

PDL BIOPHARMA, INC.  
Form 10-Q  
May 12, 2008

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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(Mark One)

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

**For the quarterly period ended March 31, 2008**

**OR**

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

**Commission File Number: 0-19756**

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## PDL BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3023969**  
(I.R.S. Employer  
Identification Number)

**1400 Seaport Boulevard**

**Redwood City, CA 94063**

(Address of principal executive offices and Zip Code)

**(650) 454-1000**

(Registrant's telephone number, including area code)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and, (2) has been subject to such filing requirements for the past 90 days: Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of May 6, 2008, there were 119,308,001 shares of the Registrant's Common Stock outstanding.



## PDL BIOPHARMA, INC.

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We own or have rights to numerous trademarks, trade names, copyrights and other intellectual property used in our business, including PDL BioPharma and the PDL logo, each of which is considered a trademark, and *Nuvion*<sup>®</sup>. All other company names and trademarks included in this Quarterly Report are trademarks, registered trademarks or trade names of their respective owners.

## 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,	
	2008	2007
<b>Revenues:</b>		
Royalties	\$ 49,955	\$ 48,595
License, collaboration and other	7,374	10,261
Total revenues	57,329	58,856
<b>Costs and expenses:</b>		
Research and development	47,681	48,091
General and administrative	20,443	11,994
Restructuring charges	5,629	
Asset impairment charges	3,521	
Gain on sale of assets	(49,671)	
Total costs and expenses	27,603	60,085
Operating income (loss)	29,726	(1,229)
Interest income and other, net	4,867	5,032
Interest expense	(3,989)	(3,557)
Income from continuing operations before income taxes	30,604	246
Income tax expense	1,004	30
Income from continuing operations	29,600	216
Loss from discontinued operations, net of income tax expense of \$28,027 and \$35 for the quarters ended March 31, 2008 and 2007, respectively	(91,475)	(10,822)
<b>Net loss</b>	<b>\$ (61,875)</b>	<b>\$ (10,606)</b>
<b>Income (loss) per basic share</b>		
Continuing operations	\$ 0.25	\$ 0.00
Discontinued operations	(0.78)	(0.09)
Net loss per basic share	\$ (0.53)	\$ (0.09)
<b>Income (loss) per diluted share</b>		
Continuing operations	\$ 0.23	\$ 0.00
Discontinued operations	(0.65)	(0.09)
Net loss per diluted share	\$ (0.42)	\$ (0.09)
<b>Shares used to compute income (loss) per basic and diluted share</b>		
Shares used to compute basic income (loss) per share	117,525	115,104
Shares used to compute diluted income (loss) per share	141,232	117,765

See accompanying notes.

## PDL BIOPHARMA, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	March 31, 2008 (unaudited)	December 31, 2007 (Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 905,661	\$ 340,634
Restricted cash	15,005	25,005
Marketable securities	22,973	71,880
Accounts receivable, net of allowances of \$2.9 million and \$17.7 million at March 31, 2008 and December 31, 2007, respectively	5,846	5,163
Assets held for sale		269,390
Prepaid and other current assets	12,339	8,362
Total current assets	961,824	720,434
Long-term restricted cash	3,269	3,269
Land, property and equipment, net	134,550	330,746
Goodwill		81,724
Other intangible assets, net	8,644	9,056
Deferred tax asset		38,319
Other assets	9,327	8,644
Total assets	\$ 1,117,614	\$ 1,192,192
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,078	\$ 8,893
Accrued compensation	17,488	27,222
Royalties payable	9,114	5,967
Other accrued liabilities	40,721	33,838
Deferred revenue	8,197	7,171
Deferred tax liability		38,319
Current portion of other long-term debt	735	678
Total current liabilities	79,333	122,088
Convertible notes	499,998	499,998
Long-term deferred revenue	27,813	27,647
Other long-term liabilities	31,847	34,849
Total liabilities	638,991	684,582
Stockholders' equity:		
Common stock, par value \$0.01 per share, 250,000 shares authorized; 118,065 and 117,577 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	1,181	1,176
Additional paid-in capital	1,131,033	1,098,251
Accumulated deficit	(653,220)	(591,345)
Accumulated other comprehensive loss	(371)	(472)
Total stockholders' equity	478,623	507,610
Total liabilities and stockholders' equity	\$ 1,117,614	\$ 1,192,192

See accompanying notes.





## PDL BIOPHARMA, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2008	2007
<b>Cash flows from operating activities:</b>		
Net loss	\$ (61,875)	\$ (10,606)
Adjustments to reconcile net loss to net cash used in operating activities:		
Asset impairment charges	3,521	
Depreciation	8,001	7,377
Amortization of convertible notes offering costs	586	585
Amortization of intangible assets	412	8,783
Loss on sale of assets, net	14,897	
Stock-based compensation expense	6,149	5,239
Loss on disposal of equipment	127	31
Tax benefit from employee stock options	21,673	
Excess tax benefit from stock-based compensation	(21,597)	
Changes in assets and liabilities:		
Accounts receivable, net	11,355	4,442
Interest receivable	(544)	(868)
Inventories		(817)
Other current assets	(6,466)	(3,628)
Other assets	566	(347)
Accounts payable	(5,815)	(8,095)
Accrued liabilities	(421)	(9,841)
Other long term liabilities	743	85
Deferred revenue	(643)	(1,456)
Total adjustments	32,544	1,490
Net cash used in operating activities	(29,331)	(9,116)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(303)	(19,434)
Maturities of marketable securities	49,836	16,047
Net proceeds from the sale of the commercial and cardiovascular assets	272,945	
Net proceeds from the sale of the manufacturing assets	236,560	
Purchase of property and equipment	(1,073)	(16,768)
Transfer out of (into) restricted cash	10,000	(10,005)
Net cash provided by (used in) investing activities	567,965	(30,160)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	4,965	4,019
Payments on other long-term debt	(169)	(1,208)
Excess tax benefit from stock-based compensation	21,597	
Net cash provided by financing activities	26,393	2,811
Net increase (decrease) in cash and cash equivalents	565,027	(36,465)
Cash and cash equivalents at beginning of the period	340,634	179,009
Cash and cash equivalents at end the period	\$ 905,661	\$ 142,544

See accompanying notes.



**PDL BIOPHARMA, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2008**

**(unaudited)**

**1. Summary of Significant Accounting Policies**

Organization and Business

We are a biotechnology company focused on the discovery and development of novel antibodies in oncology and immunologic diseases. We receive royalties and other revenues through licensing agreements with biotechnology and pharmaceutical companies based on our proprietary antibody humanization technology platform. The technology subject to these licensing agreements has contributed to the development by our licensees of 10 marketed products. Our research platform is focused on the discovery of novel antibodies for the treatment of cancer and immunologic diseases. We currently have several investigational compounds in clinical development for oncology or immunologic diseases, two of which we are developing in collaboration with Biogen Idec MA, Inc. (Biogen Idec). We began marketing and selling acute-care products in the hospital setting in the United States, Canada and other international markets in March 2005 in connection with our acquisitions of ESP Pharma, Inc. and the rights to *Retavase*®. In March 2008, we sold the rights to our *Cardene*®, *Retavase* and IV *Busulfex*® commercial products and our ularitide development-stage cardiovascular product (together, the Commercial and Cardiovascular Assets). The results of the Commercial and Cardiovascular Operations segment, which operations are comprised of those related to the Commercial and Cardiovascular Assets, are presented as discontinued operations. Discontinued operations are reported as a component within the Consolidated Statement of Operations separate from income from continuing operations. For details of such amounts, see Note 5.

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. 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 (SEC) 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, 2007 filed with the SEC. The Condensed Consolidated Balance Sheet as of December 31, 2007 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 with respect to this

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product 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 royalty fee structure that has four tiers, 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 the net sales thresholds. As a result, Genentech's average annual royalty rate during a year declines as Genentech's cumulative U.S.-based Sales increase during that year. Because we receive royalties in arrears, the average royalty rate for 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. The average royalty rate for payments we receive from Genentech 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. With respect to royalty-bearing products that are both manufactured and sold outside of the United States (ex-U.S.-based Sales), the royalty rate that we receive from Genentech is a fixed rate based on a percentage of the underlying ex-U.S.-based Sales. The mix of U.S.-based Sales and ex-U.S.-based Sales and the manufacturing location are outside of our control and have fluctuated in the past and may continue to fluctuate in the future.

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.

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.

Significant Customers and Revenues by Geographic Area

The following table summarizes revenues from our licensees which individually accounted for 10% or more of our total revenues from continuing operations for the three months ended March 31, 2008 and 2007 (as a percentage of total revenues):

	Three Months Ended	
	2008	2007
<b>Licensees</b>		
Genentech, Inc.	51%	56%
MedImmune, Inc.	28%	24%

Cash Equivalents, Restricted Cash, Marketable Securities and Concentration of Credit Risk

We consider all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. We place our cash, cash equivalents, marketable securities and restricted cash and investments with high-credit-quality financial institutions and in securities of the U.S. government, U.S. government agencies and U.S. corporations and, by policy, limit the amount of credit exposure in any one financial instrument.

**2. Stock-Based Compensation**

Stock-based compensation expense recognized under Statement of Financial Accounting Standards (SFAS) No. 123, Share-Based Payment (Revised 2004) (SFAS No. 123(R)) for employees and directors was as follows:

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(in thousands)	Three Months Ended March 31,			
		2008		2007
Research and development	\$	1,637	\$	2,579
General and administrative		2,220		1,280
Discontinued operations		2,291		1,361
Total stock-based compensation expense	\$	6,148	\$	5,220

Stock-based compensation expense for the first quarter of 2008 included stock option modification charges totaling \$3.8 million. These stock option modification charges related to accelerated vesting and extended exercise periods for certain stock options in connection with the termination of certain of our employees. The majority of the stock option modification charges related to the termination of certain employees as a result of the sale of the Commercial and Cardiovascular Assets, which is classified within discontinued operations. See Note 5 for further information.

*Stock Option Activity*

A summary of our stock option activity for the period is presented below:

(in thousands)	Number of Shares	Options	Weighted Average Exercise Price
Outstanding as of December 31, 2007	14,956	\$	19.85
Granted	86	\$	15.99
Exercised	(535)	\$	9.21
Forfeited	(1,820)	\$	21.26
Outstanding as of March 31, 2008	12,687	\$	20.07
Exercisable as of March 31, 2008	9,071	\$	19.66

Total unrecognized compensation cost related to unvested stock options outstanding as of March 31, 2008, excluding potential forfeitures, was \$44.7 million, which we expect to recognize over a weighted-average period of 2.8 years.

*Restricted Stock Activity*

A summary of our restricted stock activity for the period is presented below:

(in thousands)	Number of Shares	Restricted Stock	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2007	208	\$	20.33
Awards granted	2	\$	15.01
Awards vested	(2)	\$	19.14
Awards forfeited	(49)	\$	21.03
Unvested at March 31, 2008	159	\$	20.06

Total unrecognized compensation cost related to unvested restricted stock outstanding as of March 31, 2008, excluding potential forfeitures, was \$3.5 million, which we expect to recognize over a weighted-average period of 1.9 years.

*Employee Stock Purchase Plan (ESPP)*

The stock-based compensation expense in connection with our ESPP was \$0.3 million and \$0.4 million for the three-month periods ended March 31, 2008 and 2007, respectively.

### 3. Net Loss per Share

In accordance with SFAS No. 128, Earnings per Share (SFAS 128), we compute basic net income (loss) per share 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 are subject to repurchase. We compute diluted net income (loss) per share for our continuing operations using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted net income per share result from the assumed exercise of stock options, the issuance of restricted stock, the assumed issuance of common shares under our ESPP using the treasury stock method, and the assumed conversion of our 2.00%, \$250.0 million Convertible Senior Notes (the 2005 Notes) and our 2.75%, \$250.0 million Convertible Subordinated Notes (the 2003 Notes), including both the effect on interest expense and the inclusion of the underlying shares using the if-converted method.



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The following is a reconciliation of the numerators and denominators of the basic and diluted income from continuing operations per share computations for the three months ended March 31, 2008 and 2007:

(in thousands)	Three Months Ended March 31,	
	2008	2007
<b>Numerator</b>		
Income from continuing operations used to compute basic income from continuing operations per share	\$ 29,600	\$ 216
Add back interest expense for convertible notes, net of estimated tax	2,859	
Income used to compute diluted income per share for continuing operations	\$ 32,459	\$ 216
<b>Denominator</b>		
<b>Total weighted-average shares used to compute basic income (loss) per share</b>	117,525	115,104
Effect of dilutive stock options	705	1,792
Assumed release of common stock in escrow		845
Restricted stock outstanding		24
ESPP withholdings	32	
Assumed conversion of convertible notes	22,970	
<b>Shares used to compute diluted income from continuing operations per share</b>	141,232	117,765

We have excluded 12.5 and 8.9 million of outstanding stock options and restricted stock from our diluted earnings per share calculations for the three months ended March 31, 2008 and 2007, respectively, as such amounts would have been antidilutive. In addition, during the three months ended March 31, 2007, we excluded 23.0 million shares underlying our convertible debt securities as such amounts would have been antidilutive.

#### 4. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Specifically, we include in other comprehensive loss the changes in unrealized gains and losses on our holdings of available-for-sale securities, which are excluded from our net loss. In addition, other comprehensive loss includes the liability that has not yet been recognized as net periodic benefit cost for our postretirement benefit plan. The following table presents the calculation of our comprehensive loss:

(in thousands)	2008	2007
Net loss	\$ (61,875)	\$ (10,606)
Other comprehensive loss:		
Change in unrealized gains and losses on marketable securities, net of taxes	82	239
Change in postretirement benefit liability not yet recognized in net periodic benefit expense	18	21
Total comprehensive loss	\$ (61,775)	\$ (10,346)

#### 5. Discontinued Operations and Assets Held for Sale

We classified the Commercial and Cardiovascular Assets, excluding goodwill, as held for sale in our Consolidated Balance Sheet as of December 31, 2007. As we will not have significant or direct involvement in the future operations related to the Commercial and

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Cardiovascular Assets, we have presented the results of the Commercial and Cardiovascular Operations as discontinued operations in the Consolidated Statement of Operations for the current and comparative periods in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-lived Assets (SFAS No. 144). As of December 31, 2007, goodwill related entirely to the Commercial and Cardiovascular Operations.

In March 2008, we closed the sales of the Commercial and Cardiovascular Assets. We sold the rights to IV *Busulfex*, including trademarks, patents, intellectual property and related assets, to Otsuka Pharmaceutical Co., Ltd. (Otsuka) for \$200 million in cash and an additional \$1.4 million for the IV *Busulfex* inventories. We also sold the rights to *Cardene*, *Retavase* and ularitide, including all trademarks, patents, intellectual property, inventories and related assets (together, our Cardiovascular Assets), to EKR Therapeutics, Inc. (EKR). In consideration for the Cardiovascular Assets sold to EKR, we received upfront proceeds of \$85 million, \$6 million of which was placed in an escrow account for a period of approximately one year to cover certain product return related costs under the purchase agreement. In addition, the purchase agreement includes contingent consideration of up to \$85 million in potential future milestone payments as well as potential future royalties on certain *Cardene* and ularitide product sales.

We recognized a pre-tax loss of \$64.6 million in connection with the sale of the Commercial and Cardiovascular Assets. This loss was comprised of the total upfront consideration from the sales of the Commercial and Cardiovascular Assets of \$280.4 million plus the write-off of \$10.6 million in net liabilities, less the book values of intangible assets and inventories of \$268.2 million, the write-off of goodwill of \$81.7 million and transaction fees of \$5.7 million.

The results of our discontinued operations for the three months ended March 31, 2008 and 2007 were as follows:

(In thousands)	Three Months Ended	
	2008	March 31, 2007
Net revenues	\$ 39,359	\$ 49,127
Total costs and expenses (1)	(102,807)	(59,914)
Income tax expense (2)	(28,027)	(35)
Loss from discontinued operations	\$ (91,475)	\$ (10,822)

(1) Included within total costs and expenses is a loss of \$64.6 million that we recognized in connection with the sale of the Commercial and Cardiovascular Operations.

(2) Income tax expense attributable to our discontinued operations during the three months ended March 31, 2008 was primarily related to the tax gain on the sale of the Commercial and Cardiovascular Assets. Although we recognized a loss on the sale of these assets for financial reporting purposes, for tax purposes, we included the fair value of the contingent consideration from EKR in our proceeds, which included potential future milestone payments as well as potential future royalties on certain *Cardene* and ularitide product sales. In addition, the tax basis in the Commercial and Cardiovascular Assets was less than the book value recorded for financial reporting purposes. Therefore, we recognized a taxable gain and incurred alternative minimum tax on the sale of the Commercial and Cardiovascular Assets. The income tax payable attributable to our discontinued operations for the first quarter of 2008 was \$6.5 million. The \$21.5 million difference between the income tax payable and the income tax expense represents the tax benefit of certain tax deductions in connection with stock-based compensation, and such difference has been credited to additional paid-in capital.

In connection with the sale of the Commercial and Cardiovascular Assets, we entered into agreements with both Otsuka and EKR to provide certain transitional services. We expect to provide these transitional services over a period of approximately 12 months. Any fees or cost reimbursements received for transitional services will be classified within discontinued operations.

#### *Commercial Restructuring and Retention Plan*

In connection with the divestiture of the Commercial and Cardiovascular Assets, we committed to provide certain severance benefits to those employees whose employment positions we would eliminate in connection with the transactions. Under SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS No. 146), we recognized expenses for these severance benefits of \$1.8 million during the first quarter of 2008, which was included within discontinued operations. Of this \$1.8 million, \$1.7 million was included in other accrued liabilities as of March 31, 2008.

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During the fourth quarter of 2007, the Compensation Committee of our Board of Directors approved a modification to the existing terms of outstanding stock options held by our Commercial Employees to accelerate the vesting of up to 25% of the original grant amount upon termination of the Commercial Employees, if the sale of the Commercial and Cardiovascular Assets occurred prior to a change in control of the Company. During the first quarter of 2008, we recognized \$2.3 million of stock-based compensation expense related to the Commercial Employees, which was included within discontinued operations.

### **6. Sale of Manufacturing Assets**

In March 2008, we sold our Minnesota manufacturing facility and related operations to an affiliate of Genmab A/S (Genmab), for total cash proceeds of \$240 million. Under the terms of the purchase agreement, Genmab acquired our manufacturing and related administrative facilities in Brooklyn Park, Minnesota, and related assets therein, and assumed certain of our lease obligations related to our facilities in Plymouth, Minnesota (together, the Manufacturing Assets). In connection with the sale of the Manufacturing Assets, we entered into an agreement with Genmab under which we and Genmab will each provide transitional services to the other over a maximum period of 12 months.

We recognized a pre-tax gain of \$49.7 million upon the close of the sale in March 2008. Such gain represents the \$240 million in gross proceeds, less the net book value of the underlying assets transferred of \$185.4 million and \$4.9 million in transaction costs and other charges.

In addition, to fulfill our clinical manufacturing needs in the near-term, we entered into a clinical supply agreement with Genmab that became effective upon the close of the transaction. Under the terms of the clinical supply agreement, Genmab agreed to produce clinical trial material for certain of our pipeline products until March 2010.

## **7. Restructuring and Other Charges**

### *Overall Company Restructuring*

In an effort to reduce our operating costs to a level more consistent with a biotechnology company focused on antibody discovery and development, in March 2008 we commenced a restructuring plan pursuant to which we eliminated approximately 120 employment positions. We intend to eliminate approximately 130 additional employment positions over the next 12 months. All impacted employees were notified in March 2008. Subsequent to the completion of the restructuring, we expect to have approximately 300 employees.

Employees terminated in connection with the restructuring are eligible for a package consisting of severance payments of generally 12 weeks of salary and medical benefits along with up to three months of outplacement services. During the first quarter of 2008, we recognized restructuring charges of \$5.6 million consisting of post-termination severance costs as well as salary accruals relating to the portion of the 60-day notice period over which the terminated employees would not be providing services to the Company.

### *Facilities Related Restructuring*

During the third quarter of 2007, we initiated our move from Fremont, California to our current location in Redwood City, California. In connection with this move, we ceased use of a portion of the leased property in Fremont, California and, as a result, we recognized idle facilities charges during 2007. The leases on these facilities terminated at the end of first quarter of 2008, and nearly all related obligations were fully paid by March 31, 2008.

In addition, during 2007, we ceased use of two of our leased facilities in Plymouth, Minnesota. In connection with the sale of our Manufacturing Assets, Genmab assumed our obligations for one of these two facilities. We expect to pay all obligations accrued relating to the remaining lease by the end of the first quarter of 2009.

The following table summarizes the restructuring activity discussed above, as well as the remaining reserve balance at March 31, 2008:

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(in thousands)	Personnel Costs		Facilities Related		Total
Balance at December 31, 2007	\$	411	\$	1,912	\$ 2,323
Restructuring charges		5,547		82	5,629
Payments		(377)		(1,266)	(1,643)
Balance at March 31, 2008	\$	5,581	\$	728	\$ 6,309

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\* Excludes restructuring charges for employees terminated in connection with the sale of the Commercial and Cardiovascular Assets. See Note 5 for further information.

### *Other Charges*

In connection with our restructuring efforts, we offered retention bonuses and other incentives to two employee groups: (1) ongoing employees that we hope to retain after the restructuring, and (2) transition employees that we hope to retain through a transition period. This is in addition to the retention programs that we implemented during the fourth quarter of 2007, under which we recognized \$1.1 million in expenses in 2007. We intend to recognize the expense for these retention programs over the period from the respective dates the programs were approved through the estimated service period for transition employees or until the expected pay-out date for ongoing employees. We recognized \$2.6 million in expenses under these retention programs during the first quarter of 2008. As of March 31, 2008, the total related liability accrued was \$3.6 million. Such amounts have been classified as research and development expenses and general and administrative expenses in the financial statements. The total retention benefit under the plan is estimated to be \$16.8 million. We expect to recognize \$13.1 million of additional expense and to pay out the retention bonuses over the next seven quarters.

### **8. Asset Impairment Charges**

Total asset impairment charges recognized in continuing operations for the three months ended March 31, 2008 and 2007 were \$3.5 million and none, respectively. During the first quarter of 2008, such charges primarily represented the costs of certain research equipment that is expected to have no future useful life, and certain information technology projects that were terminated and have no future benefit to us as a result of our restructuring activities.

### **9. Non-Monetary Transaction**

In January 2008, we and Biogen Idec entered into an exclusive worldwide licensing agreement with Ophthotech Corp. (Ophthotech), a privately held company, for an anti-angiogenesis antibody to treat Age-Related Macular Degeneration (AMD). Under the terms of the agreement, we and Biogen Idec have granted Ophthotech worldwide development and commercial rights to all ophthalmic uses of volociximab (M200). In addition, we and Biogen Idec have an obligation to supply both clinical and commercial M200 product to Ophthotech. In connection with this agreement, we received an equity position in Ophthotech, and we may receive a combination of development and commercial milestone payments and royalties on future product sales.

We have estimated the fair value of the nonmarketable equity instruments received based predominately upon the price of similar Ophthotech equity instruments that Ophthotech had recently sold to independent parties for cash consideration. Based on this approach, we have estimated the fair value of our equity position to be \$1.8 million, which we recorded in other assets on the Consolidated Balance Sheet as of March 31, 2008.

For the purposes of revenue recognition, we are treating the grant of the license and the manufacturing obligation as a single unit of accounting. Because we are currently unable to estimate the time period over which we are obligated to supply the M200 product for clinical and commercial purposes, we have not recognized any revenue under the agreement. We have recorded the fair value of the consideration received as long-term deferred revenue as of March 31, 2008. We do not intend to recognize any revenue related to this agreement until such point that we are able to reasonably estimate the date at which our obligation will end.

**10. Restricted Cash**

As of March 31, 2008 and December 31, 2007, we had a total of \$18.3 million and \$28.3 million of restricted cash, respectively. As of March 31, 2008 and December 31, 2007, \$15.0 and \$25.0 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 certain 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 our Redwood City, California leases.



**11. Other Accrued Liabilities**

Other accrued liabilities consisted of the following:

(in thousands)	March 31, 2008		December 31, 2007	
Consulting and services	\$	9,715	\$	10,110
Accrued clinical and pre-clinical trial costs		5,135		6,314
Restructuring accruals		8,046		2,322
Accrued income taxes		8,593		1,357
Accrued interest		1,471		4,453
Construction-in-process				2,288
Other		7,761		6,994
Total	\$	40,721	\$	33,838

**12. Income Taxes**

Income tax expense attributable to our continuing operations during the three months ended March 31, 2008 was \$1.0 million, which was related primarily to federal and state alternative minimum taxes and foreign taxes on income earned by our foreign operations. As a result of the sale of our Commercial and Cardiovascular Assets in March 2008, we no longer have deferred tax liabilities, and due to our lack of earnings history, the gross deferred tax assets have been fully offset by a valuation allowance and no longer appear on our Consolidated Balance Sheet as of March 31, 2008.

The income tax expense for our continuing operations during the three months ended March 31, 2007 was \$30,000, which was related primarily to state taxes and foreign taxes on income earned by our foreign operations.

**13. Fair Value Measurements**

As of January 1, 2008, we adopted FASB Statement No. 157, Fair Value Measurements (FAS 157). FAS 157 established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. FAS 157 does not require any new fair value measurements in GAAP. FAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be utilized for financial reporting purposes. The fair value of our financial instruments reflect the amounts that would be received if we were to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). FAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

- Level 1 quoted prices in active markets for identical assets and liabilities
- Level 2 observable inputs other than quoted prices in active markets for identical assets and liabilities
- Level 3 unobservable inputs

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At March 31, 2008, we determined the fair values of our financial assets using Level 1 and Level 2 inputs, as reflected in the table below:

(in thousands)	Level 1	Level 2	Level 3	Total
Institutional money market funds	\$ 212,475	\$	\$	\$ 212,475
Securities of U.S. Government sponsored entities maturing within one year		626,363		626,363
Corporate securities maturing within one year		56,992		56,992
<b>Total financial assets</b>	<b>\$ 212,475</b>	<b>\$ 683,355</b>	<b>\$</b>	<b>\$ 895,830</b>

The following table presents the classification of our financial assets on our Consolidated Balance Sheet as of March 31, 2008:

(in thousands)

Cash and cash equivalents	\$	874,435
Short term marketable securities		21,395
Total financial assets	\$	895,830

We have excluded from the tables above \$1.6 million of accrued interest, which has been recorded as part of marketable securities, and \$31.2 million of cash, which is included in the cash and cash equivalents caption, in the Consolidated Balance Sheet.

#### 14. Subsequent Events

In April 2008, we declared a special cash dividend of \$4.25 per share of common stock (the Dividend), which, based on the number of stockholders as of the May 5, 2008 record date, was \$507.0 million. We paid the Dividend in May 2008 using proceeds from the sales of the Commercial and Cardiovascular Assets and the Manufacturing Assets. In connection with the Dividend, the conversion rate for the Company's outstanding 2.00% Convertible Senior Notes due February 15, 2012 (the 2012 notes) and 2.75% Convertible Subordinated Notes due 2023 (the 2023 notes) was adjusted based on the amount of the Dividend and the trading price of our stock in certain periods pursuant to the terms of the applicable indenture. For the 2023 notes, the conversion rate increased effective on May 6, 2008 from 49.6618 shares of common stock per \$1,000 principal amount of notes to 72.586 shares of common stock per \$1,000 principal amount of notes. For the 2012 notes, the conversion rate increased effective on May 6, 2008 from 42.219 shares of common stock per \$1,000 principal amount of notes to 61.426 shares of common stock per \$1,000 principal amount of notes.

#### 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 biotechnology company focused on the discovery and development of novel antibodies in oncology and immunologic diseases. We receive royalties and other revenues through licensing agreements with biotechnology and pharmaceutical companies based on our proprietary

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antibody humanization technology platform. The technology subject to these licensing agreements has contributed to the development by our licensees of 10 marketed products. We currently have several investigational compounds in clinical development for oncology and immunologic diseases, two of which we are developing in collaboration with Biogen Idec MA, Inc. (Biogen Idec). Our research platform is focused on the discovery of novel antibodies for the treatment of cancer and immunologic diseases.

During the period from March 2005 through early March 2008, we marketed and sold acute-care products in the hospital setting in the United States and Canada. We acquired the rights to three of these products, *Cardene IV*®, *IV Busulfex*® and *Retavase*®, which are non-antibody-based products, in connection with our acquisitions of ESP Pharma, Inc. as well as the rights to *Retavase* in March 2005. We subsequently acquired the rights to *Cardene SR*® in September 2006. These commercial products (together, the Commercial and Cardiovascular Assets) and the related operations (the Commercial and Cardiovascular Operations) were fully divested during the first quarter of 2008. We recognized a pre-tax loss of \$64.6 million in connection with the sale of the Commercial and Cardiovascular Assets, which is presented within discontinued operations, during the first quarter of 2008.

In March 2008, we sold our Minnesota manufacturing facility and related operations to an affiliate of Genmab A/S (Genmab), for total cash proceeds of \$240 million. Under the terms of this agreement, Genmab acquired our manufacturing and related administrative facilities in Brooklyn Park, Minnesota, and related assets therein, and assumed certain of our lease obligations related to our facilities in Plymouth, Minnesota (together, the Manufacturing Assets). In connection with this transaction, under the terms of a clinical supply agreement, Genmab agreed to produce clinical material for certain of our pipeline products until March 2010.

Also during March 2008, in an effort to reduce our operating costs to a level more consistent with a biotechnology company focused on antibody discovery and development, we commenced a restructuring plan pursuant to which we eliminated approximately 120 employment positions. We intend to eliminate approximately 130 additional employment positions over the next 12 months. Many of these positions support our provision of transition services to the acquirers of the Commercial and Cardiovascular Assets and Manufacturing Assets in connection with our sale of these assets. We offered these 130 transitional employees and the approximately 300 employees that we expect to retain after the restructuring retention bonuses and other incentives to encourage these employees to stay with the Company until the Spin-off of our biotechnology assets (see below) or with the Spin-off company after the separation transaction. In connection with this overall restructuring effort, we expect to incur significant transition-related expenses over the next 12-month period, a portion of which will be recognized as restructuring charges.

In April 2008, we announced our intent to spin off our biotechnology assets into a separate publicly traded entity apart from our antibody humanization royalty assets (the Spin-off). We expect to retain the rights to antibody humanization royalty revenues from all current and future licensed products and plan to distribute this income to our stockholders, net of any operating expenses, debt service and income taxes. Subsequent to the Spin-off, we plan to have only a nominal number of employees to support our intellectual properties and provide for certain essential reporting and management functions of a public company. We expect to capitalize the new biotechnology Spin-off company with approximately \$375 million in cash at the completion of the Spin-off transaction. This initial capitalization, along with potential milestone payments, non-humanization royalties and other payments under collaboration and other agreements, including the contingent consideration related to the sale of the Commercial and Cardiovascular Assets, is expected to fund the Spin-off company for approximately three years based on current operating plans. We expect to complete the Spin-off by the end of 2008. While we plan for the Spin-off, we continue to evaluate opportunities to sell or securitize all or part of our antibody humanization royalties; however, we can not assure that we will be able to consummate a sale or securitization of our antibody humanization patent royalty stream on terms acceptable to us, or at all.

In conjunction with our announcement of our intent to spin off our biotechnology assets, in April 2008 we declared a special cash dividend of \$4.25 per share of common stock (the Dividend), which was paid in May 2008 using proceeds from the sale of the Commercial and Cardiovascular Assets and the Manufacturing Assets. Based on the number of stockholders as of the May 5, 2008 record date, the Dividend was \$507.0 million.

We were organized as a Delaware corporation in 1986 under the name Protein Design Labs, Inc. In 2006, we changed our name to PDL BioPharma, Inc.

## Research and Development Programs

We have several investigational antibody-based compounds in clinical development for cancer and immunologic diseases, some of which we are developing in collaboration with another biotechnology company. 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. As part of our transition services agreement with EKR Therapeutics, Inc. (EKR), which purchased the rights to *Cardene*, *Retavase* and ularitide, including all trademarks, patents, intellectual property, inventories and related assets in March 2008, we continue to provide research and development services for certain life cycle management activities for *Cardene*. Under this agreement, EKR will reimburse us for all costs and expenses incurred in connection with these activities, all of which have been reflected as discontinued operations. As this is no longer an

on-going PDL-sponsored program, we have excluded *Cardene* from the table 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	Description/Indication	Phase of Development	Collaborator
Daclizumab	Asthma	Phase 2 program being evaluated	Biogen Idec
	Multiple sclerosis	Phase 2	
	Transplant maintenance	Phase 2 program advancement pending partnership	
Volociximab (M200)	Solid tumors	Phase 2 program ongoing partnership	Biogen Idec
HuLuc63	Multiple myeloma	Phase 1	
PDL192	Solid tumors	IND filed; phase 1 pending	

**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 Hoffmann La-Roche (Roche) as *Zenapax*, which is indicated for the prevention of acute organ transplant rejection following transplant surgery. We and our collaborator, 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 CHOICE trial, a phase 2, randomized, double-blind, placebo-controlled trial of daclizumab, met its primary endpoint in relapsing MS patients being treated with interferon beta. In October 2007, we presented the phase 2 CHOICE data that demonstrated daclizumab 2 mg/kg administered every two weeks as a subcutaneous injection added to interferon beta therapy significantly reduced new or enlarged gadolinium-enhancing lesions at week 24 compared to interferon beta therapy alone, in patients with active relapsing multiple sclerosis. Patients from this trial were followed for an additional 48 weeks after the treatment period to further assess safety and efficacy. We, together with Biogen Idec, initiated in the first quarter of 2008 a phase 2 monotherapy trial of daclizumab, the SELECT trial, to advance the overall clinical development program in relapsing MS.

In addition, we are independently pursuing development of daclizumab for treatment of moderate to severe asthma. We also continue to evaluate daclizumab for transplant maintenance, including potential collaboration opportunities.

**Volociximab (M200).** Volociximab is a chimeric monoclonal antibody that inhibits the functional activity of  $\alpha 5\beta 1$  integrin, a protein found on activated endothelial cells. Blocking the activity of  $\alpha 5\beta 1$  integrin has been found in various animal models to prevent angiogenesis, which is the formation of new blood vessels that feed tumors and allow them to grow and metastasize.

We and our collaborator, Biogen Idec, are currently investigating volociximab in various phase 2, open-label clinical trials in patients with advanced solid tumors. This investigation includes two exploratory clinical trials in ovarian cancer, initiated in August 2007, and two phase 1 trials in non-small cell lung cancer (NSCLC), which were initiated during the last quarter of 2007 and the first quarter of 2008. In April 2008, we and Biogen Idec terminated one of the two exploratory clinical trials in ovarian cancer, leaving a total of three ongoing phase 2 clinical trials.

**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 ongoing. We anticipate initiating phase 1 combination trials of HuLuc63 in the second half of 2008.

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***PDL192.*** PDL192 is a novel humanized monoclonal antibody. In April 2008, after completion of preclinical studies, we filed an IND for PDL 192 in solid tumor applications.



**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 10 humanized antibody products listed below are currently approved for use by the U.S. Food and Drug Administration (FDA) and are licensed under our patents.

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

- 
- (1) Cimzia was approved for marketing by the FDA in April 2008. We expect to receive and recognize royalty revenues on sales of Cimzia beginning in the third quarter of 2008.
- (2) Roche is obligated to pay us royalties on *Zenapax* only once product sales have reached a certain threshold; we have not received royalties on sales of *Zenapax* since the first quarter of 2006 and we do not expect to receive royalty revenue from Roche's sales of *Zenapax* in the future.

**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 collaborate on certain other programs, or on our drug development capabilities, with other pharmaceutical or biotechnology companies to maximize the value of these programs, mitigate risks and reduce costs, and may enter into other collaboration agreements in the future.

**Summary of the First Quarter of 2008**

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In the first quarter of 2008, our total revenues from continuing operations were \$57.3 million, a 3% decrease from \$58.9 million in the comparable period in 2007. This revenue decline was driven primarily by a decrease in license, collaboration and other revenues.

Our total expenses from continuing operations in the first quarter of 2008 were \$27.6 million, a significant decrease from \$60.1 million in the first quarter of 2007 primarily as a result of a \$49.7 million gain realized on the sale of our Manufacturing Assets in the 2008 period. Total costs and expenses in the first quarter of 2008 also included restructuring charges of \$5.6 million and asset impairment charges of \$3.5 million. We did not recognize any such charges or gains in the comparable period in 2007. Our income from continuing operations for the first quarter of 2008 was \$29.6 million, compared to \$0.2 million in the prior-year comparable period. In the first three months of 2008, net cash used in operating activities was \$29.3 million, a decrease from \$9.1 million used in operating activities in the comparable period in 2007. At March 31, 2008, we had cash, cash equivalents, marketable securities and restricted cash of \$946.9 million, compared to \$440.8 million at December 31, 2007, an increase primarily attributable to the proceeds realized from the sales of the Commercial and Cardiovascular Assets and the Manufacturing Assets. As of March 31, 2008, we had \$526.7 million in total debt outstanding, which included \$500.0 million in convertible notes, \$250.0 million of which are callable in each of 2008 and 2010 and due in 2023 and 2012, respectively.

We expect that in the foreseeable future, our revenue growth will be generated primarily by royalties. We expect that our operating expenses in the near-term will decrease significantly relative to recent historical expense levels due to the sales of the Commercial and Cardiovascular Assets and the Manufacturing Assets in March 2008, and the restructuring that is in process and that will continue over the next several quarters. However, we expect to incur additional charges and expenses during 2008 and into 2009 related to the restructuring, including severance payments to terminated employees, and related to retention incentives we have offered to transitional and ongoing employees. Subsequent to the completion of our restructuring activities, we expect that our expenses could increase in future years as we increase the number of our pipeline programs, advance our clinical programs into more expensive late-stage clinical trials and as a result of the extensive resource commitments required to achieve regulatory approval of potential products.

## 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 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 or our licensees 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 our contract manufacturers 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 are currently reliant on third-party manufacturers for all of our 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 retain qualified clinical, scientific, marketing, administrative and management personnel. We face significant competition for experienced personnel and have experienced significant attrition in late 2007 and early 2008 as a result of the uncertainty created by the strategic initiatives we undertook during this period. We also implemented a restructuring in March 2008, which includes a significant reduction in force, and we expect to continue to face challenges in retaining qualified personnel as we transition to a more streamlined organization.

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. The items in our financial statements requiring significant estimates and judgments are as follows:

### **Revenue Recognition**

We enter into patent license, collaboration and humanization agreements that may contain multiple elements, such as upfront license fees, reimbursement of research and development expenses, milestones related to the achievement of particular stages in product development and royalties. Under our collaboration arrangements, we may receive nonrefundable upfront fees, time-based licensing fees and reimbursement for all or a portion of certain predefined research and development or post-commercialization expenses, and our licensees may make milestone payments to us when they or we achieve certain levels of development with respect to the licensed technology. Generally, when there is more than one deliverable under the agreement, we account for the revenue as a single unit of accounting under Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangement with Multiple Deliverables*, for revenue recognition purposes. As a combined unit of accounting, the up-front payments are recognized ratably as the underlying services are provided under the arrangement. We recognize at-risk milestone payments upon achievement of the underlying milestone event and when they are due and payable under the arrangement. Milestones are deemed to be at risk when, at the onset of an arrangement, management believes that they will require a reasonable amount of effort to be achieved and are not simply reached by the lapse of time or perfunctory effort. We currently determine attribution methods for each payment stream based on the specific facts and circumstances of the arrangement. The EITF may provide additional guidance on the topic of *Revenue Recognition for a Single Deliverable for a Single Unit of Accounting (with Multiple Deliverables) That Have Multiple Payment Streams*, which could change our method of revenue recognition in future periods.

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

### **Clinical Trial Expenses**

We base our cost accruals for clinical trials on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations (CROs). In the normal course of business, we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements vary from contract to contract, are subject to negotiation and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, we recognize direct expenses related to each patient enrolled in a clinical trial on an estimated cost-per-patient basis as services are performed. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from CROs, such as estimated costs per patient, to calculate our accrual for direct clinical expenses at the end of each reporting period. For indirect expenses, which relate to site and other administrative costs to manage our clinical trials, we rely on information provided by the CRO, including costs incurred by the CRO as of a particular reporting date, to calculate our indirect clinical expenses. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial, which we confirm directly with the CRO.

If our CROs were to either under or over report the costs that they have incurred or if there is a change in the estimated per patient costs, it could have an impact on our clinical trial expenses during the period in which they report a change in estimated costs to us. Adjustments to our clinical trial accruals primarily relate to indirect costs, for which we place significant reliance on our CROs for accurate information at the end of each reporting period. Based upon the magnitude of our historical adjustments, we believe that it is reasonably possible that a change in estimate related to our clinical accruals could be approximately 1% of our annual research and development expenses.

### **Employee Stock-Based Compensation**

Under the provisions of SFAS No. 123(R), Stock-Based Compensation (SFAS No. 123(R)), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change.

Further, SFAS No. 123(R) requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period. For the first quarter of 2008, we estimated our future forfeiture rate to be approximately 10%, which is based on historical forfeiture rates adjusted for certain one-time events and the impact of more recent trends on our future forfeitures. A five percentage point change in the rate of estimated stock option forfeitures could result in an increase or decrease to stock-based compensation expense of approximately \$1.0 million.

### Valuation and Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we periodically evaluate whether current facts or circumstances indicate that the carrying value of our depreciable assets held and to be used may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset, or the appropriate grouping of assets, is compared to the carrying value to determine whether impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. We report an asset to be disposed of at the lower of its carrying value or its estimated net realizable value.

## RESULTS OF OPERATIONS

### Three Months Ended March 31, 2008 and 2007

#### Revenues

(in thousands)	Three Months Ended			% Change
	March 31,			
	2008	2007		
Royalties	\$ 49,955	\$ 48,595		3%
License, collaboration and other	7,374	10,261		(28)%
Total revenues	\$ 57,329	\$ 58,856		(3)%

Our total revenues decreased by \$1.5 million, or 3%, in the three months ended March 31, 2008 from the comparable period in 2007 for reasons discussed below.

#### Royalties

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Royalty revenues increased by \$1.4 million, or 3.0%, in the three months ended March 31, 2008, from the comparable period in 2007. This increase primarily was due to higher royalties received from the sales of *Tysabri and Synagis*, which are marketed by Elan Corporation, Plc and MedImmune (AstraZeneca), respectively, which was partially offset by a decrease in royalties received from sales of products marketed by Genentech. Although Genentech reported higher product sales from its royalty-bearing products for its fourth quarter of 2007 as compared to its fourth quarter of 2006 (in each case impacting our royalty revenues for the following quarter), the average effective royalty rate applied to Genentech's product sales during the first quarter of 2008 was lower than the rate applied in the comparable 2007 period primarily due to a significant decline in the amount and percentage of *Herceptin* product manufactured and sold outside the United States. This resulted in a greater percentage of *Herceptin* product sales in the first quarter of 2008 being subject to the tiered fee structure as opposed to the higher, fixed royalty rate that applies to Genentech products that are both manufactured and sold outside the U.S. In addition, of Genentech product sales subject to the tiered fee structure, royalties were received on sales in both the third and fourth tiers in the first quarter of 2007, while in the first quarter of 2008, all royalties were based on product sales at the fourth and lowest tier (see details of Genentech royalty structure discussed below).

Under most of the agreements for the license of rights under our humanization patents, we receive a flat-rate royalty based upon our licensee's 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 royalty fee structure that has four tiers, 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 the net sales thresholds. As a result, Genentech's average annual royalty rate during a year declines as Genentech's cumulative 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. The average royalty rate for payments we receive from Genentech 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. With respect to royalties that fall under the tiered fee structure, we allocate the royalty revenues among the different products based on the relative underlying net product sales reported to us by Genentech. With respect to royalty-bearing products that are both manufactured and sold outside of the United States (ex-U.S.-based Sales), the royalty rate that we receive from Genentech is a fixed rate based on a percentage of the underlying ex-U.S.-based Sales. The mix of U.S.-based Sales and ex-U.S.-based Sales and the manufacturing location are outside of our control and have fluctuated in the past and may continue to fluctuate in future periods.

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):

Licensee	Product Name	Three Months Ended March 31,	
		2008	2007
Genentech	<i>Avastin</i>	20%	19%
	<i>Herceptin</i>	28%	39%
MedImmune	<i>Synagis</i>	33%	30%

#### *License, Collaboration and Other*

(in thousands)	Three Months Ended March 31,			% Change
	2008	2007		
License and milestone from collaborations	\$ 1,825	\$ 5,868		(69)%
R&D services from collaborations	3,299	3,993		(17)%
License and other	2,250	400		463%
Total revenue from license, collaboration and other	\$ 7,374	\$ 10,261		(28)%

License, collaboration and other revenues consist 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 decreased by \$2.9 million, or 28%, in the three months ended March 31, 2008 from the comparable period in 2007 primarily due to the absence in the 2008 period of certain revenues recognized in the first quarter of 2007 related to the termination of our agreement with Roche to co-develop daclizumab for transplant indications, which termination was effective in April 2007, and a decrease in revenues recognized under our collaboration agreement with Biogen Idec. These decreases were partially offset by \$2.0 million in milestone payments, reflected as license and other, that we received in the first quarter of 2008 from certain of our licensees.

We continue to evaluate potential opportunities to collaborate with respect to certain development stage programs or our drug development capabilities 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**

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(in thousands)	Three Months Ended			% Change
	March 31,			
	2008	2007		
Research and development	\$ 47,681	\$ 48,091		(1)%
General and administrative	20,443	11,994		70%
Restructuring charges	5,629			*
Asset impairment charges	3,521			*
Gain on sale of assets	(49,671)			*
Total costs and expenses	\$ 27,603	\$ 60,085		(54)%

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\* Not presented as calculation is not meaningful.

Certain expenses related to the Commercial and Cardiovascular Operations, which were previously presented as cost of product sales, research and development expenses and general and administrative expenses in prior periods, have been presented as discontinued operations for all periods presented in the current financial statements.

We expect that our operating expenses in the near-term will decrease significantly relative to recent historical expense levels due to the sale of the Manufacturing Assets in March 2008 and the restructuring activities that are in process and that will continue over the next several quarters. However, we expect to incur additional charges and expenses during 2008 and into 2009 related to the restructuring, including severance payments to terminated employees, and related to retention incentives we have offered to transition and ongoing employees. In addition, we are actively seeking to sublease excess capacity in our Redwood City facilities. If we are able to sublease any of this excess capacity, our lease expenses would decline. The process of subleasing office space can be a lengthy and uncertain process and we cannot assure if and when we may sublease any of our excess capacity or the amount of excess capacity that we may sublease.

Subsequent to the completion of our restructuring activities, we expect that our expenses could increase in future years as we increase the number of our pipeline programs, advance our clinical programs into more expensive late-stage clinical trials and as a result of the extensive resource commitments required to achieve regulatory approval of potential products.

#### *Research and Development Expenses*

Our research and development activities include research, process development, pre-clinical development, manufacturing and clinical development, which activities generally include regulatory, safety, medical writing, biometry, U.S. and European clinical operations, compliance, quality and program management. Research and development expenses consist primarily of costs of personnel to support these research and development activities, as well as outbound milestone payments and technology licensing fees, costs of preclinical studies, costs of conducting our clinical trials, such as fees to CROs and clinical investigators, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility and overhead costs, principally information technology. Research and development costs also include stock-based compensation expense accounted for under SFAS No. 123(R) as a component of personnel-related costs. Total stock-based compensation expenses recognized as research and development expenses were \$1.6 million and \$2.6 million during the quarters ended March 31, 2008 and 2007, respectively.

The decrease in our research and development expenses during the first quarter of 2008 in comparison to the first quarter of 2007 is attributable to decreases in our *Nuvion*® and PDL 192 program costs, partially offset by increases in development costs for HuLuc63 and daclizumab. The \$7.3 million decrease in *Nuvion* costs is due to the decision to terminate the *Nuvion* phase 3 development program during the third quarter of 2007, and the \$2.4 reduction in development expenses for PDL 192 was primarily driven by a decrease in PDL 192 manufacturing activity in the first quarter of 2008 in comparison to 2007. The \$7.7 million and \$2.0 million increases in program costs for HuLuc63 and daclizumab, respectively, were due to manufacturing campaigns that occurred in the first quarter of 2008, whereas there were no such manufacturing campaigns in the first quarter of 2007 for these products.

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

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Product Candidate	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase (1)	Research and Development Expenses for the Three Months Ended March 31,	
					2008	2007
Daclizumab	Asthma	Phase 2 program being evaluated		Not yet disclosed	\$ 9,291	\$ 7,261
	Multiple sclerosis	Phase 2	Biogen Idec	Not yet disclosed		
	Transplant maintenance	Phase 2 program advancement pending partnership		Not yet disclosed		
Volociximab (M200)	Solid tumors	Phase 2 program ongoing partnership	Biogen Idec	2008	4,836	4,276
HuLuc63	Multiple myeloma	Phase 1		Not yet disclosed	11,555	3,817
PDL192	Solid tumors	IND filed; phase 1 pending		2008	3,082	5,451
Nuvion (visilizumab)		Terminated in August 2007			4,385	11,657
Other Program-Related Costs (2)	Multiple programs and products				2,619	1,539
Non-Program-Related Costs (3)					11,913	14,090
<b>Total Research and Development Expenses</b>					<b>\$ 47,681</b>	<b>\$ 48,091</b>

- (1) 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.
- (2) 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.
- (3) 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.

*General and Administrative Expenses*

General and administrative expenses generally consist of costs of personnel, professional services, consulting and other expenses related to our administrative, marketing and clinical affairs functions, and an allocation of facility and overhead costs. General and administrative expenses also include stock-based compensation expenses accounted for under SFAS No. 123(R) as a component of personnel-related costs. Total stock-based compensation expenses recognized as general and administrative expenses were \$2.2 million and \$1.3 million for the quarters ended March 31, 2008 and 2007, respectively.

General and administrative expenses increased by \$8.4 million during the first quarter of 2008 in comparison to the same quarter in 2007. The increase was due primarily to increases in legal costs of \$3.8 million, primarily related to our strategic review process and ongoing litigation, and in professional services fees of \$1.0 million related to our strategic review process. In addition, in the first quarter of 2008, (1) we classified \$0.9 million of facilities costs related to idle research and development capacity in our Redwood City facilities as general and administrative expenses, (2) we accrued \$0.8 million in retention bonuses that were provided to our employees, (3) stock-based compensation increased by \$0.4 million due to modification charges for certain stock options in connection with the termination of certain employees and (4) depreciation allocated to general and administrative expenses increased by \$0.5 million as we placed into service in late 2007 leasehold improvements associated with our Redwood City facilities.

**Restructuring Charges***Overall Company Restructuring*

In an effort to reduce our operating costs to a level more consistent with a biotechnology company focused solely on antibody discovery and development, in March 2008, we commenced a restructuring plan pursuant to which we eliminated approximately 120 employment positions and we intend to eliminate approximately 130 additional employment positions over the next 12 months. All impacted employees were notified in March 2008. In addition, we are undertaking other substantial cost cutting measures.

Employees subject to termination are eligible for a package consisting of severance payments of generally 12 weeks of salary and medical benefits along with up to three months of outplacement services. During the first quarter of 2008, under SFAS No. 146, we recognized restructuring charges of \$5.6 million consisting of post-termination severance costs.

*Facilities Related Restructuring*

During the third quarter of 2007, we initiated our move from Fremont, California to our new location in Redwood City, California. In connection with this move, we ceased use of a portion of the leased property in Fremont, California and, as a result, we recognized idle facilities charges during 2007. The lease on these facilities terminated at the end of first quarter of 2008 and nearly all related obligations were paid as of March 31, 2008.

In addition, during 2007, we ceased use of two of our leased facilities in Plymouth, Minnesota. In connection with the sale of our Manufacturing Assets, Genmab assumed our obligations for one of these two facilities. We expect to pay all remaining obligations accrued relating to these leases by the end of the first quarter of 2009.

The following table summarizes the restructuring activity related to continuing operations discussed above, as well as the remaining related reserve balance at March 31, 2008:

(in thousands)	Personnel Costs		Facilities Related		Total
Balance at December 31, 2007	\$	411	\$	1,912	\$ 2,323
Restructuring charges		5,547		82	5,629
Payments		(377)		(1,266)	(1,643)
Balance at March 31, 2008	\$	5,581	\$	728	\$ 6,309

\* Excludes restructuring charges for employees terminated in connection with the sale of our Commercial and Cardiovascular Assets. See Discontinued Operations for further information.

**Gain on Sale of Assets**

In March 2008, we completed the sale of our Manufacturing Assets to Genmab for total cash proceeds of \$240 million. We recognized a pre-tax gain of \$49.7 million upon the close of the sale. Such gain represents the \$240 million in gross proceeds, less the value of the underlying assets of \$185.4 million and \$4.9 million in transaction costs and other charges. Under the terms of the purchase agreement, Genmab will provide transitional services to us over a maximum period of 12 months to support certain of our commitments that arose from the sales of the Commercial and Cardiovascular Assets as well as to support certain of our general and administrative functions.

To fulfill our manufacturing needs in the near-term, we have entered into a clinical supply agreement with Genmab that was effective upon the close of the transaction. Under the terms of the clinical supply agreement, Genmab agreed to produce clinical trial material for certain of our pipeline products until March 2010.

### Asset Impairment Charges

Total asset impairment charges for the quarters ended March 31, 2008 and 2007 were \$3.5 million and none, respectively. During the first quarter of 2008, such charges primarily represented the costs of certain research equipment that is expected to have no future useful life, and certain information technology projects that were terminated and have no future benefit to us as a result of our restructuring activities.

### Discontinued Operations

The results of the Commercial and Cardiovascular Operations segment are reflected as discontinued operations for all periods presented. In March 2008, we completed the sales of the Commercial and Cardiovascular Assets. We sold the rights to IV *Busulfex*, including trademarks, patents, intellectual property and related assets, to Otsuka Pharmaceutical Co., Ltd. (Otsuka) for \$200 million in cash and an additional \$1.4 million for the IV *Busulfex* inventories. We also sold the rights to *Cardene*, *Retavase* and ularitide, including all trademarks, patents, intellectual property, inventories and related assets (together, our Cardiovascular Assets), to EKR. In consideration for the Cardiovascular Assets, we received an upfront fee of \$85 million, \$6 million of which was placed in an escrow account for a period of approximately one year to cover certain product return related costs under the purchase agreement. In addition, the purchase agreement includes contingent consideration of up to \$85 million in future development and commercial milestone payments as well as royalties on certain future *Cardene* and ularitide product sales.

Loss from discontinued operations increased by \$80.7 million, net of tax, to \$91.5 million in the three months ended March 31, 2008 from \$10.8 million in the prior year comparable period. This increase primarily was due to the \$64.6 million pre-tax loss recognized on the sale of the Commercial and Cardiovascular assets in the first quarter of 2008 and the related tax impact of \$28.0 million. This increase was partially offset by decreases in net financial operating results, which resulted principally from the absence of amortization expense from intangible assets during the first quarter of 2008 as a result of the Commercial and Cardiovascular Assets being classified as held for sale on our Consolidated Balance Sheet from December 2007 until they were divested on March 7, 2008.

The \$64.6 million pre-tax loss that we recognized in the first quarter of 2008 was comprised of the upfront consideration for the sales of the Commercial and Cardiovascular Assets of \$280.4 million plus the write-off of \$10.6 million in net liabilities, less the book values of intangible assets and inventories of \$268.2 million, the write-off of goodwill of \$81.7 million and transaction fees of \$5.7 million.

For the periods presented below, the results of our discontinued operations are as follows:

(In thousands)	Three Months Ended	
	March 31,	
	2008	2007
Net revenues	\$ 39,359	\$ 49,127
Total costs and expenses (1)	(102,807)	(59,914)
Income tax expense (2)	(28,027)	(35)
Loss from discontinued operations	\$ (91,475)	\$ (10,822)

(1) Included within total costs and expenses is a loss of \$64.6 million that we recognized upon the close of the sale of the Commercial and Cardiovascular Assets.



(2) Income tax expense attributable to our discontinued operations during the three months ended March 31, 2008 was primarily related to the tax gain on the sale of the Commercial and Cardiovascular Assets. Although we recognized a loss on the sale of these assets for financial reporting purposes, for tax purposes, we included the fair value of the contingent consideration from EKR in our proceeds, which included potential future milestone payments as well as potential future royalties on certain *Cardene* and ularitide product sales. In addition, the tax basis in the Commercial

and Cardiovascular Assets was less than the book value recorded for financial reporting purposes. Therefore, we recognized a taxable gain and incurred alternative minimum tax on the sale of the Commercial and Cardiovascular Assets. The income tax payable attributable to our discontinued operations for the first quarter of 2008 was \$6.5 million. The \$21.5 million difference between the income tax payable and the income tax expense represents the tax benefit of certain tax deductions in connection with stock-based compensation, and such difference has been credited to additional paid-in capital.

In connection with the sale of the Commercial and Cardiovascular Assets, we committed to provide certain transitional services to both Otsuka and EKR. We expect to provide these transitional services over a period of approximately 12 months. Any fees received for the transitional services will be classified within discontinued operations.

#### *Commercial Restructuring and Retention Plan*

In connection with the divestiture of the Commercial and Cardiovascular Assets, we committed to provide certain severance benefits to those employees whose employment positions we would eliminate as a result of these transactions. Under SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS No. 146), we recognized an expense for these severance benefits of \$1.8 million during the first quarter of 2008, which were included within discontinued operations. Of this \$1.8 million, \$1.7 million was included in other accrued liabilities as of March 31, 2008.

During the fourth quarter of 2007, the Compensation Committee of our Board of Directors approved a modification to the existing terms of outstanding stock options held by our Commercial Employees to accelerate the vesting up to 25% of the original grant amount upon termination of the Commercial Employees if the sale of the Commercial and Cardiovascular Assets occurred prior to a change in control of the Company. During the first quarter of 2008, we recognized \$2.3 million of stock-based compensation expense related to the Commercial Employees, which was included within discontinued operations.

#### **Interest and Other Income, Net and Interest Expense**

(in thousands)	Three Months Ended			% Change
	March 31,			
	2008	2007		
Interest and other income, net	\$ 4,867	\$ 5,032		(3)%
Interest expense	(3,989)	(3,557)		12%
Total interest and other income, net and interest expense	\$ 878	\$ 1,475		(40)%

Interest income for the three months ended March 31, 2008 was relatively flat from the comparable period in 2007. Although our average cash and investment balances were higher in the first quarter of 2008 as compared to the prior year, the interest rates earned on our investments were lower.

Interest expense for the three months ended March 31, 2008 increased from the comparable period in 2007 primarily as a result of lower capitalized interest in the three months ended March 31, 2008, since we completed the construction of the Redwood City facility in the fourth quarter of 2007.

**Income Taxes**

Income tax expense attributable to our continuing operations during the three months ended March 31, 2008 was \$1.0 million, which was related primarily to federal and state alternative minimum taxes and foreign taxes on income earned by our foreign operations. As a result of the sale of our Commercial and Cardiovascular Assets in March 2008, we no longer have deferred tax liabilities, and due to our lack of earnings history, the gross deferred tax assets have been fully offset by a valuation allowance and no longer appear on our Consolidated Balance Sheet as of March 31, 2008.

The income tax expense for our continuing operations during the three months ended March 31, 2007 was \$30,000, which was related primarily to state taxes and foreign taxes on income earned by our foreign operations.

## LIQUIDITY AND CAPITAL RESOURCES

To date, we have financed our operations primarily through public and private placements of equity and debt securities, royalty revenues, license revenues, collaboration and other revenues under agreements with third parties, interest income on invested capital and, from March 2005 to March 2008, net product sales. At March 31, 2008, we had cash, cash equivalents, marketable securities and restricted cash in the aggregate of \$946.9 million, compared to \$440.8 million at December 31, 2007.

Net cash used in operating activities for the three months ended March 31, 2008 was \$29.3 million, compared to \$9.1 million in the corresponding period in 2007. The increase in net cash used in operating activities during the first three months of 2008 was primarily attributable to the tax impact of the tax gains that we recognized on the sales of our Commercial and Cardiovascular Assets, lower net product sales due to the divestiture of the Commercial and Cardiovascular Assets in early March 2008 and an increase in legal expenses associated with our strategic review process and ongoing litigation. These factors that contributed to the increase in cash used in operations were partially offset by lower operating expenses as a result of the sales in early March 2008 of the Commercial and Cardiovascular Assets and the Manufacturing Assets and the related reductions in headcount, personnel costs and operating expenses (which for the Commercial and Cardiovascular Operations have been reflected as discontinued operations), and to changes in our working capital due to the timing of payments relating to cash receipts from receivables and cash payments for our liabilities.

Net cash provided by investing activities was \$568.0 million for the three months ended March 31, 2008, compared to net cash used in investing activities of \$30.2 million in the comparable period in 2007. The net cash provided by investing activities in the first three months of 2008 of \$568.0 million was attributable primarily to net proceeds of \$509.5 million received in connection with the sales of the Commercial and Cardiovascular Assets and the Manufacturing Assets and the maturing of an aggregate of \$59.8 million of our short term investments and restricted cash.

Net cash provided by financing activities for the three months ended March 31, 2008 was \$26.4 million, compared to \$2.8 million in the comparable period in 2007. In the first quarter of 2008, the cash provided by financing activities was principally due to the excess tax benefit from stock-based compensation expense as well as proceeds from stock option exercises. In the first quarter of 2007, the cash provided by financing activities was principally due to proceeds from stock option exercises.

In April 2008, we declared a special cash dividend of \$4.25 per share of common stock (the Dividend) using proceeds from the sale of the Commercial and Cardiovascular Assets and the Manufacturing Assets. Based on the number of stockholders as of the May 5, 2008 record date, the Dividend was \$507.0 million.

In April 2008, we announced the Spin-off. As noted above, we expect to retain the rights to antibody humanization royalty revenues from all current and future licensed products and plan to distribute this income to our stockholders, net of any operating expenses, debt service and

income taxes. Subsequent to the Spin-off, we plan to have only a nominal number of employees to support our intellectual properties and provide for certain essential reporting and management functions of a public company. We expect to capitalize the new biotechnology Spin-off company with approximately \$375 million in cash at the completion of the transaction. This initial capitalization, along with potential milestone payments, non-humanization royalties and other payments under collaboration and other agreements, including the contingent consideration related to the sale of the Commercial and Cardiovascular Assets, is expected to fund the Spin-off company for approximately three years based on current operating plans. We expect to complete the Spin-off by the end of 2008. While we plan for the Spin-off, we continue to evaluate opportunities to sell or securitize all or part of our antibody humanization royalties; however, we can not assure that we will be able to consummate a sale or securitization of our antibody humanization patent royalty stream on terms acceptable to us, or at all.

In conjunction with our restructuring efforts and significant cost-cutting measures currently underway, we believe that the revenues generated from our royalties and collaboration agreements, taking into account the distribution of the Dividend totaling \$507.0 million as mentioned above, will be sufficient to fund our operations over the next year and the foreseeable future. If and after we consummate the Spin-off, we believe that the revenues generated from our royalties will be sufficient to fund our operations into the foreseeable future. As noted above, we will continue to evaluate opportunities to sell or securitize all or part of our antibody humanization royalties, although we cannot assure that we will be able to consummate such a sale or securitization on terms acceptable to us or at all. Our future capital requirements will depend on numerous factors, as described below, and the sale of another or all of our key assets could fundamentally change how we fund our operations. Such factors that impact our future capital requirements include, among others, royalties from sales of products by third-party licensees, including *Avastin*, *Herceptin*, *Lucentis*, *Mylotarg*, *Raptiva*, *Synagis*, *Tysabri*

and *Xolair*; interest income; and the costs of and outcome defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. Our future capital requirements also will depend on, among other factors our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; 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 collaborators 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; our ability to obtain and retain funding from third parties under collaborative arrangements; the demand for our potential products, if and when approved; and potential acquisitions of technology, product candidates or businesses by us. However, if and after we consummate the Spin-off, the factors identified in the preceding sentence would no longer impact our capital requirements. In addition to the foregoing, the sale or securitization of all or part of our antibody humanization patent royalty stream could fundamentally change how we fund our operations. In order to develop and commercialize our potential products we or the Spin-off company 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 would 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, 2008 were as follows:

	1 Year	1-3 Years	4-5 Years	5 Years	Total
<b>CONTRACTUAL OBLIGATIONS</b>					
Operating leases	\$ 3,926	\$ 7,351	\$ 6,963	\$ 62,461	\$ 80,701
Convertible notes	11,875	273,748	252,500		538,123
Contract manufacturing	7,740	12,500			20,240
Other liabilities (1)	4,976	7,318	7,824	44,271	64,389
Total contractual obligations	\$ 28,517	\$ 300,917	\$ 267,287	\$ 106,732	\$ 703,453

(1) Includes lease payments related to certain of our facilities in Redwood City, California, a milestone payment due to one of our licensors and post-retirement benefit obligations.

In addition to the amounts disclosed in the table above, we have committed to make payments for certain retention and severance related benefits. See Notes 5 and 7 to the Consolidated Financial Statements for further details. Further, we have committed to make potential future milestone payments to third parties as part of in-licensing and product development programs. Payments under these agreements generally become due and payable only upon achievement of certain clinical development, regulatory and/or commercial milestones. Because the achievement of these milestones has not yet occurred, such contingencies have not been recorded in our Consolidated Balance Sheet as of March 31, 2008. We estimate that such milestones that could be due and payable over the next year approximate \$2 million and milestones that could be due and payable over the next three years approximate \$4 million.

In addition, in connection with the sale of the Cardiovascular Assets to EKR and under certain circumstances, we may be required to reimburse EKR for the cost of certain Retavase manufacturing obligations during 2008, not to exceed \$2.5 million.

## RISK FACTORS

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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, 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 ended our solicitation of interest in the Company and its assets, other than our humanization royalty stream assets, and have undertaken to restructure the Company, which could distract our management and employees, disrupt operations, make more difficult our ability to attract and retain key employees and cause other difficulties.**

From October 2007 until March 2008, we pursued a process to solicit interest in the purchase of the Company or our key assets, including the Commercial and Cardiovascular Assets and humanization royalty stream assets. In March 2008, we announced the end of this process and that we would focus on discovering and developing innovative antibodies for cancer and immunologic diseases. In April 2008, we decided to separate our antibody humanization royalty assets from our biotechnology operations by spinning off our biotechnology assets into a separate publicly traded entity.

In an effort to reduce operating costs to a level more consistent with a biotechnology company focused solely on antibody discovery and development, in March 2008, we commenced a restructuring pursuant to which we eliminated approximately 120 employment positions. We intend to eliminate approximately 130 additional employment positions over the next 12 months. Many of these positions support our provision of transition services to Otsuka, EKR and Genmab in connection with our sale of assets to these parties. We offered these 120 transition employees and the employees that we expect to retain after the restructuring retention bonuses and other incentives to encourage these employees to stay with the Company. The disruption, anxiety and uncertainty caused by our restructuring could cause employees to seek other employment opportunities notwithstanding the retention incentives we have implemented. The loss of personnel during this period could disrupt operations and adversely impact our ability to perform the transition services we are obligated to perform for Otsuka, EKR and Genmab.

This disruption and uncertainty may also make the recruitment of key personnel more difficult. We are currently engaged in a search for a new Chief Executive Officer, and the disruption and uncertainty caused by our restructuring may make such recruitment more difficult. The failure to recruit a new Chief Executive Officer could adversely impact our future performance or our plans for the timing of future transactions.

Our restructuring efforts may continue to divert the attention of our management and employees away from our operations, harm our reputation and increase our expenses. We cannot assure you that we will not undertake additional restructuring activities, that any of our restructuring efforts will succeed, or that we will be able to realize the cost savings and other anticipated benefits from our restructuring plans or that we will successfully spin off our biotechnology assets.

In addition, employees whose positions we will eliminate in connection with this reduction may seek employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot provide assurance that the confidential nature of our proprietary information will be maintained in the course of such future employment.

**We have decided to separate our antibody humanization royalty assets from our biotechnology operations by spinning off our biotechnology assets into a separate publicly traded entity, the process for which may divert the attention of our management and employees, will increase our professional services expenses, may disrupt our operations and is subject to other risks.**

In April 2008, we announced that we had decided to separate our antibody humanization royalty assets from our biotechnology operations by spinning off our biotechnology assets into a separate publicly traded entity and that we expected to complete this separation by the end of 2008. Our ability to timely effect the Spin-off is subject to the completion of numerous tasks, including the preparation of carve-out audited financial statements for our biotechnology operations, the completion of required regulatory filings and obtaining the consent of third parties to the transfer of contractual rights to the Spin-off entity. The failure to obtain necessary consents from third parties to the transfer of contractual rights in the Spin-off could delay or make impractical our plan to effect a Spin-off of our biotechnology assets.



The process to plan for and effect the Spin-off of our biotechnology assets will demand a significant amount of time and effort from our management and employees. The diversion of our management's and employees' attention to the Spin-off process may disrupt our operations, including by adversely impacting the progress of our discovery and development efforts and our relationships with collaborators.

We expect to initially fund the biotechnology Spin-off with \$375 million in cash. We expect that this initial capitalization, along with potential milestone payments, non-humanization royalties and other payments under collaboration and other agreements, including the contingent consideration related to our sale of our Cardiovascular Assets would fund the biotechnology Spin-off for approximately three years based on current operating plans. Changes in our development or operations plans, however, could affect the initial cash funding needed to adequately capitalize the biotechnology entity.

We will incur significant expenditures for professional services in connection with our planning and implementation of the Spin-off, including for legal and accounting services.

**We may not receive the contingent consideration related to the sale of our Cardiovascular Assets.**

In March 2008, we sold our Cardiovascular Assets to EKR for \$85 million in cash at closing, and up to an additional \$85 million in development and sales milestones, as well as royalty payments. Receipt of these milestone and royalty payments is dependent upon certain contingencies, including the receipt of marketing approval from the FDA for a new formulation of Cardene and future net sales of this new formulation. We cannot assure you that these development and sales milestones will be met and that we will be able to receive any of the additional \$85 million in milestone payments and any of the royalty payments based on future net sales.

**We may not be able to consummate a transaction to sell or securitize the value of our antibody humanization patent royalty stream received from currently marketed licensed products.**

The sale or securitization of our antibody patent royalty stream is uncertain and the conclusion of any transaction or structure leading to such a transaction would be subject to numerous conditions including potential negotiation with third parties, market conditions and determination of the final form. We may not be able to consummate a transaction relating to our antibody humanization patent royalty stream on terms acceptable to us, or at all. The consummation of any transaction or structure relating to the royalty stream, even if on acceptable terms, could be adversely impacted or prevented by failure to satisfy closing conditions or regulatory delays.

**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, 2008, we had an accumulated deficit of \$653.2 million. We expect our operating expenses in the near term to decrease significantly relative to expense levels during 2005 to 2007 because we have divested the Commercial and Cardiovascular Assets we formerly held and have undertaken a significant restructuring and reduction in force. We will, however, incur a significant amount of restructuring costs through 2008, including severance payments to terminated employees and additional costs and retention incentives to retained employees. After these divestitures and our restructuring are complete, operating expenses may increase on average if we are successful in advancing potential products in clinical trials primarily because of the extensive resource commitments required to achieve regulatory approval.

Since we or our collaborators 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, our expenses may continue to exceed our revenues. 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 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 licensing and other revenues from third-party collaborators, 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. The likelihood of reaching and time required to reach sustained profitability are highly uncertain.

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

Our revenues and revenue growth 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, because we have divested the Commercial and Cardiovascular Assets, sales of which constituted 40% and 44% of our total revenues (including discontinued operations) in 2006 and 2007, respectively, we expect our revenues to decline significantly in the near term. Antibody humanization royalties constituted 74% and 85% of our revenues from continuing operations in 2006 and 2007, respectively. We continue to evaluate the possible sale or securitization of our antibody humanization royalties, either before or after our planned Spin-off of our biotechnology assets, and distribution of proceeds from such a sale or securitization to stockholders. Any sale of our antibody humanization royalties would decrease our revenue while a securitization of our antibody humanization royalties would increase our expenses as we would become obligated to make periodic principal and interest payments. Our antibody humanization royalty revenues, even after any potential sale or securitization, may be unpredictable and fluctuate since they depend upon:

- the seasonality and rate of growth of sales of existing and licensed products;
- the mix of U.S.-based Sales and ex-U.S.-based Sales in connection with our master patent license agreement with Genentech;
- the existence of competing products;
- the continued safety of approved licensed products;
- the marketing and promotional efforts of our licensees from whom we receive royalty payments;
- our ability to successfully defend and enforce our patents; and
- the timing of milestone payments, licensing and signing fees and completion of manufacturing, development or other services we must pay or that we may receive under licensing, collaboration and royalty arrangements.

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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 royalty fee structure that has four tiers, 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 the 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. The average royalty rate for payments we receive from Genentech is lowest in the first calendar quarter of each year, which would be for Genentech's sales from the fourth calendar quarter from the preceding year, when more of Genentech's U.S.-based Sales bear royalties at lower royalty rates. With respect to Genentech's royalty-bearing products that are both manufactured and sold outside of the United States (ex-U.S.-based Sales), the royalty rate that we receive from Genentech is a fixed rate based on a percentage of the underlying ex-U.S.-based Sales. The mix of U.S.-based Sales and ex-U.S.-based Sales and the manufacturing location are outside of our control and have fluctuated in the past and may continue to fluctuate in future periods.

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.

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 we record during the quarter in which such expenses are reported to us or to our collaborators and agreed to by us or our collaborators. 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.

**We face significant competition.**

We face significant competition from entities with substantially greater resources than we do, more experience and capabilities in the discovery and development of pharmaceuticals and superior personnel resources. 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. These entities have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, asthma and cancers and technologies that may compete with our antibody technology platform. These competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our products may also face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of our products.

Any product that our collaborators 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 collaborators 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.

**Changes in the U.S. and international health care industry, including regarding reimbursement rates, could adversely affect the commercial value of our development products.**

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 may 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 the products we develop. Any product we introduce 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 obtain or maintain prices sufficient to realize an appropriate return on our investment in product development, should any of our development products be approved for marketing. 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 development products. These factors will also affect the products that are marketed by our collaborators and licensees. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

**Our antibody humanization patents, which are of significant value to us, are being challenged and a successful challenge or refusal to take a license could limit our future revenues.**

Our Queen patents are of significant value to us. Royalty revenues received under agreements for the license of rights under our Queen patents accounted for 82% of revenues from continuing operations in 2005, 74% of revenues from continuing operations in 2006 and 85% of revenues from continuing operations in 2007. We expect that these royalty revenues will constitute the vast majority of our revenues now that we have completed the divestiture of the commercial products. We expect that 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 the majority of our total revenues until our Queen patents expire in 2014. We continue to evaluate the possible sale or securitization of our antibody humanization royalties, either before or after our planned Spin-off of our biotechnology assets, and distribution of the proceeds from such a sale or securitization to stockholders. Any sale of our antibody humanization royalties would decrease our revenue while a securitization of our antibody humanization royalties would increase our expenses as we would become obligated to make periodic principal and interest payments.

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, 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, with the exception of Alexion Pharmaceuticals, Inc. (Alexion), 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 not enter into or 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. More recently, in March 2007, the FDA approved Alexion's *Soliris* (eculizumab) humanized antibody product for marketing and we filed a lawsuit against Alexion seeking monetary damages for infringement of certain of our Queen patents and other relief. In June 2007, Alexion filed an answer denying that its *Soliris* product infringes our patents, asserting certain defenses and counterclaiming for non-infringement and invalidity, and thereafter amended its answer to include a defense of unenforceability. In July 2007, the discovery stage of this litigation began and discovery is ongoing. We intend to vigorously assert our rights under the patents-in-suit and defend against Alexion's counterclaims. 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.

**The amount of royalty revenues we receive depends on, among other things, the efforts and successes of our licensees.**

The amount and timing of any royalties we may receive from our licensees will depend, in part, on the product development and marketing efforts and successes of our licensees. Our licensees may not successfully complete the product development, regulatory and marketing efforts required to sell royalty-bearing products. Competition from other products or therapies could adversely affect sales of our licensees' products. In addition, even if a licensee receives regulatory approval to sell a drug on which we would receive royalties, the licensee or a regulatory agency, such as the FDA, could terminate or suspend the marketing of the drug 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.

**We must protect our patent and other intellectual property rights to succeed.**

Our success is dependent in significant part on our ability to develop and protect patent and other intellectual property rights and operate without infringing the intellectual property rights of others.

Our pending patent applications may not result in the issuance of valid patents or the claims and claim scope of 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 that does not infringe our patent rights. 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 have claims that could prevent the issuance of patents to us or result in a significant reduction in the claim scope of our issued patents. In addition, patent applications are confidential for a period of time after filing. We therefore may not know that a competitor has filed a patent application covering subject matter similar to subject matter in one of our patent applications or that we were the first to invent the innovation we seek to patent. This may lead to disputes including interference proceeding or litigation to determine rights to patentable subject

matter. These disputes are often expensive and may result in our being unable to patent an innovation.

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 need to obtain patent licenses from others in order to manufacture or sell our potential products and we may not be able to obtain these licenses on terms acceptable to us or at all.**

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 may need 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.

For example, the European Patent Office (EPO) granted Celltech Therapeutics Limited (Celltech), which UCB Group acquired, a patent covering humanized antibodies, which we have opposed. At an oral hearing in January 2005, the Opposition Division of the European Patent Office revoked this patent. Celltech has appealed this decision. The appeal was dismissed by the Technical Board of Appeal of the European Patent Office at an oral hearing in March 2008 and the patent remains revoked. Also, we do not know whether the EPO will grant Celltech a patent on a 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 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 need to negotiate additional licenses under those patents or 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 need 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 or at all.

We do not have licenses to issued U.S. patents which may cover one of our development-stage products. If we successfully develop this product, we might need to obtain licenses to these patents to commercialize the product. In the event that we need to obtain licenses to these patents, we may not be able to do so on acceptable terms or at all.

**If our collaborations are not successful or are terminated by our collaborators, 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 collaborators 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.

In September 2005, we entered into a collaboration agreement with Biogen Idec under which Biogen Idec became our collaborator on the development of daclizumab in certain indications, including MS, and volociximab (M200) in all indications. This agreement is particularly important to us. The collaboration agreement 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 we 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 collaborators can terminate our collaborative agreements under certain conditions, and in some cases on short notice. A collaborator 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 collaborator 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 collaborators 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 collaborator's own financial, competitive, marketing and strategic capabilities and priorities. These considerations include:

- the commitment of each collaborator'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 collaborator 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 collaborators 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.

In addition, our collaborators may independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these collaborators.

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

We are engaged in research activities intended to, among other things, 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.

To supplement our own research efforts, from time to time we may in-license or otherwise acquire from others rights to products in-development or early-stage technology. Acquiring rights to products in this manner poses risks, including because we may not be able to successfully integrate the research, development and commercialization capabilities necessary to bring these products to market.

**The failure to gain market acceptance of our product candidates among the medical community would adversely affect our revenue.**

Even if approved, 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 we obtain the necessary regulatory and reimbursement approvals. 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 our products until clinical data or other factors demonstrate the safety and efficacy of our product as compared to conventional drug and other treatments. Even if we establish the clinical safety and efficacy of our product candidates, physicians may elect not to use our product 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 inconvenience to patients. Our product candidates, if successfully developed, may compete with a number of drugs and therapies that may be administered more easily. The failure of our product candidates to achieve significant market acceptance would materially harm our business, financial condition and results of operations.

**The clinical development of drug products is inherently uncertain and expensive and subject to extensive government regulation.**

Our future success depends in large part upon the success of our clinical development efforts. Clinical development, however, is a lengthy, time-consuming and expensive process and subject to significant risks of failure. In addition, we must expend significant amounts to comply with extensive government regulation of the clinical development 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, our clinical trials may not adequately demonstrate the safety and effectiveness of our product candidates.

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 and intended use of the product candidate and is difficult to predict. Further, we, the FDA, European Medicines Agency (EMA), 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 EMA'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 EMA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

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. For example, in August 2007, we announced that we would terminate the phase 3 program of our *Nuvion*<sup>®</sup> (visilizumab) antibody in intravenous steroid-refractory ulcerative colitis because data from treated patients showed insufficient efficacy and an inferior safety profile in the visilizumab arm compared to IV steroids alone.

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.

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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.

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.

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.

**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 clinical trials 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.

**We must attract and retain highly skilled employees in order to succeed.**

To be successful, we must attract and retain qualified clinical, scientific, management and other personnel and we face significant competition for experienced personnel. If we are unsuccessful in attracting and retaining qualified personnel, particularly at the management level, our business could be impaired. The uncertainty caused by the strategic review and asset sales processes and restructuring we have recently undertaken has created anxiety among our employees. We believe this has caused attrition to increase because of employees' uncertainty regarding the continuation of employment. We have put in place certain severance and retention programs in an effort to mitigate the number of voluntary terminations, however, our programs may not provide effective incentive to employees to stay with us.

The uncertainty may also make the recruitment of highly skilled personnel more difficult. We are currently engaged in a search for a new Chief Executive Officer, and the disruption and uncertainty caused by our restructuring and plan to spin off our biotechnology assets may make such recruitment more difficult. The failure to recruit a new Chief Executive Officer could adversely impact our future performance.

**Pursuant to rules adopted under the Sarbanes-Oxley Act of 2002, we must evaluate the effectiveness of our disclosure controls and internal control over financial reporting on a periodic basis, publicly disclose the results of these evaluations and publicly disclose whether we have implemented any changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.**

Our management is required to periodically evaluate the effectiveness of our disclosure controls and procedures and our internal control over financial reporting and our independent registered public accounting firm must attest to the effectiveness of our internal control over financial reporting as of the end of each fiscal year. We are also required to disclose in our periodic reports with the SEC any changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Our evaluation of our disclosure controls and procedures may reveal material weaknesses in our internal control over financial reporting. If we identify a material weakness we would be required to conclude that our internal control over financial reporting is ineffective and disclose this conclusion, which could adversely affect the market price of our common stock. For example, we disclosed we had material weaknesses in our quarterly reports on Form 10-Q for the periods ended September 30, 2005, June 30, 2007, September 30, 2007 and March 31, 2008 and our annual report on Form 10-K for the year ended December 31, 2007.

In addition, 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. Compliance with these rules has 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.

**We rely on sole source, third-party contract manufacturers to manufacture our products.**

As we have completed the sale of our Manufacturing Assets to Genmab, we do not have the capability to manufacture any of our development-stage products. We have entered into a two-year supply agreement with Genmab that became effective upon the closing of the sale

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in March 2008. If we experience supply problems with Genmab, there may not be sufficient supplies of our development-stage products for us to meet clinical trial demand, in which case our operations and results could suffer.

Our products must be manufactured in FDA-approved facilities and the process for qualifying and obtaining approval for a manufacturing facility is time-consuming. The manufacturing facilities on which we rely will be subject to ongoing, periodic unannounced inspection by the FDA and state agencies to ensure compliance with good manufacturing practices.

If our relationship with Genmab was to terminate unexpectedly or on short notice or expire without being renewed, our ability to meet clinical trial demand for our development-stage products could be adversely affected while we qualify a new manufacturer for that product and our operations and future results could suffer. In addition, we would need to expend significant amounts to qualify a new manufacturer and transfer technology from Genmab to the new manufacturer which would also adversely affect our results of operations.

Product supply interruptions, whether as a result of regulatory action or the termination of a relationship with a manufacturer, 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.

Our ability to file for, and to obtain, regulatory approvals for our products, as well as the timing of such filings, will depend on the abilities of the contract manufacturers we engage. We or our contract manufacturers 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 standard operating procedures;
- on-going compliance with FDA regulations;
- production costs; and
- development of advanced manufacturing techniques and process controls.

**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. 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 contract manufacturers' inability to maintain 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.

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

We depend on outside vendors for the supply of raw materials used to produce our product candidates for use in clinical trials. Once a supplier's materials have been selected for use in the manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

**We must comply with extensive government regulations and laws.**

We are subject, directly or through our customers, to extensive regulation by federal government, state governments, and the foreign countries in which we conduct our business.

In particular, we are subject to extensive and rigorous government regulation as a developer of drug products. 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 biopharmaceutical products. Our product candidates and any future products may 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.

We must rely on our contract manufacturers and third-party 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.

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;
- 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 violate any applicable law or other governmental regulations, we may be subject to civil and criminal penalties, damages and fines, including 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.

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We expend a significant amount on compliance efforts and the expenses have been, and may in the future be unpredictable, and adversely affect our results. Changing laws, regulations and standards may also create uncertainty and increase insurance costs. We are committed to compliance and 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 be unable to obtain or maintain regulatory approval for our products.**

Even if the FDA grants us marketing approval for a product, 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 or our contractors must demonstrate the ability to manufacture the pharmaceutical product to be approved. 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 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. Although we do not currently have any marketed products, the foregoing considerations would be important to our future selection of contract manufacturers.

The FDA enforces post-marketing regulatory requirements, such as cGMP requirements, through periodic unannounced inspections. For example, in April 2008 the FDA made an unannounced visit to our Redwood City, California, offices to inspect our post-marketing safety surveillance practices for the commercial products we marketed and sold from March 2005 until March 2008. At the conclusion of the week-long inspection, we received from the FDA two Inspectional Observations on Form 483, each of which we responded to in April 2008. Failure to pass an FDA inspection or timely or effectively respond to inspectional observations or otherwise adversely impact our operations.

Our collaborators, licensees and we also are subject to foreign regulatory requirements regarding the manufacture, development, marketing and sale of pharmaceutical products and, if the particular product is manufactured in the United States, FDA and other U.S. export provisions. These requirements 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.

Further, regulatory approvals may be withdrawn if we do not comply with regulatory standards or if problems with our 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.

**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.

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

We face an inherent business risk of exposure to product liability claims in the event that the use of products during research and development efforts or after commercialization results in adverse effects. This risk 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.

**Increased leverage as a result of our sale of notes in 2003 and 2005 may harm our financial condition and results of operations.**

At March 31, 2008, we had \$640.5 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 that 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.

**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 unpaid interest. 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 may not have sufficient funds available for any required repurchases of these securities. In addition, the terms of any agreements related to borrowing which we may enter into from time to time may prohibit or limit our repurchase of 2003 Notes or make our repurchase of 2003 Notes an event of default under certain circumstances. If a repurchase event occurs at a time when a credit agreement prohibits us from purchasing the 2003 Notes, we could seek the consent of the lender to purchase the 2003 Notes or could attempt to refinance the debt covered by the credit agreement. If we do not obtain a consent, we may not repurchase the 2003 Notes. Our failure to repurchase tendered 2003 Notes would constitute an event of default under the indenture for the 2003 Notes, which might also constitute a default under the terms of our other debt, including the 2005 Notes. In such circumstances, our financial condition and the value of our securities could be materially harmed.

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

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

**The conversion of any of the outstanding 2003 Notes or 2005 Notes into shares of our common stock would have a dilutive effect, which could cause our stock price to go down.**

The 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 the 2003 Notes and 2005 Notes. If any or all of the 2003 Notes or 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 the 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. Such payments could have a material adverse effect on our cash position.





**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.**

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 progress, level and timing of research and development activities related to clinical trials we are conducting or that are being conducting with our collaborators, including clinical trials with respect to daclizumab and volociximab;
- the cost and outcomes of regulatory submissions and reviews;
- the continuation or termination of third party manufacturing or sales and marketing arrangements;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights; and
- 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.

**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 March 31, 2007 to March 31, 2008, our common stock closed as high as \$27.70 per share and as low as \$9.32 per share. Additionally, the stock market from time to time has experienced significant price and volume fluctuations 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;
- approval or introduction of competing products and technologies;
- disappointing sales of products from which we receive royalties or withdrawal from the market of an approved product from which we receive royalties;
- a change in the mix of U.S.-based Sales and ex-U.S.-based Sales in connection with our master patent license agreement with Genentech;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies, including market reaction to various announcements regarding products licensed under our technology;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- 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 collaborators or insiders; and
- comments and expectations of results made by securities analysts.

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, 2008, 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, 2007.

### ITEM 4. CONTROLS AND PROCEDURES

*Evaluation of disclosure controls and procedures.* Under the supervision and with the participation of our management, including our Interim 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) of 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 Interim Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2008, that due to the material weakness discussed below, our disclosure controls and procedures were not effective to ensure the information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

*Changes in internal controls.* A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the filing of our Annual Report on Form 10-K for the year ended December 31, 2007, we identified a material weakness that related to ineffective controls in our financial statement close process. Specifically, we did not have a sufficient number of accounting personnel with relevant technical accounting and financial reporting expertise to effectively design and operate controls over various non-routine and estimation classes of transactions including the classification of clinical affairs expenses, the accounting for clinical trial expenses related to change orders, the accounting for asset retirement obligations related to leased facilities, the accounting for retention bonuses, the estimated forfeiture rate for the purposes of recording employee stock-based compensation, and the impairment analysis related to intangible assets. As a result of this material weakness, errors were identified by our auditors in the 2007 consolidated financial statements related to the classification of expenses between research and development expenses and general and administrative expenses, an understatement of clinical development expenses, the understatement of lease expenses, the understatement of retention bonus expenses, and stock-based compensation expense. These errors were corrected

in the consolidated financial statements as of and for the year ended December 31, 2007.

We have taken steps to remediate the deficiencies that gave rise to this material weakness, including enhancing controls that had not been operating effectively and designing and implementing new controls to remediate design deficiencies within our financial statement close process. Although we have made progress towards remediation of the deficiencies giving rise to the material weakness, we do not believe that sufficient time has passed to allow for an adequate testing sample nor have we completed our testing of the new or enhanced controls. As such, we were unable to conclude that the material weakness described above was remediated as of March 31, 2008.

There were no other changes in our internal controls over financial reporting during the quarter ended March 31, 2008 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.

#### 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. In April 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 this decision of the Opposition Divisions. 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. Two notices of appeal have since been filed by Boehringer Ingelheim GmbH and Celltech R&D Limited.

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. patents.

Opposition to 040 Patent

At an oral hearing in February 2005, the Opposition Division 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 in the United States District Court for the District of Delaware for infringement of certain claims of United States Patent Number 5,693,761, United States Patent Number 5,693,762 and United States Patent Number 6,180,370 (collectively, the patents-in-suit), which are three of our antibody humanization patents, commonly referred to as the Queen patents. We are seeking monetary damages and other relief. In June 2007, Alexion filed an answer denying that its Soliris product infringes the patents-in-suit, asserting certain defenses and counterclaiming for non-infringement and invalidity, and thereafter amended its answer to include a defense of unenforceability. In July 2007, the discovery stage of this litigation began and discovery is ongoing. We intend to vigorously assert our rights under the patents-in-suit and defend against Alexion's counterclaims.

**ITEM 1A. RISK FACTORS**

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, 2007 except that:

- We added the first risk factor in this Item 1A;
- We deleted the risk factors entitled "We may not be able to consummate the sale of our manufacturing related assets in Minnesota to GMN, Inc." and "The process of pursuing and implementing multiple significant transactions and transaction structures simultaneously diverts the attention of our management and employees, increases our professional services expenses and may disrupt our operations" because the risks described in these risk factors are no longer relevant; and



- We deleted the risk factor entitled We may not be able to consummate the sale of our manufacturing related assets in Minnesota to GMN, Inc. because we consummated that sale; and
- We also revised the other risk factors listed below that are not identified in the above bullets in this Item 1A.

**We have decided to separate our antibody humanization royalty assets from our biotechnology operations by spinning off our biotechnology assets into a separate publicly traded entity, the process for which may divert the attention of our management and employees, will increase our professional services expenses, may disrupt our operations and is subject to other risks.**

In April 2008, we announced that we had decided to separate our antibody humanization royalty assets from our biotechnology operations by spinning off our biotechnology assets into a separate publicly traded entity and that we expected to complete this separation by the end of 2008. Our ability to timely effect the Spin-off is subject to the completion of numerous tasks, including the preparation of carve-out audited financial statements for our biotechnology operations, the completion of required regulatory filings and obtaining the consent of third parties to the transfer of contractual rights to the Spin-off entity. The failure to obtain necessary consents from third parties to the transfer of contractual rights in the Spin-off could delay or make impractical our plan to effect a Spin-off of our biotechnology assets.

The process to plan for and effect the Spin-off of our biotechnology assets will demand a significant amount of time and effort from our management and employees. The diversion of our management's and employees' attention to the Spin-off process may disrupt our operations, including by adversely impacting the progress of our discovery and development efforts and our relationships with partners.

We expect to initially fund the biotechnology Spin-off with \$375 million in cash. We expect that this initial capitalization, along with potential milestone payments, non-humanization royalties and other payments under collaboration and other agreements, including the contingent consideration related to our sale of our Cardiovascular Assets, would fund the biotechnology Spin-off for approximately three years based on current operating plans. Changes in our development or operations plans, however, could affect the initial cash funding needed to adequately capitalize the biotechnology entity.

We will incur significant expenditures for professional services in connection with our planning and implementation of the Spin-off, including for legal and accounting services.

**We have ended our solicitation of interest in the Company and its assets, other than our humanization royalty stream assets, and have undertaken to restructure the Company, which could distract our management and employees, disrupt operations, make more difficult our ability to attract and retain key employees and cause other difficulties.**

From October 2007 until March 2008, we pursued a process to solicit interest in the purchase of the Company or our key assets, including the Commercial and Cardiovascular Assets and humanization royalty stream assets. In March 2008, we announced the end of this process and that we would focus on discovering and developing innovative antibodies for cancer and immunologic diseases. In April 2008, we decided to separate our antibody humanization royalty assets from our biotechnology operations by spinning off our biotechnology assets into a separate publicly traded entity.

In an effort to reduce operating costs to a level more consistent with a biotechnology company focused solely on antibody discovery and development, in March 2008, we commenced a restructuring pursuant to which we have eliminated approximately 120 employment positions. We intend to eliminate approximately 130 additional employment positions over the next 12 months. Many of these positions support our provision of transition services to Otsuka, EKR and Genmab in connection with our sale of assets to these parties. We have offered these 130 transition employees and the employees that we expect to retain after the restructuring retention bonuses and other incentives to encourage these employees to stay with the Company. The disruption, anxiety and uncertainty caused by our restructuring could cause employees to seek other employment opportunities notwithstanding the retention incentives we have implemented. The loss of personnel during this period could disrupt operations and adversely impact our ability to perform the transition services we are obligated to perform for Otsuka, EKR and Genmab.

This disruption and uncertainty may also make the recruitment of key personnel more difficult. We are currently engaged in a search for a new Chief Executive Officer, and the disruption and uncertainty caused by our restructuring may make such recruitment more difficult. The failure to recruit a new Chief Executive Officer could adversely impact our future performance or our plans for the timing of future transactions.

Our restructuring efforts may continue to divert the attention of our management and employees away from our operations, harm our reputation and increase our expenses. We cannot assure you that we will not undertake additional restructuring activities, that any of our restructuring efforts will succeed, or that we will be able to realize the cost savings and other anticipated benefits from our restructuring plans or that we will successfully spin off our biotechnology assets.

In addition, employees whose positions we will eliminate in connection with this reduction may seek employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot provide assurance that the confidential nature of our proprietary information will be maintained in the course of such future employment.

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

Our revenues and revenue growth 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, because we have divested the Commercial and Cardiovascular Assets, sales of which constituted 40% and 44% of our total revenues (including discontinued operations) in 2006 and 2007, respectively, we expect our revenues to decline significantly in the near term. Antibody humanization royalties constituted 74% and 85% of our revenues from continuing operations in 2006 and 2007, respectively. We continue to evaluate the possible sale or securitization of our antibody humanization royalties, either before or after our planned Spin-off of our biotechnology assets, and distribution of

proceeds from such a sale or securitization to stockholders. Any sale of our antibody humanization royalties would decrease our revenue while a securitization of our antibody humanization royalties would increase our expenses as we would become obligated to make periodic principal and interest payments. Our antibody humanization royalty revenues, even after any potential sale or securitization, may be unpredictable and fluctuate since they depend upon:

- the seasonality and rate of growth of sales of existing and licensed products;
- the mix of U.S.-based Sales and ex-U.S.-based Sales in connection with our master patent license agreement with Genentech;
- the existence of competing products;
- the continued safety of approved licensed products;
- the marketing and promotional efforts of our licensees from whom we receive royalty payments;
- our ability to successfully defend and enforce our patents; and
- the timing of milestone payments, licensing and signing fees and completion of manufacturing, development or other services we must pay or that we may receive under 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 royalty fee structure that has four tiers, 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 the 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. The average royalty rate for payments we receive from Genentech is lowest in the first calendar quarter of each year, which would be for Genentech's sales from the fourth calendar quarter from the preceding year, when more of Genentech's U.S.-based Sales bear royalties at lower royalty rates. With respect to Genentech's royalty-bearing products that are both

manufactured and sold outside of the United States (ex-U.S.-based Sales), the royalty rate that we receive from Genentech is a fixed rate based on a percentage of the underlying ex-U.S.-based Sales. The mix of U.S.-based Sales and ex-U.S.-based Sales and the manufacturing location are outside of our control and have fluctuated in the past and may continue to fluctuate in future periods.

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.

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 we record 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 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.

**Our antibody humanization patents, which are of significant value to us, are being challenged and a successful challenge or refusal to take a license could limit our future revenues.**

Our Queen patents are of significant value to us. Royalty revenues received under agreements for the license of rights under our Queen patents accounted for 82% of revenues from continuing operations in 2005, 74% of revenues from continuing operations in 2006 and 85% of revenues from continuing operations in 2007. We expect that these royalty revenues will constitute the vast majority of our revenues now that we have completed the divestiture of the commercial products. We expect that 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 the majority of our total revenues until our Queen patents expire in 2014. We continue to evaluate the possible sale or securitization of our antibody humanization royalties, either before or after our planned Spin-off of our biotechnology assets, and distribution of the proceeds from such a sale or securitization to stockholders. Any sale of our antibody humanization royalties would decrease our revenue while a securitization of our antibody humanization royalties would increase our expenses as we would become obligated to make periodic principal and interest payments.

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, 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, with the exception of Alexion Pharmaceuticals, Inc. (Alexion), 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 not enter into or 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. More recently, in March 2007, the FDA approved Alexion's *Soliris* (eculizumab) humanized antibody product for marketing and we filed a lawsuit against Alexion seeking monetary damages for infringement of certain of our Queen patents and other relief. In June 2007, Alexion filed an answer denying that its *Soliris* product infringes our patents, asserting certain defenses and counterclaiming for non-infringement and invalidity, and thereafter amended its answer to include a defense of unenforceability. In July 2007, the discovery stage of this litigation began and discovery is ongoing. We intend to vigorously assert our rights under the patents-in-suit and defend against Alexion's counterclaims. 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.

**ITEM 6. EXHIBITS**

- \*10.1 Stock Option Agreement between the Company and L. Patrick Gage effective November 16, 2007
- \*10.2 Notice of Option Grant for L. Patrick Gage effective November 16, 2007
- \*10.3 Offer Letter between the Company and Dr. Mark McCamish effective February 16, 2007
- \*10.4 Offer Letter between the Company and Jaisim Shah effective July 18, 2000
- 10.5 Asset Purchase Agreement between the Company and EKR Therapeutics, Inc. dated February 4, 2008
- 10.6 Asset Purchase Agreement between the Company and GMN, Inc. dated February 21, 2008

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\* Management contract or compensatory plan or arrangement.

Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.



**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 12, 2008

PDL BIOPHARMA, INC.  
(Registrant)

/s/ L. Patrick Gage  
L. Patrick Gage  
Interim Chief Executive Officer  
(Principal Executive Officer)

/s/ Andrew L. Guggenlime  
Andrew L. Guggenlime  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

/s/ Herb C. Cross  
Herb C. Cross  
Corporate Controller  
(Principal Accounting Officer)