2007, we received a letter from Sun Pharmaceutical Industries Ltd. (Sun) purporting to be a Notice of Certification (the Paragraph IV Certification) with respect to an Abbreviated New Drug Application (ANDA) Sun filed with the FDA seeking approval to sell in the United States generic injectable nicardipine hydrochloride. Sun claimed in the Paragraph IV Certification that neither the manufacture, use nor sale of Sun s ANDA product would infringe our United States Patent Number 5,164,405, titled Nicardipine pharmaceutical composition for parenteral administration (the 405 Patent). In April 2007, we filed a patent infringement lawsuit against Sun seeking, among other things, to enjoin Sun s infringement of our 405 Patent and to stay any sale of Sun s ANDA product until at least the expiration of our 405 Patent. We intend to vigorously enforce our rights under the 405 Patent in this action.

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, 2006.

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

Sales of our *Cardene* IV product have accounted for a significant portion of our total revenues and growth in our sales since we acquired rights to it through our acquisition of ESP Pharma in March 2005. For example, our *Cardene* product sales, net, accounted for 22% of total revenues in 2005 and 26% of total revenues in 2006. However, our *Cardene* IV product faces competition from branded and generic intravenous antihypertensive products marketed in the United States and it may be harder to continue to penetrate this market and continue to grow *Cardene* IV product sales especially at the recent rate. While we have recently increased committed sales and marketing resources and expect to sustain this increased commitment of resources in an effort to ensure the continued growth of our *Cardene* IV product sales, there can be no assurance that we can continue a significant growth rate. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing antihypertensive and other related drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for the *Cardene* IV product to continue its success, we will have to maintain and expand its position in the marketplace against these competitors drugs.

In March 2007, we received a letter from Sun Pharmaceutical Industries Ltd. (Sun) purporting to be a Notice of Certification (the Paragraph IV Certification) with respect to an Abbreviated New Drug Application (ANDA) Sun filed with the FDA seeking approval to sell in the United States a generic version of injectable nicardipine hydrochloride, which, if approved, would likely compete with our *Cardene* IV product. Sun claimed in the Paragraph IV Certification that neither the manufacture, use nor sale of Sun s ANDA product would infringe our United States Patent Number 5,164,405, titled Nicardipine pharmaceutical composition for parenteral administration (the 405 Patent). In April 2007, we filed a patent infringement lawsuit against Sun seeking, among other things, to enjoin Sun s infringement of our 405 Patent and to stay any sale of Sun s ANDA product until at least the expiration of our 405 Patent. Although we intend to vigorously defend our rights under the 405 Patent, we may not prevail. If the outcome of this case were to be unfavorable for us, we believe we would face significant competition from Sun s ANDA product, which likely would cause significant declines in the amount of revenues and profit margins we recognize from the sale of our *Cardene* IV product.

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 March 31, 2007, 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 March 31, 2006, these three U.S. wholesalers represented approximately 83% of our outstanding accounts receivable from product sales.

Since our acquisition in March 2005 of rights to our *Cardene* IV, *Retavase* and IV *Busulfex* products and certain off-patent products, which we have since divested, we received and continued to receive through 2006 a significant number of returns of these products that were sold prior to our acquisition of these rights. The level of these returns 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. The level of returns of products sold prior to our March 2005 acquisition have declined from the rates we experienced in 2006 and we believe these return rates will continue to decline as our product channel is cleared of these products.

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 rights to our *Cardene* IV, *Retavase* and IV *Busulfex* products. 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. For example, in the second quarter of fiscal 2006 we increased our estimate of the rate of product returns and the effect of this change was to reduce product sales, net, in that quarter by approximately $5.6 million. 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.

Table of Contents

If our collaborations are not successful or are terminated by our partners, 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 limited 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 arrangement with Biogen Idec is particularly important to us. In September 2005, we entered into an agreement with Biogen Idec under which Biogen Idec became our partner on the development of daclizumab in certain indications, including MS, and volociximab (M200) in all indications. Our collaboration agreement with Biogen Idec also covers the development of *HuZAF* (fontilizumab), which we and Biogen Idec were developing in severe rheumatoid arthritis. However, we and Biogen Idec agreed to discontinue development of the *HuZAF* antibody and do not currently have any plans for further development of the *HuZAF* antibody.

Our collaboration agreement with Biogen Idec provides significant combined resources for the development, manufacture and potential commercialization of covered products. We and Biogen Idec each assume certain responsibilities and share expenses. Because of the broad scope of the collaborations, we are particularly dependent upon the performance by Biogen Idec of their obligations under the agreement. The failure of Biogen Idec to perform their obligations, our failure to perform our obligations, our failure to effectively manage the relationship, or a material contractual dispute between us and Biogen Idec 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 collaboration will vary depending on the work performed by us and Biogen Idec in any particular reporting period.

The arrangement with Roche pursuant to which were co-developing daclizumab for asthma and transplant maintenance was also particularly important to us. In 2006, however, Roche decided to first discontinue its involvement in the co-development of daclizumab in treating asthma and then later to discontinue its co-development of daclizumab in transplant maintenance and terminate the Roche Co-Development Agreement effective in May 2007.

We rely on other collaborators, 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 the collaboration agreement we had with Roche, and in November 2006, Roche elected to terminate the entire collaboration agreement. 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.

Table of Contents

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. Although we reviewed, documented and tested our internal control over financial reporting successfully in 2004, 2005 and 2006, our inability to do so in the future could adversely affect our stock price.

The Section 404 compliance process has also resulted in increased expenses and the devotion of significant management resources and we expect that the expenses for this process will continue to increase modestly.

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;

Table of Contents

the occurrence of key events under collaborative arrangements, including milestones, development decisions or program or collaboration terminations;

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;

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; and

the structure of out-licensing, collaboration and royalty 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 in our revenues from quarter to quarter.

Additionally, our master patent license agreement with Genentech provides for a tiered royalty structure under which the royalty rate Genentech must pay on royalty-bearing products sold in the United States or manufactured in the United States and sold anywhere (U.S.-based Sales) in a given calendar year decreases on incremental U.S.-based Sales above several net sales thresholds. As a result, Genentech s average annual royalty rate declines as Genentech s U.S.-based Sales increase. Because we receive royalties in arrears, the average royalty rate for the payments we receive from Genentech in the second calendar quarter which would be for Genentech s sales from the first calendar quarter is higher than the average royalty rate for following quarters and is lowest in the first calendar quarter when more of Genentech s U.S.-based Sales bear royalties at lower royalty rates.

License, collaboration and other revenues 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 revenues 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 revenues 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 revenues would be accelerated and recognized in the period in which the termination occurred. In such a case, it may cause our revenues 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 revenues 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, revenues historically recognized under our prior agreements may not be an indicator of revenues 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. Moreover, the underlying terms of in-licensing and royalty arrangements, especially those with tiered payment structures, will impact the timing of costs and expenses recognized during any particular quarter. 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

54

Table of Contents

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 operating expenses are significantly higher than prior to the adoption of SFAS 123(R).

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.

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.

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 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, 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 operating expenses are significantly higher than prior to the adoption of SFAS 123(R).

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.

Table of Contents

ITEM 6. EXHIBITS

3.1	Amended and Restated Bylaws of PDL Biopharma, Inc., as amended April 27, 2007 (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed May 2, 2007)
10.1	2005 Equity Incentive Plan, as amended through April 4, 2007
10.2	Offer Letter between the Company and Richard Murray, Ph.D. effective February 4, 2003
10.3	Offer Letter between the Company and David Iwanicki effective March 9, 2005
10.4	Offer Letter between the Company and Peter Calcott effective September 6, 2005
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: May 10, 2007

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)