MOMENTA PHARMACEUTICALS INC
Form 10-Q
May 09, 2012
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 10-Q

**(MARK ONE)**

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2012**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Transition Period from to**

**Commission File Number 000-50797**

# Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **04-3561634** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **675 West Kendall Street, Cambridge, MA** | **02142** |
| (Address of Principal Executive Offices) | (Zip Code) |

**(617) 491-9700**

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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 x | Accelerated filer o |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o |

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

Indicate the number of shares outstanding of each of the Registrant s classes of Common Stock as of May 2, 2012.

| **Class** | **Number of Shares** |
|---|---|
| Common Stock $0.0001 par value | 51,519,754 |

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**MOMENTA PHARMACEUTICALS, INC.**

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## PART I. FINANCIAL INFORMATION

**Item 1. Financial Statements**

### MOMENTA PHARMACEUTICALS, INC.

### CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

(unaudited)

| | March 31, 2012 | December 31, 2011 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 38,657 | $ 49,245 |
| Marketable securities | 343,604 | 299,193 |
| Accounts receivable | 22,372 | 28,171 |
| Unbilled revenue | 1,113 | 2,765 |
| Prepaid expenses and other current assets | 3,072 | 2,547 |
| Restricted cash | 17,500 | 17,500 |
| Total current assets | 426,318 | 399,421 |
| Property and equipment, net of accumulated depreciation | 20,252 | 13,327 |
| Intangible assets, net | 7,507 | 7,772 |
| Other long-term assets | 389 | 389 |
| Total assets | $ 454,466 | $ 420,909 |
| **Liabilities and Stockholders Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,421 | $ 4,709 |
| Accrued expenses | 6,834 | 9,131 |
| Deferred revenue | 6,136 | 2,156 |
| Deferred rent | 234 | 32 |
| Total current liabilities | 22,625 | 16,028 |
| Deferred revenue, net of current portion | 29,518 | 1,608 |
| Deferred rent, net of current portion | 80 | 144 |
| Other long-term liabilities | 51 | 51 |
| Total liabilities | 52,274 | 17,831 |
| **Stockholders Equity:** | | |
| Preferred stock, $0.01 par value per share; 5,000 shares authorized at March 31, 2012 and December 31, 2011, 100 shares of Series A Junior Participating Preferred Stock, $0.01 par value per share designated and no shares issued and outstanding | | |
| | 5 | 5 |

| | | | | |
|---|---|---|---|---|
| Common stock, $0.0001 par value per share; 100,000 shares authorized at March 31, 2012 and December 31, 2011, 51,500 and 51,285 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively | | | | |
| Additional paid-in capital | | 510,546 | | 506,557 |
| Accumulated other comprehensive income (loss) | | 26 | | (81) |
| Accumulated deficit | | (108,385) | | (103,403) |
| | | | | |
| Total stockholders equity | | 402,192 | | 403,078 |
| | | | | |
| Total liabilities and stockholders equity | $ | 454,466 | $ | 420,909 |

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

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**MOMENTA PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**

(in thousands, except per share amounts)

(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2012** | **2011** |
| Collaboration revenues: | | |
| Product revenue | $ 22,029 | $ 75,761 |
| Research and development revenue | 2,199 | 2,411 |
| Total collaboration revenue | 24,228 | 78,172 |
| Operating expenses: | | |
| Research and development* | 18,562 | 12,943 |
| General and administrative* | 10,955 | 8,310 |
| Total operating expenses | 29,517 | 21,253 |
| | | |
| Operating (loss) income | (5,289) | 56,919 |
| | | |
| Other income (expense): | | |
| Interest income | 307 | 128 |
| Interest expense | | (41) |
| Total other income | 307 | 87 |
| | | |
| Net (loss) income | $ (4,982) | $ 57,006 |
| | | |
| Net (loss) income per share: | | |
| Basic | $ (0.10) | $ 1.15 |
| Diluted | $ (0.10) | $ 1.13 |
| | | |
| Weighted average common shares outstanding: | | |
| Basic | 50,240 | 49,532 |
| Diluted | 50,240 | 50,334 |
| | | |
| Comprehensive (loss) income | $ (4,875) | $ 56,953 |

*Non-cash share-based compensation expense included in operating expenses is as follows:

| | | |
|---|---|---|
| Research and development | $ 1,355 | $ 837 |
| General and administrative | $ 1,899 | $ 929 |

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

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**MOMENTA PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2012** | **2011** |
| **Cash Flows from Operating Activities:** | | |
| Net (loss) income | $ (4,982) | $ 57,006 |
| Adjustments to reconcile net (loss) income to net cash provided by operating activities: | | |
| Depreciation and amortization | 1,275 | 1,117 |
| Share-based compensation expense | 3,254 | 1,766 |
| Amortization of premium on investments | 513 | 245 |
| Amortization of intangibles | 265 | 75 |
| Loss on disposal of assets | 3 | |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 5,799 | (27,869) |
| Unbilled revenue | 1,652 | 3,337 |
| Prepaid expenses and other current assets | (525) | (383) |
| Accounts payable | 4,712 | 334 |
| Accrued expenses | (2,297) | (3,411) |
| Deferred rent | 138 | (17) |
| Deferred revenue | 31,890 | (530) |
| Net cash provided by operating activities | 41,697 | 31,670 |
| **Cash Flows from Investing Activities:** | | |
| Purchases of property and equipment | (8,203) | (2,479) |
| Purchases of marketable securities | (189,362) | (137,316) |
| Proceeds from maturities of marketable securities | 144,545 | 65,732 |
| Net cash used in investing activities | (53,020) | (74,063) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from issuance of common stock under stock plans | 735 | 778 |
| Payments on financed leasehold improvements | | (193) |
| Principal payments on capital lease obligations | | (215) |
| Net cash provided by financing activities | 735 | 370 |
| Decrease in cash and cash equivalents | (10,588) | (42,023) |
| Cash and cash equivalents, beginning of period | 49,245 | 100,681 |
| Cash and cash equivalents, end of period | $ 38,657 | $ 58,658 |
| **Supplemental Cash Flow Information:** | | |
| Cash paid for interest | $ | $ 41 |

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

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**MOMENTA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED, CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

## 1. The Company

***Business***

Momenta Pharmaceuticals, Inc. (the Company or Momenta ) was incorporated in the state of Delaware in May 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs, applying its technology to the development of generic or follow-on versions of complex drug products as well as to the discovery and development of complex novel drugs. The Company presently derives all of its revenue from collaborative partnerships.

***Basis of Presentation***

The accompanying unaudited, condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP, for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three months ended March 31, 2012 are not necessarily indicative of the results that may be expected for the full year. These unaudited, condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes included in the Notes to Consolidated Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, which was filed with the SEC on February 28, 2012.

## 2. Summary of Significant Accounting Policies

***Principles of Consolidation***

The Company s consolidated financial statements include the Company s accounts and the accounts of the Company s wholly-owned subsidiary, Momenta Pharmaceuticals Securities Corporation. All intercompany transactions have been eliminated.

***Use of Estimates***

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates and judgments, including those related to revenue recognition, accrued expenses, and share-based payments. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

***Revenue Recognition***

The Company recognizes revenue in accordance with Accounting Standards Codification, or ASC, 605, Revenue Recognition, which requires that certain criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

*Collaborative Agreements*

In November 2003, the Company entered into a collaboration and license agreement (the 2003 Sandoz Collaboration ) with Sandoz AG and Sandoz Inc. (collectively, Sandoz ) to jointly develop and commercialize enoxaparin sodium injection, a generic version of Lovenox®, a low molecular weight heparin or LMWH. In July

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2006, the Company entered into a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG, and in June 2007, the Company and Sandoz AG executed a definitive collaboration and license agreement (as amended, the Second Sandoz Collaboration Agreement ) related to the development and commercialization of M356, which is designed to be a generic version of Copaxone® (glatiramer acetate injection). Together, this series of agreements is referred to as the 2006 Sandoz Collaboration.

In December 2011, the Company entered into a development, license and option agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, Baxter ) related to the development and commercialization of up to six follow-on biologic products. The Company refers to this agreement as the Baxter Agreement.

*Product Revenue*

Profit share and/or royalty revenue is reported as product revenue and is recognized based upon net sales or profit share of licensed products in licensed territories in the period the sales occur as provided by the collaboration agreement. These amounts are determined based on amounts provided by the collaboration partner and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations, or GPO, fees, and product returns, which could be adjusted based on actual results in the future.

*Research and Development Revenue*

The Company applies the guidance pursuant to Financial Accounting Standards Board s ( FASB ) Accounting Standards Update ( ASU ) No. 2009-13, Multiple-Deliverable Revenue Arrangements (Topic 615) ( ASU 2009-13 ) for all multiple-element arrangements entered into on or after January 1, 2011 and for any multiple-element arrangements that were entered into prior to January 1, 2011 but materially modified on or after January 1, 2011. ASU 2009-13 amends the guidance on the accounting for arrangements involving the delivery of more than one element and addresses the determination of the unit(s) of accounting for multiple-element arrangements and how the arrangement s consideration should be allocated to each unit of accounting. Pursuant to ASU 2009-13, the Company evaluates each required non-contingent deliverable to determine if it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. The arrangement s consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of the selling price ( BESP ). The BESP reflects the Company s best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis. The Company expects, in general, to use BESP for allocating consideration to each deliverable. In general, the consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered and limited to the consideration not contingent upon future deliverables. The Company applied ASU 2009-13 to its Baxter Agreement.

Under the 2003 Sandoz Collaboration and the Second Sandoz Collaboration Agreement, the Company has received and may continue to receive consideration in the form of non-refundable, upfront fees related to intellectual property rights and licenses, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and profit-sharing or royalties on product sales. These multiple-element arrangements were entered into prior to January 1, 2011 and have not been materially modified thereafter; therefore the Company continues to apply its prior accounting policy with respect to the non-refundable, upfront license fees and research and development services for these arrangements. Under this prior accounting policy, in general, revenue from non-refundable, upfront fees related to intellectual property rights and licenses where the Company has continuing involvement is recognized ratably over the estimated period of ongoing involvement, which is typically the development term, because there was no objective and reliable evidence of fair value for any undelivered

item to allow the delivered item to be considered a separate unit of accounting. Research and development funding is recognized as earned over the period of effort.

Under the 2003 Sandoz Collaboration, the Company has received consideration in the form of milestone payments and under the Second Sandoz Collaboration Agreement and the Baxter Agreement the Company may receive consideration in the form of milestone payments in future periods. The Company applies the guidance pursuant to ASU No. 2010-17, Revenue Recognition Milestone Method ( ASU 2010-17 ) for all sales-based, commercial and research and development milestones achieved. In accordance with ASU 2010-17, at the inception of each arrangement that includes milestone payments, the Company evaluates each milestone to determine whether (a) the milestone can only be achieved based in whole or in part on either (i) the Company s performance or (ii) on the occurrence of a specific outcome resulting from the Company s performance, (b) there is considerable uncertainty at the date the arrangement is entered into that the event will be achieved and (c) the achievement of the event would result in additional payments being due to the Company.

Additionally, the Company evaluates whether each milestone is considered substantive. The Company designates a milestone as substantive only if it meets all of the following three criteria (i) the consideration is commensurate with either (a) the Company s performance to achieve the milestone or (b) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company s performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

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The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. The Company has concluded that all of the development and regulatory milestones pursuant to its 2003 Sandoz Collaboration, Second Sandoz Collaboration Agreement and Baxter Agreement are substantive. Revenues from development and regulatory milestones, if they are non-refundable and deemed substantive, are recognized upon successful accomplishment of the milestones as research and development revenue. Milestones that are not considered substantive are accounted for as license payments and are evaluated as such in accordance with ASU 2009-13. Sales-based and commercial milestones are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

***Fair Value Measurements***

The Company has certain financial assets recorded at fair value which have been classified as Level 1 or 2 within the fair value hierarchy as described in the accounting standards for fair value measurements. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

- Level 1 Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities;

- Level 2 Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves; and

- Level 3 Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, unbilled revenue, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities. The carrying amounts of the capital lease obligations approximate their fair values due to their variable interest rates.

***Concentration of Credit Risks***

The Company s primary exposure to credit risk derives from its cash, cash equivalents, marketable securities and accounts receivable.

The Company invests its cash in bank deposits, money market accounts, corporate debt securities, United States treasury obligations, commercial paper and United States government-sponsored enterprise securities in accordance with its investment policy. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk.

***Marketable Securities***

Available-for-sale debt securities are recorded at fair market value. Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive income (loss) in stockholders equity unless the security has experienced a credit loss, the Company intends to sell the security or the Company has determined that it is more likely than not that it will have to sell the security before its expected recovery, in which case the unrealized loss would be recognized in results of operations. Realized gains and losses are reported in interest income on a specific identification basis. There were no charges taken for other-than-temporary declines in fair value of marketable securities and no realized gains or losses on marketable securities during the three months ended March 31, 2012 and 2011.

***Accounts Receivable and Unbilled Revenue***

Accounts receivable represents amounts due to the Company at March 31, 2012 and December 31, 2011 from one collaborative partner related to sales of enoxaparin sodium injection and reimbursement of research and development expenses. Unbilled revenue represents amounts owed at March 31, 2012 and December 31, 2011 from the same collaborative partner for reimbursement of research and development expenses. The Company has not recorded any allowance for uncollectible accounts or bad debt write-offs and it monitors its receivables to facilitate timely payment.

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***Deferred Revenue***

Deferred revenue represents consideration received from our collaboration partners in advance of achieving certain criteria that must be met for revenue to be recognized in conformity with GAAP.

***Property and Equipment***

Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs which do not improve or extend the life of the respective assets are charged to expense. Upon disposal, the related cost and accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leased assets meeting certain capital lease criteria are capitalized and the present value of the related lease payments is recorded as a liability. Assets under capital lease arrangements are depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter.

***Long-Lived Assets***

The Company evaluates the recoverability of its property, equipment and intangible assets when circumstances indicate that an event of impairment may have occurred. The Company recognizes an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the fair value of such assets or businesses. No impairment charges have been recognized through March 31, 2012.

***Research and Development***

Research and development costs are expensed as incurred. Research and development costs include salaries and related expenses for personnel, license fees, consulting fees, nonclinical and clinical trial costs, contract research and manufacturing costs, and the costs of laboratory equipment and facilities.

Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are received.

***Share-Based Compensation Expense***

The Company recognizes the fair value of share-based compensation in its consolidated statements of operations. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under the Company s stock option plans and employee stock purchase plan. The Company recognizes share-based compensation expense equal to the fair value of stock options on a straight-line basis over the requisite service period. Restricted stock awards are recorded as compensation cost, based on the market value on the date of the grant, on a straight-line basis over each award s explicit or implicit service periods. The Company estimates an award s implicit service period based on its best estimate of the period over which an award s vesting conditions will be achieved. The Company reviews and evaluates these estimates on a quarterly basis and will recognize any remaining unrecognized compensation as of the date of an estimate revision over the revised remaining implicit service period. The Company issues new shares upon stock option exercises, upon the grant of restricted stock awards and under the Company s employee stock purchase plan.

The Company estimates the fair value of each option award on the date of grant using the Black-Scholes-Merton option-pricing model. The Black-Scholes-Merton option-pricing model requires the Company to develop certain subjective assumptions including the expected volatility of the Company s stock, the expected term of the award and the expected forfeiture rate associated with the Company s stock option plans. The Company considers, among other factors, the implied volatilities of its own currently traded options to provide an estimate of volatility based upon current trading activity. The Company uses a blended volatility rate based upon its own historical performance, as well as the implied volatilities of its own currently traded options, as it believes this appropriately reflects the expected volatility of its stock. The Company uses a blend of its own historical data and peer data to estimate option exercise and employee termination behavior, adjusted for known trends, to arrive at the estimated expected life of an option. For purposes of identifying peer entities, the Company considers characteristics such as industry, stage of life cycle and financial leverage. The Company reviews and evaluates these assumptions regularly to reflect recent historical data. The risk-free interest rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of grant.

The Company applies an estimated forfeiture rate to current period expense to recognize share-based compensation expense only for those stock and option awards expected to vest. The Company estimates forfeitures based upon historical data, adjusted for known trends, and will

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adjust its estimate of forfeitures if actual forfeitures differ, or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of change and will also impact the amount of share-based compensation expense in future periods.

Unvested stock options held by consultants are revalued using the Company s estimate of fair value at each balance sheet date.

***Net (Loss) Income Per Share***

The Company computes basic net (loss) income per share by dividing net (loss) income by the weighted average number of shares outstanding, which includes common stock issued as a result of public offerings, stock option exercises, stock purchased under the Company s employee stock purchase plan and vesting of shares of restricted common stock. Diluted net (loss) income per share is computed by dividing net (loss) income by the weighted average number of shares and potential shares from outstanding stock options and unvested restricted stock determined by applying the treasury stock method.

***Income Taxes***

The Company determines its deferred tax assets and liabilities based on the differences between the financial reporting and tax bases of assets and liabilities. The deferred tax assets and liabilities are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

The Company applies judgment in the determination of the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense.

In March 2012, the Company entered into a Tax Incentive Agreement with the Massachusetts Life Sciences Center ( MLSC ) under the MLSC s Life Sciences Tax Incentive Program (the Program ) to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences in the Commonwealth of Massachusetts. The Program was established in 2008 in order to incentivize life sciences companies to create new sustained jobs in Massachusetts. Under the Tax Incentive Agreement, the Company expects to receive a job creation tax award in the amount of $1.2 million. Jobs must be maintained for at least five years, during which time a portion of the grant proceeds can be recovered by the Massachusetts Department of Revenue if the Company does not meet and maintain its job creation commitments. The Company will recognize the award as other income in its consolidated statements of comprehensive (loss) income over the period the Company satisfies its job creation commitments.

The Company files income tax returns in the United States federal jurisdiction and multiple state jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination for years before 2004, except to the extent that in the future it utilizes net operating losses or tax credit carry forwards that originated before 2004. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

***Segment Reporting***

Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, the discovery, development and commercialization of pharmaceutical products. All of the Company s revenues through March 31, 2012 have come from two collaborative partners and are based solely on activities in the United States.

***Comprehensive Loss***

In May 2011, the FASB issued ASC Update No. 2011-05, Comprehensive Income (Topic 820): Presentation of Comprehensive Income. Update No. 2011-05 requires that net income, items of other comprehensive income and total comprehensive income be presented in one continuous statement or two separate consecutive statements. The amendments in this Update also require that reclassifications from other comprehensive income to net income be presented on the face of the financial statements. The Company adopted Update No. 2011-05 for its first quarter ending March 31, 2012, with the exception of the presentation of reclassifications on the face of the financial statements, which has been deferred by the FASB until further notice. Update No. 2011-05 is related to presentation only and does not impact the Company s results of operations or financial position. See the unaudited condensed consolidated statements of comprehensive (loss) income for relevant disclosures.

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***Recently Issued Accounting Standards***

In December 2011, the FASB issued ASC Update No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities. Update No. 2011-11 requires an entity to disclose both gross and net information about instruments and transactions eligible for offset in its statement of financial position as well as instruments and transactions executed under a master netting or similar arrangement and was issued to enable users of financial statements to understand the effects or potential effects of those arrangements on its financial position. Update No. 2011-11 is required to be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning on or after January 1, 2013. As this accounting standard only requires enhanced disclosure, the adoption of this standard is not expected to have an impact on the Company s financial position or results of operations.

**3. Net (Loss) Income Per Share**

The following table sets forth the Company s reconciliation of basic and diluted share amounts (amounts in thousands, except per share amounts):

| | For the Three Months Ended March 31, 2012 | For the Three Months Ended March 31, 2011 |
|---|---|---|
| Numerator: | | |
| Net (loss) income | $ (4,982) | $ 57,006 |
| | | |
| Denominator: | | |
| Basic weighted average shares outstanding | 50,240 | 49,532 |
| Weighted average stock equivalents from assumed exercise of stock options and restricted stock awards | | 802 |
| Diluted weighted average shares outstanding | 50,240 | 50,334 |
| | | |
| Basic net (loss) income per share | $ (0.10) | $ 1.15 |
| Diluted net (loss) income per share | $ (0.10) | $ 1.13 |
| | | |
| Weighted average anti-dilutive shares related to: | | |
| Outstanding stock options | 3,148 | 2,324 |
| Restricted stock awards | 933 | 37 |

For the three months ended March 31, 2012, the effect of all potentially dilutive securities is anti-dilutive as the Company had a net loss for that period. Accordingly, basic and diluted net loss per share is the same for the three months ended March 31, 2012.

The weighted average anti-dilutive shares shown in the foregoing table were not included in the computation of diluted net (loss) income per share. In those reporting periods in which the Company has reported net income, anti-dilutive shares comprise those common stock equivalents that have either an exercise price above the average stock price for the period or average unrecognized share-based compensation expense related to the common stock equivalents is sufficient to buy back the entire amount of shares. In those reporting periods in which the Company has a net loss, anti-dilutive shares comprise the impact of those number of shares that would have been dilutive had the Company had net

income plus the number of common stock equivalents that would be anti-dilutive had the Company had net income. Furthermore, performance-based restricted common stock awards which vest based upon FDA marketing approval for M356, the Company s second major generic program, in the United States, were excluded from diluted shares outstanding as the vesting condition had not been met as of the end of the first quarter of 2012 and 2011.

**4. Fair Value Measurements**

The tables below present information about the Company s assets that are measured at fair value on a recurring basis as of March 31, 2012 and December 31, 2011 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, which is described further within Note 2, *Summary of Significant Accounting Policies*.

In May 2011, the FASB issued ASC Update No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs. Update No. 2011-04 clarifies the FASB s intent about the application of certain existing fair value measurement and disclosure requirements and changes certain principles or requirements for measuring or disclosing information about fair value. It requires, for all Level 3 fair value measurements, new quantitative information about significant unobservable inputs used. The Company has adopted Update No. 2011-04 for its first quarter ending March 31, 2012. Update No. 2011-04 does not impact the Company s results of operations or financial position.

The Company s financial assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period, typically utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and

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economic events. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. The Company did not adjust or override any fair value measurements provided by its pricing services as of March 31, 2012 and December 31, 2011.

There have been no transfers of assets between the fair value measurement classifications.

The following tables set forth the Company s financial assets that were recorded at fair value at March 31, 2012 and December 31, 2011 (in thousands):

| Description | Balance as of March 31, 2012 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 37,000 | $ 23,500 | $ 13,500 | $ |
| Marketable securities: | | | | |
| U.S. Government-sponsored enterprise obligations | 141,737 | | 141,737 | |
| Corporate debt securities | 117,987 | | 117,987 | |
| Commercial paper obligations | 75,723 | | 75,723 | |
| Foreign government bonds | 8,157 | | 8,157 | |
| Total | $ 380,604 | $ 23,500 | $ 357,104 | $ |

| Description | Balance as of December 31, 2011 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 45,316 | $ 45,316 | $ | $ |
| Marketable securities: | | | | |
| U.S. Government-sponsored enterprise obligations | 163,997 | | 163,997 | |
| Corporate debt securities | 64,245 | | 64,245 | |
| Commercial paper obligations | 66,245 | | 66,245 | |
| Foreign government bond | 6,705 | | 6,705 | |
| U.S. Treasury obligation | 1,001 | 1,001 | | |
| Total | $ 347,509 | $ 46,317 | $ 301,192 | $ |

In the tables above, as of March 31, 2012 and December 31, 2011, corporate debt securities include $18.6 million and $28.5 million, respectively, of Federal Deposit Insurance Corporation, or FDIC, guaranteed senior notes issued by financial institutions under the FDIC s Temporary Liquidity Guarantee Program.

The Company did not have any non-recurring fair value measurements on any assets or liabilities at March 31, 2012 and December 31, 2011.

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**5. Cash, Cash Equivalents and Marketable Securities**

The following tables summarize the Company s cash, cash equivalents and marketable securities as of March 31, 2012 and December 31, 2011 (in thousands):

| As of March 31, 2012 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Cash and money market funds | $ 25,158 | $ | $ | $ 25,158 |
| U.S. Government-sponsored enterprise obligations | | | | |
| Due in one year or less | 39,343 | 6 | (2) | 39,347 |
| Due in two years or less | 102,390 | 17 | (17) | 102,390 |
| Corporate debt securities | | | | |
| Due in one year or less | 86,003 | 25 | (27) | 86,001 |
| Due in two years or less | 32,035 | | (49) | 31,986 |
| Commercial paper obligations due in one year or less | 89,143 | 79 | | 89,222 |
| Foreign government bonds due in one year or less | 8,163 | | (6) | 8,157 |
| Total | $ 382,235 | $ 127 | $ (101) | $ 382,261 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 38,656 | $ 1 | $ | $ 38,657 |
| Marketable securities | 343,579 | 126 | (101) | 343,604 |
| Total | $ 382,235 | $ 127 | $ (101) | $ 382,261 |

| As of December 31, 2011 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Cash and money market funds | $ 46,245 | $ | $ | $ 46,245 |
| U.S. Government-sponsored enterprise obligations | | | | |
| Due in one year or less | 53,730 | 10 | (4) | 53,736 |
| Due in two years or less | 110,344 | 11 | (94) | 110,261 |
| Corporate debt securities | | | | |
| Due in one year or less | 63,224 | 12 | (48) | 63,188 |
| Due in two years or less | 1,060 | | (3) | 1,057 |
| Commercial paper obligations due in one year or less | 66,193 | 52 | | 66,245 |
| Foreign government bond due in one year or less | 6,722 | | (17) | 6,705 |
| U.S. Treasury obligations due in one year or less | 1,001 | | | 1,001 |
| Total | $ 348,519 | $ 85 | $ (166) | $ 348,438 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 49,244 | $ 1 | $ | $ 49,245 |

| | | | | |
|---|---|---|---|---|
| Marketable securities | 299,275 | 84 | (166) | 299,193 |
| Total | $ 348,519 | $ 85 | $ (166) | $ 348,438 |

At March 31, 2012, the Company held 38 marketable securities that were in a continuous unrealized loss position for less than one year. At December 31, 2011, the Company held 35 marketable securities that were in a continuous unrealized loss position for less than one year.

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The unrealized losses were caused by fluctuations in interest rates. The following table summarizes the aggregate fair value of these securities at March 31, 2012 and December 31, 2011 (in thousands):

| | As of March 31, 2012 | | As of December 31, 2011 | |
|---|---|---|---|---|
| | Aggregate Fair Value | Unrealized Losses | Aggregate Fair Value | Unrealized Losses |
| U.S. Government-sponsored enterprise obligations | $ 54,867 | $ (19) | $ 104,107 | $ (98) |
| Corporate debt securities | $ 86,077 | $ (76) | $ 36,582 | $ (51) |
| Foreign government bonds | $ 8,157 | $ (6) | $ 6,705 | $ (17) |

At March 31, 2012 and December 31, 2011, no marketable securities were in a continuous unrealized loss position for greater than one year.

To determine whether an other-than-temporary impairment exists, the Company considers whether it intends to sell the debt security and, if it does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. The Company reviewed its investments with unrealized losses and concluded that no other-than-temporary impairment existed at March 31, 2012 as it has the ability and intent to hold these investments to maturity and it is not more likely than not that it will be required to sell the security before the recovery of its amortized cost basis.

**6. Intangible Assets**

As of March 31, 2012 and December 31, 2011, intangible assets, net of accumulated amortization, are as follows (in thousands):

| | | As of March 31, 2012 | | As of December 31, 2011 | |
|---|---|---|---|---|---|
| | Weighted Average Amortization Period (in years) | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization |
| Core and developed technology | 10 | $ 10,257 | $ (2,750) | $ 10,257 | $ (2,485) |
| Non-compete agreement | 2 | 170 | (170) | 170 | (170) |
| Total intangible assets | 10 | $ 10,427 | $ (2,920) | $ 10,427 | $ (2,655) |

The Company s intangible assets are described within Note 10, *Related Party Transactions*.

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets as there is no other pattern of use that is reasonably estimable. Amortization expense was approximately $0.3 million and $75,000 for the three months ended March 31, 2012 and 2011, respectively.

The Company expects to incur amortization expense of appropriately $1.1 million per year for each of the next five years.

**7. Restricted Cash**

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Watson Pharmaceuticals Inc. ( Watson ), Amphastar Pharmaceuticals Inc. ( Amphastar ) and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar). The $17.5 million is held in an escrow account by Hanover Insurance.

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**8. Collaboration and License Agreements**

***2003 Sandoz Collaboration***

Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell enoxaparin sodium injection in the United States. The Company agreed to provide development and related services on a commercially reasonable basis, which included developing a manufacturing process to make enoxaparin sodium injection, scaling up the process, contributing to the preparation of an Abbreviated New Drug Application, or ANDA, in Sandoz s name to be filed with the United States Food and Drug Administration, or FDA, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product. The Company identified two significant deliverables in this arrangement consisting of: (i) a license and (ii) development and related services. The Company determined that the license did not meet the criteria for separation as it did not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company determined that a single unit of accounting exists with respect to the 2003 Sandoz Collaboration.

In July 2010, the FDA granted marketing approval of the ANDA for enoxaparin sodium injection filed by Sandoz. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents, or FTEs, performing development and related services. The profit-share or royalties Sandoz is obligated to pay the Company under the 2003 Sandoz Collaboration differ depending on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there is one or more third-party which is not Sanofi-Aventis marketing a Lovenox-Equivalent Product. Until October 2011, no third-party competitors were marketing a Lovenox-Equivalent Product; therefore, Sandoz paid the Company 45% of the contractual profits from the sale of enoxaparin sodium injection. The Company earned $22.0 million in profit share/royalty product revenue and $75.8 million in profit share product revenue from Sandoz during the three months ended March 31, 2012 and 2011, respectively. Profits on sales of enoxaparin sodium injection are calculated by deducting from net sales the cost of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was obligated to pay the Company a royalty on its net sales of enoxaparin sodium injection until the contractual profits from those net sales in a product year (July 1 June 30) reached a certain threshold, which was achieved in December 2011, at which point the Company reverted back to receiving profit share revenue. Additionally, in October 2011, FDA approved the ANDA for the enoxaparin product of Watson and Amphastar. In January 2012, following the Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued against them by the United States District Court, Watson announced that it and Amphastar intended to launch their enoxaparin product. Consequently, Sandoz is obligated to pay the Company a royalty on net sales in each post-launch contract year, which for net sales up to a pre-defined sales threshold is payable at a 10% rate, and for net sales above the sales threshold increases to 12%.

If certain milestones were achieved with respect to enoxaparin sodium injection under certain circumstances, Sandoz agreed to make payments to the Company which would reach $55 million if all such milestones were achieved. Under the 2003 Sandoz Collaboration, in July 2010, upon the achievement of a regulatory milestone the Company earned and recognized $5.0 million in research and development revenue. In addition, no third-party competitors had marketed a Lovenox-Equivalent Product as of July 2011, the one year anniversary of the FDA s approval of enoxaparin sodium for injection. As a result, for the year ended December 31, 2011, the Company earned and recognized $10.0 million in product revenue upon the achievement of a commercial milestone. The Company is no longer eligible to receive milestones under the 2003 Sandoz Collaboration because the remaining milestones were contingent upon there being no third-party competitors marketing an interchangeable generic version of a Lovenox-Equivalent Product.

A portion of the development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, are offset against profit-sharing amounts, royalties and milestone payments. Sandoz also may offset a portion of any product liability costs and certain other expenses arising from patent litigation against any profit-sharing amounts, royalties and milestone payments.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services, except with respect to any amounts due Sandoz for manufacturing raw material purchases, which are recorded on a net basis as an offset to the related development expense. There have been no such manufacturing raw material purchases since 2006.

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***2006 Sandoz Collaboration***

Pursuant to the terms of the Stock Purchase Agreement, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG, an affiliate of Sandoz AG, at a per share price of $15.93 (the closing price of the Company s common stock on the NASDAQ Global Market was $13.05 on the date of the Stock Purchase Agreement) for an aggregate purchase price of $75.0 million, resulting in a paid premium of $13.6 million. The Company recognizes revenue from the $13.6 million paid premium on a straight-line basis over the estimated development period of approximately six years beginning in June 2007. The Company recognized research and development revenue relating to this paid premium of approximately $0.5 million for each of the three months ended March 31, 2012 and 2011. Under the 2006 Sandoz Collaboration, the Company and Sandoz AG expanded the geographic markets for enoxaparin sodium injection covered by the 2003 Sandoz Collaboration to include the European Union and further agreed to exclusively collaborate on the development and commercialization of M356 for sale in specified regions of the world. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions. The Company has agreed to provide development and related services on a commercially reasonable basis, which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market any products covered by the 2006 Sandoz Collaboration. The Company identified two significant deliverables in this arrangement consisting of (i) a license and (ii) the development and related services. The Company determined that the license did not meet the criteria for separation as it does not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company has determined that a single unit of accounting exists with respect to the 2006 Sandoz Collaboration.

The term of the Second Sandoz Collaboration Agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party pursuant to the provisions of the Second Sandoz Collaboration Agreement. Sandoz AG has agreed to indemnify the Company for various claims, and a certain portion of such costs may be offset against certain future payments received by the Company.

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization responsibilities and costs will be borne by Sandoz AG. Under the 2006 Sandoz Collaboration, the Company is paid at cost for any external costs incurred in the development of products where development activities are funded solely by Sandoz AG or partly in proportion where development costs are shared between the Company and Sandoz AG. The Company also is paid at a contractually specified rate for FTEs performing development services where development activities are funded solely by Sandoz AG or partly by proportion where development costs are shared between the Company and Sandoz AG. The parties will share profits in varying proportions, depending on the product. The Company is eligible to receive up to $163.0 million in milestone payments upon the achievement of certain regulatory, commercial and sales-based milestones that include $10.0 million in regulatory milestones related to the approval by the FDA of M356 and $153.0 million in sales-based and commercial milestones. The Company has concluded that the regulatory milestones pursuant to its 2006 Sandoz Collaboration are substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Revenues from non-refundable regulatory milestones are recognized upon successful accomplishment of the milestones as research and development revenue. Sales-based and commercial milestones are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services, except with respect to any amounts due

Sandoz for shared development costs, which are recorded on a net basis.

***Baxter Agreement***

In December 2011, the Company and Baxter entered into the Baxter Agreement under which the Company agreed to collaborate, on a world-wide basis, on the development and commercialization of two follow-on biologic products. In addition, Baxter has the right, for a three year period, to select up to four additional follow-on biologic products to be included in the collaboration. The Baxter Agreement became effective in February 2012, following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended.

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Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize designated products for all therapeutic indications. The Company has agreed to provide development and related services on a commercially reasonable basis through acceptance of an Investigational New Drug application, or IND, for each product, which include high-resolution analytics, characterization, and product and process development. Baxter is responsible for clinical development, manufacturing and commercialization activities and will exclusively distribute and market any products covered by the Baxter Agreement. The Company has the right to participate in a joint steering committee, consisting of an equal number of members from the Company and Baxter, to oversee and manage the development and commercialization of products under the collaboration. Costs, including development costs, payments to third parties for intellectual property licenses, and expenses for legal proceedings, including the patent exchange process pursuant to the Biologics Price Competition and Innovation Act of 2009, will be borne by the parties in varying proportions, depending on the type of expense and the stage of development. The Company has the option to participate, at its discretion, in a cost and profit share arrangement for the four additional products up to 30%. If the profit share is elected, the royalties payable would be reduced by up to nearly half. Absent a cost share arrangement, the Company will generally be responsible for research and process development costs prior to filing an IND, and the cost of in-human clinical trials, manufacturing in accordance with current good manufacturing practices and commercialization will be borne by Baxter.

In addition, the Company has agreed, for a period commencing six months following the effective date and ending on the earlier of (i) three years from the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement) or (ii) the selection of the four additional products, to notify Baxter of bona fide offers from third parties to develop or commercialize a follow-on biologic product that could be an additional product candidate. Following such notification, if Baxter does not select such proposed product or products for inclusion in the collaboration, the Company has the right to develop, manufacture, and commercialize such product or products on its own or with a third party. The Company also agreed to provide Baxter with a right of first negotiation with respect to collaborating in the development of a competing product for a period of three years following the effectiveness of an IND exemption or waiver or regulatory authority authorization to dose humans, subject to certain restrictions as outlined in the Baxter Agreement. Following the third anniversary of the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement), the Company may develop, on its own or with a third party, any follow-on biologic products not named under the Baxter Agreement, subject to certain restrictions.

Under the terms of the Baxter Agreement, the Company received an initial cash payment of $33 million. The Company is eligible to receive from Baxter license payments totaling $28 million for the exercise of the options with respect to the additional four product candidates that can be named under the Baxter Agreement, payments of $5 million each for extensions of the period during which such additional products may be named, which is referred to as the naming period, and a license payment of $7 million upon the achievement of certain development criteria, as defined in the agreement, for M834 (a named follow-on biologic product). The Company is also eligible to receive from Baxter an aggregate of approximately $384 million in potential milestone payments, comprised of (i) up to $84 million in substantive milestone payments upon achievement of specified technical and development milestone events across the six product candidates, and (ii) regulatory milestones totaling up to $300 million, on a sliding scale, across the six product candidates where, based on the products regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval. The technical and development milestones include (i) achievement of certain criteria that will ultimately drive commercial feasibility for manufacturing the products and (ii) acceptance by the FDA of an IND application. The first anticipated technical and development milestone is $6 million and is due to the Company upon achievement of technical criteria for the M923 product (a named follow-on biologic product). The timing of this milestone is uncertain as the Company has not finalized its product development plans.

In addition, if any of the six products are successfully developed and launched, Baxter will be required to pay to the Company royalties on net sales of licensed products worldwide, with a base royalty rate in the high single digits with the potential for significant tiered increases based on the number of competitors, the interchangeability of the product, and the sales tier for each product. The maximum royalty with all potential increases would be slightly more than double the base royalty.

The term of the collaboration shall continue throughout the development and commercialization of the products, on a product-by-product and country-by-country basis, until there is no remaining payment obligation with respect to a product in the relevant territory, unless earlier terminated by either party pursuant to the terms of the Baxter Agreement.

The Baxter Agreement may be terminated by:

- either party for breach by or bankruptcy of the other party;

- the Company in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;

- Baxter for its convenience; or

- the Company in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided that we also have certain rights to directly commercialize such product, as opposed to terminating the Baxter Agreement, in event of such a breach by Baxter.

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In accordance with ASU No. 2009-13, the Company identified all of the deliverables at the inception of the Baxter Agreement. The deliverables were determined to include (i) the development and product licenses to the two initial follow-on biologic products and the four additional follow-on biologic products, (ii) the research and development services related to the two initial follow-on biologic products and the four additional follow-on biologic products and (iii) the Company s participation in a joint steering committee. The Company has determined that each of the license deliverables do not have stand-alone value apart from the related research and development services deliverables as there are no other vendors selling similar, competing products on a stand-alone basis, Baxter does not have the contractual right to resell the license, and Baxter is unable to use the license for its intended purpose without the Company s performance of research and development services. As such, the Company determined that separate units of accounting exist for each of the six licenses together with the related research and development services, as well as the joint steering committee with respect to this arrangement. The estimated selling prices for these units of accounting were determined based on similar license arrangements and the nature of the research and development services to be performed for Baxter and market rates for similar services. The arrangement consideration of $61 million, which includes the $33 million upfront payment and aggregate option payments of $28 million, was allocated to the units of accounting based on the relative selling price method. Of the $61 million, $10.3 million has been allocated to the first initial product license together with the related research and development services, $10.3 million to each of the four additional product licenses with the related research and development services, $9.4 million has been allocated to the second initial product license together with the related research and development services due to that product s stage of development at the time the license was delivered, and $114,000 has been allocated to the joint steering committee unit of accounting. The Company will commence revenue recognition for each of the six units of accounting related to the products upon delivery of the related development and product license and will record this revenue on a straight-line basis over the applicable performance period during which the research and development services will be delivered. The Company will recognize the revenue related to the joint steering committee deliverable over the applicable performance period during which the research and development services will be delivered. The Company has commenced recognition of the revenue allocated to the two initial products but not for the four additional products as those licenses have not been delivered. The Company recognized revenue relating to this agreement of approximately $0.6 million for the three months ended March 31, 2012. The portion of the upfront payment that is unearned at March 31, 2012 is included in deferred revenue.

Any associated royalty or profit sharing payments will be considered contingent fees that will be recorded as earned in future periods. Baxter s option to extend the naming period is considered to be substantive. As such, potential fees associated with the naming period extensions will be recognized in future periods if and when Baxter exercises its right to extend the naming period for any additional products.

The Company has concluded that all of the technical, development and regulatory milestones pursuant to the Baxter Agreement are substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve these milestones, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Revenues from non-refundable technical, development and regulatory milestones will be recognized upon successful accomplishment of the milestones as research and development revenue.

***Massachusetts Institute of Technology***

The Company has two patent license agreements with the Massachusetts Institute of Technology ( M.I.T. ) that grant the Company various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to methods and technologies for analyzing and characterizing sugars and certain heparins, heparinases and other enzymes and synthesis methods. Subject to typical retained rights of M.I.T. and the United States government, the Company was granted exclusive rights under certain of these patents and applications in certain fields.

The Company must meet certain diligence requirements in order to maintain the licenses under the two agreements. Under the agreements, the Company must expend at least $1.0 to $1.2 million per year towards the research, development and commercialization of products and processes covered by the agreements. In addition, the Company is obligated to make first commercial sales and meet certain minimum sales thresholds of products or processes including, under the amended and restated license agreement, a first commercial sale of a product or process no later than June 2013 and minimal sales of products thereafter ranging from $0.5 million to $5.0 million annually. M.I.T. may convert the exclusive licenses under the amended and restated license agreement to non-exclusive licenses, as its sole remedy, if the Company fails to meet its diligence obligations. Under the license agreement covering sequencing machines, M.I.T. has the right to treat a failure by the Company to fulfill its diligence obligations as a material breach of the license agreement.

In exchange for the licenses granted in the two agreements, the Company has paid M.I.T. license issue fees and annual aggregate license and maintenance fees of $157,500. The Company is also required to pay M.I.T. royalties on certain products and services covered by the licenses and sold by the Company or its affiliates or sublicensees, a percentage of certain other income received by the Company from corporate partners and sublicensees, and certain patent prosecution and maintenance costs. The Company recorded $39,000 as license and maintenance fees in each of the three months ended March 31, 2012 and 2011, and $0.4 million and $1.4 million as royalty fees in the three months ended March 31, 2012 and 2011, respectively, related to these agreements.

The Company granted Sandoz a sublicense under the amended and restated license agreement with M.I.T to certain of the patents and patent applications licensed to the Company. If M.I.T. converts the Company s exclusive licenses under this agreement to non-exclusive licenses due to the Company s failure to meet diligence obligations, or if M.I.T. terminates this agreement, M.I.T. will honor the exclusive nature of the sublicense the Company granted to Sandoz so long as Sandoz continues to fulfill its obligations to the Company under the

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collaboration and license agreement the Company entered into with Sandoz and, if the Company s agreement with M.I.T. is terminated, Sandoz agrees to assume the Company s rights and obligations to M.I.T.

**9. Share-Based Payments**

***2004 Stock Incentive Plan***

The Company s 2004 Stock Incentive Plan, as amended, allows for the granting of incentive and nonstatutory stock options, restricted stock awards, stock appreciation rights and other share-based awards to employees, officers, directors, consultants and advisors. At December 31, 2011, the Company was authorized to issue up to 13,369,141 shares of common stock with annual increases (to be added on the first day of the Company s fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) equal to the lowest of (i) 1,974,393 shares, (ii) 5% of the then outstanding number of common shares or (iii) such other amount as the Board of Directors may authorize. Effective January 1, 2012, the Company s Board of Directors increased the number of authorized shares by 1,974,393 shares. At March 31, 2012, the Company had 6,525,430 shares available for grant under the 2004 Stock Incentive Plan.

***Share-Based Compensation Expense***

Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the Company s employee stock purchase plan for the three months ended March 31, 2012 and 2011 was $3.3 million and $1.8 million, respectively.

Share-based compensation expense related to outstanding employee stock option grants and the Company s employee stock purchase plan was $1.8 million and $1.5 million for the three months ended March 31, 2012 and 2011, respectively. During the three months ended March 31, 2012, the Company granted 806,575 stock options, of which 697,875 were in connection with annual merit awards and 108,700 were granted to new hires. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended March 31, 2012 and 2011 was $9.37 and $8.75 per option, respectively.

The following table summarizes the weighted average assumptions the Company used in its fair value calculations at the date of grant:

| | Weighted Average Assumptions | | | |
|---|---|---|---|---|
| | Stock Options | | Employee Stock Purchase Plan | |
| | For the Three Months Ended March 31, 2012 | For the Three Months Ended March 31, 2011 | For the Three Months Ended March 31, 2012 | For the Three Months Ended March 31, 2011 |
| Expected volatility | 65% | 69% | 66% | 78% |

| | | | | |
|---|---|---|---|---|
| Expected dividends | | | | |
| Expected life (years) | 6.5 | 6.5 | 0.5 | 0.5 |
| Risk-free interest rate | 1.4% | 2.9% | 0.1% | 0.2% |

At March 31, 2012, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $13.2 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.9 years.

During the three months ended March 31, 2012, holders of options issued under the Company s stock plans exercised their right to acquire an aggregate of 41,946 shares of common stock. Additionally, during the three months ended March 31, 2012, the Company issued 22,457 shares of common stock to employees under the Company s employee stock purchase plan.

***Restricted Stock Awards***

The Company has also made awards of restricted common stock to employees, officers and directors. During the three months ended March 31, 2012, the Company awarded 134,892 shares of restricted common stock to its officers in connection with its annual merit grant, which generally fully vest over the four years following the grant date. During the three months ended March 31, 2012, the Company awarded 24,750 shares of performance-based restricted common stock to newly hired employees of the Company. The performance condition for these awards is the marketing approval from the FDA for M356, the Company s second major generic program, in the United States. To date, the Company has 855,540 shares of unvested restricted common stock tied to this M356 performance condition to its employees and officers. The awards of restricted common stock are generally forfeited if the employment relationship terminates with the Company prior to vesting.

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The Company recorded share-based compensation expense related to outstanding restricted stock awards, including the performance-based shares, because the Company determined that it was probable the performance condition would be achieved, of $1.4 million and $0.4 million for the three months ended March 31, 2012 and 2011, respectively. As of March 31, 2012, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $11.9 million, which is expected to be recognized over the weighted average remaining requisite service period of 2.3 years.

A summary of the status of nonvested shares of restricted stock as of March 31, 2012 and the changes during the three months then ended are presented below:

| | Number of Shares (in thousands) | | Weighted Average Grant Date Fair Value |
|---|---|---|---|
| Nonvested at January 1, 2012 | 1,107 | $ | 14.29 |
| Granted | 159 | | 15.42 |
| Vested | (62) | | 12.27 |
| Forfeited | (9) | | 14.55 |
| | | | |
| Nonvested at March 31, 2012 | 1,195 | $ | 14.54 |

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of March 31, 2012 are summarized below:

| Vesting Schedule | Nonvested Shares (in thousands) |
|---|---|
| Time-based | 340 |
| Performance-based | 855 |
| | |
| Nonvested at March 31, 2012 | 1,195 |

**10. Related Party Transactions**

In April 2007, the Company entered into an asset purchase agreement, or the Purchase Agreement, with Parivid, LLC, or Parivid, a provider of data integration and analysis services to the Company, and S. Raguram, the principal owner and Chief Technology Officer of Parivid. Parivid is considered to be a related party because a co-founder and former member of the Company s Board of Directors is the brother of S. Raguram. Pursuant to the Purchase Agreement, the Company acquired patent rights, software, know-how and other intangible assets, and assumed certain specified liabilities, of Parivid related to the acquired assets in exchange for $2.5 million in cash paid at closing and up to $11.0 million in contingent milestone payments in a combination of cash and/or stock in the manner and on the terms and conditions set forth in the Purchase Agreement.

In July 2011, the Company entered into an Amendment to the Purchase Agreement pursuant to which the parties agreed that a milestone payment would be made in cash rather than through the issuance of Company stock. In August 2011, the Company paid Parivid $6.7 million in

cash, in lieu of stock, pursuant to this Amendment as consideration for the completion and satisfaction of a milestone related to the enoxaparin sodium injection developed technology that was achieved in July 2011. The Company capitalized the payment as developed technology, which is included in intangible assets in the condensed consolidated balance sheets. The developed technology is being amortized over the estimated useful life of the enoxaparin sodium injection developed technology of approximately 10 years.

**11. Legal Contingencies**

In August 2008, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against the Company, Sandoz and Novartis AG in the United Stated Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit alleges infringement by the Company, Sandoz and Novartis AG of Orange Book patents owned by Yeda and licensed by Teva and seeks monetary, injunctive and declaratory relief. In November 2008, the Company and Sandoz each filed responsive pleadings denying the allegations of infringement, setting forth affirmative defenses based on invalidity, non-infringement and inequitable conduct and counterclaims seeking declaratory relief

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that the patent rights of Teva and Yeda pertaining to M356 are either not infringed, invalid or unenforceable. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against the Company and Sandoz. In April 2011, Teva filed a motion for summary judgment of no inequitable conduct. In June 2011, the court denied Teva s motion and granted a bench trial, which occurred in July 2011, to hear the issue of inequitable conduct only. The trial on the remaining issues occurred in September 2011 in the consolidated case. There is no defined timeframe for the court to issue a decision.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and the Company for patent infringement related to certain non-Orange Book patents after Teva s motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, the Company and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending.

While the Company has vigorously defended these suits, a delay in a final judgment could significantly delay, impair or prevent its ability to commercialize M356 and the Company s business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or the Company will prevail in either lawsuit. At this time, the Company believes a loss is not probable.

In September 2011, the Company sued Amphastar, Watson and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of the Company s patents. Also in September, 2011, the Company filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted the Company s motion for a preliminary injunction and entered an order enjoining Amphastar, Watson and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and required the Company and Sandoz to post a security bond of $100 million to maintain the preliminary injunction. Amphastar, Watson and International Medical Systems, Ltd. filed a notice to appeal the decision and an emergency motion to dissolve or stay the preliminary injunction. In January 2012, the Court of Appeals for the Federal Circuit granted the motion to stay the preliminary injunction, pending appeal. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company loses the case at the District Court and it is determined that the preliminary injunction was improvidently granted, and Amphastar and Watson are able to prove they suffered damages as a result of the preliminary injunction, the Company could be liable for damages for up to $35 million of the security bond.

While the Company intends to vigorously prosecute this action against Watson and Amphastar, and believes that it can ultimately prove its case in court, this suit could last a number of years. As a result, absent preliminary injunctive relief, recovery of lost profits and damages could await a final judgment after an appeal of a district court decision. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz will prevail in this patent enforcement suit.

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**Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.**

Our Management s Discussion and Analysis of Financial Condition and Results of Operations includes the identification of certain trends and other statements that may predict or anticipate future business or financial results. There are important factors that could cause our actual results to differ materially from those indicated. See Risk Factors in Item 1A of Part II of this Quarterly Report Form 10-Q.

*Statements contained or incorporated by reference in this Quarterly Report Form 10-Q that are not based on historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the* Exchange *Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, current and future development and manufacturing efforts, regulatory filings, clinical trial results and the sufficiency of our cash for future operations. Forward-looking statements can be identified by terminology such as anticipate, believe, could, could increase the likelihood, hope, target, project, goals, potential, predict, might, estimate, expect, intend, is planned, may, should, will, will enable, would be expected, look forward, may provide, would or similar terms, variations of such terms or the negative of those terms.*

*We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below under Item 1A of Part II Risk Factors. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

**Business Overview**

***The Company***

We are a biotechnology company specializing in the structural characterization, process engineering and biologic systems analysis of complex molecules such as polysaccharides, polypeptides, and biologics (including proteins and antibodies). Our initial technology was built on the ability to characterize complex polysaccharides. Over the last decade, we have expanded our expertise into technologies that enable us to develop a diversified product portfolio of complex generic, follow-on biologic, and novel therapeutics. Our business strategy has been to develop both generic and novel therapeutics, and we are working with collaborative partners to develop and commercialize our complex generics and follow-on biologics. This strategy was validated by the marketing approval and commercial launch of enoxaparin sodium injection, a generic version of Lovenox®, in July 2010. Since its launch through March 31, 2012, we have recorded enoxaparin sodium injection product revenues totaling $379 million, driven primarily by its initial status as a sole generic. We believe that our scientific capabilities, engineering approaches, intellectual property and regulatory strategies, and unique business model position us to develop and commercialize competitively differentiated products in our target areas of complex generics, follow-on biologics and novel therapeutics.

***Our Programs***

Our complex generic programs target marketed products that were originally approved by the United States Food and Drug Administration, or FDA, as New Drug Applications, or NDAs. Therefore, we were able to access the existing generic regulatory pathway and submit Abbreviated New Drug Applications, or ANDAs, for these products. Our first commercial product, enoxaparin sodium injection, which we developed and commercialized in collaboration with Sandoz, an affiliate of Novartis AG, received FDA marketing approval in July 2010 as a generic version of Lovenox. Lovenox is a complex mixture of polysaccharide chains derived from naturally sourced heparin which is used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. The enoxaparin ANDA submitted by our collaborative partner Sandoz was the first ANDA for a generic Lovenox to be approved by FDA, validating our novel approaches to the structural characterization, process engineering and biologic systems analysis of complex molecules such as Lovenox. From July 2010 through early October 2011, the enoxaparin marketed by Sandoz was the sole generic version of Lovenox, and consequently, under the terms of our collaborative agreement with Sandoz, we earned a substantial profit share on Sandoz s net sales of enoxaparin. In developing our enoxaparin product, we filed for patent protection for certain of our enoxaparin-related technology and we have sought, and continue to seek, to enforce our issued patents.

Our second complex generic product candidate, M356, is designed to be a generic version of Copaxone® (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with relapsing-remitting multiple sclerosis, or RRMS. Copaxone consists of a synthetic mixture of polypeptide chains. With M356, we extended our core polysaccharide characterization and process engineering capabilities to develop capabilities for the structural characterization, process engineering and biologic systems analysis of this complex polypeptide mixture. We are also collaborating with Sandoz to develop and commercialize M356, and the Sandoz ANDA for M356 is

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currently under FDA review. In our development of M356 we filed for patent protection for certain of our M356-related technology, and if necessary, we may seek to enforce issued patents relating to our M356 product.

Our follow-on biologics (FOBs) program is targeted toward developing biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. In March 2010, an abbreviated regulatory process was codified in Section 351(k) of the Patient Protection and Affordable Care Act of 2010. This new pathway opens the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. Forecasters predict a rapidly growing multi-billion dollar global market for these products. Most of these biologic therapeutics are complex mixtures, and for several years we have been investing in novel approaches to the structural characterization, process engineering and analysis of biologic systems. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines state that FDA will use a step-wise review that considers the totality-of-the-evidence in determining extent of the development program. This approach puts a substantial emphasis on structural and functional characterization data in evaluating biosimilar products for approval. We believe the framework that the FDA has outlined in the draft guidance documents aligns with our strategy for follow-on biologics. Our goal is to engineer biologic therapeutics that will show minimal to no structural or functional differences from the reference brand product, thereby justifying a more selective and targeted approach to nonclinical and/or human clinical testing to support demonstration of biosimilarity and interchangeability.

Our novel therapeutics program leverages the capabilities and expertise built during the development of our complex generics and FOB programs to address unmet clinical needs. Our most advanced efforts have been in the area of polysaccharide mixtures. M402, our novel polysaccharide-based drug candidate, is in development as a potential anti-cancer agent that targets several different key biological mechanisms involved in cancer progression and metastasis. Our other polysaccharide-based drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared to other currently marketed anticoagulants to support the treatment of ACS. We will not move forward with further clinical trials of adomiparin unless we have a partner for that program. In addition to these two development candidates, we are also seeking to discover and develop additional novel drugs. Our goal is to leverage the multi-targeting nature of complex mixture molecules to develop novel therapeutics which could positively modulate multiple pathways in a disease. We believe that our core technology platform will enable us to map the critical nodes that regulate complex diseases. We will then be able to define the optimal therapeutic intervention to target the appropriate nodes. We have built significant capabilities in biological characterization and engineering of proteins through our FOB platform that allow us to create unique and novel formulations of protein and antibody drug compositions for specific disease indications. To add to these capabilities, in December 2011, we acquired selected assets of Virdante Pharmaceuticals, Inc. relating to sialic switch technology. Sialic acid is a type of sugar modification on selected proteins that is understood to regulate anti-inflammatory and immunomodulatory functions of these proteins. These assets add to our core ability to modify and engineer protein backbones to precisely regulate biological networks and develop novel biologic product candidates.

***Our Collaborations***

In 2003, we entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc. to jointly develop, manufacture and commercialize enoxaparin sodium injection. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration to Sandoz AG, an affiliate of Novartis Pharma AG. We refer to Sandoz AG and Sandoz Inc. together as Sandoz.

In 2006 and 2007, we entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, each with Novartis Pharma AG, and a collaboration and license agreement, or the Second Sandoz Collaboration Agreement, with Sandoz AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Second Sandoz Collaboration Agreement, we and Sandoz AG jointly develop, manufacture and commercialize M356. In connection with the 2006 Sandoz Collaboration, we sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of $15.93 (the closing price of our common stock on the NASDAQ Global Market

was $13.05 on the date of purchase) for an aggregate purchase price of $75.0 million, resulting in an equity premium of $13.6 million.

Prior to the launch of enoxaparin sodium injection in 2010, the collaboration revenues derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration primarily consisted of amounts earned by us for reimbursement by Sandoz of research and development services and development costs. In July 2010, Sandoz began the commercial sale of enoxaparin sodium injection. The profit-share or royalties Sandoz is obligated to pay us under the 2003 Sandoz Collaboration differ depending on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there is one or more third-party competitors which is not Sanofi-Aventis marketing a Lovenox-Equivalent Product. From July 2010 through September 2011, no third-party competitor was marketing a Lovenox-Equivalent Product; therefore, during that period, Sandoz paid us 45% of the contractual profits from the sale of enoxaparin sodium injection. In September 2011, FDA approved the ANDA for the enoxaparin product of Amphastar Pharmaceuticals, Inc. or Amphastar. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was

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obligated to pay us a royalty on its net sales of enoxaparin sodium injection until the contractual profits from those net sales in a product year (July 1 June 30) reached a certain threshold. Upon the achievement of the contractual profit threshold in December 2011, Sandoz was obligated to pay us a profit share for the remainder of the product year. In January 2012, following the Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued by the United States District Court, Watson Pharmaceuticals, Inc., or Watson, and Amphastar launched their third-party competitor enoxaparin product. Consequently, in each product year, for net sales of enoxaparin up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales payable at a 10% rate, and for net sales above the sales threshold, payable at a 12% rate.

Certain development and legal expenses may reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz. Any product liability costs and certain other expenses arising from patent litigation may also reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz, but only up to 50% of these amounts due to us from Sandoz each quarter. Our contractual share of these development and legal expenses is subject to an annual adjustment in each of the next four years, but the amount of any future payment due to the annual adjustment is not expected to be material.

In December 2011, we and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively Baxter, entered into a global collaboration and license agreement, or the Baxter Agreement, to develop and commercialize up to six FOBs. The Baxter Agreement became effective in February 2012. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities. To accelerate efforts in the FOB space and address this growing global market, we expect to significantly increase the headcount and related operating expenses dedicated to our FOB program in 2012 and 2013. We expect that the increase in operating expenses will be offset in future years by revenues from option fees and milestone payments under the Baxter Agreement, subject to achievement of technical criteria.

As of March 31, 2012, we had an accumulated deficit of $108.4 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. In the second half of 2010, we began to derive revenue from our profit share on the commercial sale of enoxaparin sodium injection. Due to the launch by Watson and Amphastar of an enoxaparin sodium injection product in January 2012, our enoxaparin product revenue has significantly decreased. Depending on the future outcome of enoxaparin litigation, we may incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. Additionally, we plan to continue to evaluate possible acquisitions or licensing of rights to additional technologies, products or assets that fit within our growth strategy. Accordingly, we will need to generate significant revenue to return to profitability.

**Financial Operations Overview**

***Revenue***

From our inception through March 31, 2012, our revenue has been primarily derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. In the three months ended March 31, 2012, we began recognizing revenue under the Baxter Agreement. In the near term, our current and future revenues are dependent upon the continued sale by Sandoz of enoxaparin sodium injection, payments earned under the Baxter Agreement and potential profit share payments and milestones from our 2006 Sandoz Collaboration. In the longer term, our revenue growth will be dependent upon the successful pursuit of external business development opportunities and clinical development, regulatory approval and launch of new commercial products. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of revenue we earn under our collaborative or strategic relationships.

***Research and Development***

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, clinical trial costs, contract research and manufacturing costs and the costs of laboratory equipment and facilities. We expense research and development costs as incurred. Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

***Product Programs Complex Generic and Follow-On Biologics***

*Enoxaparin sodium injection Generic Lovenox*

Lovenox is distributed worldwide by Sanofi-Aventis U.S. LLC, or Sanofi-Aventis, and is also known outside the United States as Clexane® and Klexane®. Under our 2003 Sandoz Collaboration, we work with Sandoz exclusively to develop, manufacture and

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commercialize enoxaparin sodium injection in the United States and Sandoz is responsible for funding substantially all of the United States-related enoxaparin sodium injection development, regulatory, legal and commercialization costs, other than legal expenses incurred by each party in connection with the patent suits filed against Teva Pharmaceutical Industries Ltd., or Teva, in December 2010 and Amphastar and Watson in September 2011. In these cases, Momenta and Sandoz each bear their own legal expenses.

Sandoz submitted ANDAs in its name to the FDA for enoxaparin sodium injection in syringe and vial forms, seeking approval to market enoxaparin sodium injection in the United States. The ANDA for the syringe form of enoxaparin sodium injection was approved in July 2010 and the ANDA for the vial form of enoxaparin sodium injection was approved in December 2011.

In December 2010, we sued Teva in the United States District Court for the District of Massachusetts for infringement of two of our patents. The patents claim methods of producing enoxaparin having specified quality attributes. We will continue to prosecute this case and enforce our patents.

In September 2011, we and Sandoz sued Amphastar, Watson, and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Watson, Amphastar and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted our motion for a preliminary injunction and entered an order enjoining Watson, Amphastar and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and requiring us and Sandoz to post a security bond of $100 million in connection with the litigation. Watson, Amphastar and International Medical Systems, Ltd. appealed the decision to the Court of Appeals for the Federal Circuit, and in January 2012, the Court of Appeals stayed the preliminary injunction, pending a decision on appeal. We will continue to pursue our claims in the District Court and we have confidence in the strength of our patents.

*M356 Generic Copaxone*

In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva. In Europe, Copaxone is marketed by Teva and Sanofi-Aventis. Under the 2006 Sandoz Collaboration, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356 and two other follow-on products for sale in specified regions of the world.

Under the 2006 Sandoz Collaboration, costs, including development costs and the costs of clinical studies, will be borne by the parties in varying proportions depending on the type of expense and the related product. For M356, we are generally responsible for all of the development costs in the United States. For M356 outside of the United States and for enoxaparin sodium injection in the European Union, we share development costs in proportion to our profit sharing interest. All commercialization responsibilities and costs will be borne by Sandoz AG worldwide as they are incurred for all products. We are reimbursed at cost for any full-time equivalent employee expenses as well as any external costs incurred in the development of products to the extent development costs are born by Sandoz AG. Sandoz AG is responsible for funding all of the legal expenses incurred under the 2006 Collaboration; however a portion of certain legal expenses will be offset against the profit-sharing amounts in proportion to our profit sharing interest.

In December 2007, Sandoz submitted to the FDA an ANDA in its name seeking approval to market M356 in the United States containing a Paragraph IV certification. This is a certification by the ANDA applicant that the patent relating to the drug product that is the subject of the ANDA is invalid or unenforceable or will not be infringed. In July 2008, the FDA notified Sandoz that it had accepted the ANDA for review as of December 27, 2007. In addition, the FDA s published database indicates that the first substantially complete ANDA submitted for glatiramer acetate injection containing a Paragraph IV certification was filed on December 27, 2007, making Sandoz s ANDA eligible for the grant of a 180-day generic exclusivity period upon approval. Under applicable laws, there are a number of ways an ANDA applicant may forfeit its 180-day exclusivity, including if the applicant fails to achieve at least tentative approval within 30 months after the date on which the ANDA is filed. Because tentative approval for the M356 ANDA was not received in the specified 30 months, the 180-day exclusivity period will be forfeited unless the exception to the forfeiture rule applies. We will not know whether the exception applies unless and until the FDA approves the ANDA. The review of Sandoz s ANDA is ongoing. We and Sandoz are in regular communication with the FDA to address any additional questions or requests that it may have as it continues the review of Sandoz s application.

Subsequent to FDA s acceptance of the ANDA for review, in August 2008, Teva and related entities sued Sandoz, Novartis AG and us in the United States District Court for the Southern District of New York for patent infringement related to four of the seven Orange Book patents listed for Copaxone. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the foreign affiliates of Sandoz. We and Sandoz asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone and in October 2010, the court consolidated

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the Mylan case with the case against us and Sandoz. A trial was held in two phases: in July 2011 on the issue relating to inequitable conduct and in September 2011 for the remaining issues in the consolidated case. Post-trial briefs have been filed and a decision is pending.

In a separate lawsuit, in December 2009, Teva and related entities sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents. We and Sandoz filed a motion to dismiss, and a motion to stay litigation pending resolution of the motion to dismiss. Both motions were opposed by Teva and are pending. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the foreign affiliates of Sandoz. There is no defined timeline for the court to rule in either suit.

*Follow-On Biologics (FOBs)*

We are also applying our technology platform to the development of biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. Therapeutic proteins represent a sizable segment of the United States drug industry, with sales expected to be approximately $60 billion in 2012. Given the inadequacies of standard technology, many of these therapeutic proteins have not been thoroughly characterized. Most of these products are complex glycoprotein mixtures, consisting of proteins that contain branched sugars that vary from molecule to molecule. These sugars can impart specific biological properties to the therapeutic protein and can often comprise a significant portion of the mass of the molecule. In addition to the structural characterization of several marketed therapeutic proteins, we are also advancing our structure-process capabilities as we further define the relationship between aspects of the manufacturing process and the structural composition of the final protein product. We believe that our investment in our analytics and characterization technology coupled with our investment in the science of better understanding the relationship of the biologic manufacturing process to structural composition provides us with the opportunity develop a competitive advantage for our future FOB product candidates.

In December 2011, we and Baxter entered into the Baxter Agreement under which we agreed to collaborate, on a world-wide basis, on the development and commercialization of up to six FOB products. The Baxter Agreement became effective in February 2012.

Most protein drugs have been approved by the FDA under the Biologics License Application, or BLA, regulatory pathway. The BLA pathway was created to review and approve applications for biologic drugs that are typically produced from living systems. Until 2010, there was no abbreviated regulatory pathway for the approval of generic or biosimilar versions of BLA-approved products in the United States; however, there have been guidelines for biosimilar products in the European Union for several years.

In March 2010, with the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI, an abbreviated pathway for the approval of FOBs was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable, based on its similarity to an existing brand product.

Under the BPCI, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original brand product was approved under a BLA. There are many biologics at this time for which this 12-year period has expired or is nearing expiration. We believe that scientific progress in the analysis and characterization of complex mixture drugs is likely to play a significant role in FDA s approval of biosimilar (including interchangeable) biologics in the years to come.

In December 2011, the FDA released its proposed biosimilar user fee program which includes a fee-based meeting process for consultation between applicants and the division of FDA responsible for reviewing biosimilar and interchangeable biologics applications under the new approval pathway. It contemplates well-defined meetings where the applicant can propose and submit analytic, physicochemical and biologic characterization data along with a proposed development plan. The proposed development plan may have a reduced scope of clinical development based on the nature and extent of the characterization data. There are defined time periods for meetings and written advice. In February 2012, the FDA published draft guidance documents for the development and registration of biosimilars and interchangeable biologics. The draft guidance documents indicate that the FDA will consider the totality of the evidence developed by an applicant in determining the nature and extent of the nonclinical and clinical requirements for a biosimilar or interchangeable biologic product.

The new law is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning will be subject to uncertainty for years to come.

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***Product Candidates  Novel Drugs***

*M402*

M402 is a novel polysaccharide-based product candidate engineered to have potent anti-cancer properties and low anticoagulant activity. Polysaccharide-based compounds like heparin are complex molecules present in the tumor microenvironment which present growth factors, cytokines, and chemokines necessary for tumor cell growth, migration and survival. M402 is designed to exploit this biology by binding to and down regulating multiple factors involved in disease progression and metastasis. Data from multiple preclinical studies have shown that M402 has the potential to modulate angiogenesis and tumor progression and metastasis through a variety of polysaccharide-based-binding proteins.

A preclinical study, in collaboration with the Cancer Research Institute (Cambridge, UK), demonstrated the efficacy of M402 in a murine pancreatic cancer model. The study showed that M402, in combination with gemcitabine, significantly improved survival and substantially lowered the incidence of metastasis compared to mice treated with gemcitabine alone.

In April 2012, we initiated a Phase 1/2 proof-of-concept clinical study in patients with advanced metastatic pancreatic cancer. The Phase 1/2 trial consists of two parts and will evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of M402 in combination with gemcitabine. Part A of the study is an open-label, multiple ascending dose study designed to determine the best dose to take forward into Part B which is a larger, randomized controlled study to evaluate the antitumor activity of M402 in combination with gemcitabine versus gemcitabine alone in patients with metastatic pancreatic cancer.

*Adomiparin*

Our other novel drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed anticoagulants to support the treatment of ACS. We will not move forward with further clinical trials of adomiparin unless we have a partner for the program.

***Discovery Program***

We believe our core analytical tools enable new insights into exploring the biology of many diseases, which will lead to an enhanced understanding of the relative role of different biological targets and related cell-to-cell signaling pathways. Many complex diseases are a result of multiple biological activities.  Our goal is to leverage the multi-targeting nature of complex mixture molecules to develop novel therapeutics which could positively modulate multiple pathways in a disease. We believe that our core technology platform will enable us to map the critical nodes that regulate complex diseases and then use the appropriate collection of  drugs  whether polysaccharides, proteins, peptides or monoclonal antibodies  to target the appropriate nodes simultaneously. This unique approach, while early, opens up the range of diseases that can be targeted.

***General and Administrative***

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, legal, accounting, investor relations, information technology, business development and human resource functions. Other costs include facility and insurance costs not otherwise included in research and development expenses and professional fees for legal and accounting services and other general expenses.

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**Results of Operations**

***Three Months Ended March 31, 2012 and 2011***

***Collaboration Revenue***

Collaboration revenue for the three months ended March 31, 2012 was $24.2 million, compared with $78.2 million for the three months ended March 31, 2011.

Collaboration revenues are summarized as follows (in thousands):

| | Three Months Ended March 31, 2012 | Three Months Ended March 31, 2011 |
|---|---|---|
| Collaboration revenues: | | |
| Product revenue | $ 22,029 | $ 75,761 |
| Research and development revenue | 2,199 | 2,411 |
| Total collaboration revenue | $ 24,228 | $ 78,172 |

Product revenue includes profit share/royalty revenue earned from Sandoz on sales of enoxaparin sodium injection following its commercial launch in July 2010. The decrease in product revenue is due to lower net sales of enoxaparin by Sandoz following the launch of an authorized generic in October 2011 and the launch of a third-party competitor enoxaparin in January 2012, and the resulting change in the basis of our earned product revenues from profit share to royalty-based. For the first quarter of 2011, we earned a profit share of $75.8 million on Sandoz s reported net sales of enoxaparin of $247 million. For the first quarter of 2012, we earned $22.0 million on a profit share for a portion and a royalty on a portion of Sandoz reported net sales of enoxaparin of $176 million.

Research and development revenue for the periods shown consists of amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs, amounts earned by us under the 2006 Sandoz Collaboration for amortization of the equity premium, reimbursement of research and development services and reimbursement of development costs, and revenue earned by us under the Baxter Agreement.

There are a number of factors that make it difficult for us to predict the magnitude of future enoxaparin sodium injection product revenue, including the impact of generic competition on the Sandoz market share; the pricing of products that compete with enoxaparin sodium injection and other actions taken by our competitors; the inventory levels of enoxaparin sodium injection maintained by wholesalers, distributors and other customers; the frequency of re-orders by existing customers; and the change in estimates for product reserves. Accordingly, our enoxaparin sodium injection product revenue in previous quarters will not be indicative of future enoxaparin sodium injection product revenue. The change in Sandoz contractual payment obligations, along with additional generic competition, has caused and will continue to cause our revenue from

enoxaparin sodium injection to be significantly reduced compared to 2011.

***Research and Development Expense***

Research and development expense for the three months ended March 31, 2012 was $18.6 million, compared with $12.9 million for the three months ended March 31, 2011. The increase of $5.7 million, or 44%, from the 2011 period to the 2012 period resulted from increases of: $1.6 million in facility-related expenses, principally due to increased rent and operating costs for our headquarters and the commencement in the first quarter of 2012 of a short-term sublease for expansion space; $1.2 million in personnel and related costs associated with our headcount growth to support our programs; $1.1 million in laboratory expenses in support of our programs; $0.6 million in depreciation and amortization expense primarily due to the amortization of a 2011 milestone payment in connection with a 2007 asset purchase and increased capital expenditures to support our programs; $0.6 million in consulting fees and third-party research costs related to our M356 and novel drug programs; and $0.5 million in share-based compensation expense principally associated with grants of performance-based restricted stock. We expect future research and development expenses to increase in support of our product candidates.

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The following table summarizes the primary components of our research and development expenditures for our principal commercial and development programs for the three months ended March 31, 2012 and 2011 and the total external costs (including amortization) incurred by us for each of our major commercial and development projects. The table excludes costs incurred by our collaborative partner on such major commercial and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. Consequently, we do not analyze internal research and development costs by project in managing our research and development activities.

| | Research and Development Expense (in thousands) | | |
|---|---|---|---|
| **Commercial and Development Programs (Status)** | **Three Months Ended March 31, 2012** | **Three Months Ended March 31, 2011** | **Project Inception to March 31, 2012** |
| Enoxaparin sodium injection (ANDA approved July 2010) | $ 468 | $ 642 | $ 50,428 |
| M356 (ANDA Filed) | 1,607 | 1,187 | 42,289 |
| Adomiparin (Phase 2a) | 11 | 38 | 35,836 |
| Other development programs | 1,195 | 843 | |
| Discovery programs | 256 | 289 | |
| Research and development internal costs | 15,025 | 9,944 | |
| Total research and development expense | $ 18,562 | $ 12,943 | |

The decrease of $0.2 million in external expenditures for enoxaparin sodium injection from the 2011 period to the 2012 period was primarily due to a shift to commercial activity being contracted directly with Sandoz. The increase of $0.4 million in M356 external expenditures from the 2011 period to the 2012 period was primarily due to timing of process development activities, manufacturing and third-party research costs. Adomiparin external expenditures remained consistent from the 2011 period to the 2012 period reflecting our decision to not move forward with further clinical trials unless we have a collaborative partner for this program. The increase of $0.4 million in other development program spend from the 2011 period to the 2012 period was due to process development and third-party research costs related to our FOBs program. Discovery program external expenditures remained consistent from the 2011 period to the 2012 period as we fund research collaborations associated with these programs.

The research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $5.1 million from the 2011 period to the 2012 period was due to additional research and development headcount and related costs in support of our development programs.

The lengthy process of securing FDA approval for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate when, if ever, our product candidates will generate revenues and cash flows.

***General and Administrative***

General and administrative expense for the three months ended March 31, 2012 was $11.0 million, compared to $8.3 million for the three months ended March 31, 2011. General and administrative expense increased by $2.7 million, or 33%, from the 2011 period to the 2012 period due to increases of: $1.6 million in professional fees principally due to increased legal fees relating to enoxaparin litigation; $1.0 million in share-based compensation expense principally associated with grants of performance-based restricted stock; $0.4 million in facility-related expenses principally due to increased rent and operating costs for our headquarters and the commencement in the first quarter of 2012 of a short-term sublease for expansion space; and $0.3 million in personnel and related costs associated with our headcount growth. These increases were offset by a decrease of $0.8 million in royalty and license fees payable primarily to Massachusetts Institute of Technology based on a decrease in Sandoz s net sales of enoxaparin sodium injection.

We expect our general and administrative expenses, including internal and external legal and business development costs that support our various product development efforts, to vary from period to period in relation to our commercial and development activities.

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***Interest Income and Expense***

Interest income was $0.3 million and $0.1 million for the three months ended March 31, 2012 and 2011, respectively. The increase of $0.2 million from the 2011 period to the 2012 period was primarily due to higher average investment balances.

Interest expense was zero and $41,000 for the three months ended March 31, 2012 and 2011, respectively, because we repaid all borrowings on our equipment line of credit during 2011.

**Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of equity securities, payments from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, including profit share/royalty payments related to sales of enoxaparin sodium injection, and borrowings from our lines of credit and capital lease obligations. Since our inception, we have received $405.9 million through private and public issuance of equity securities, including the issuance of shares to Novartis Pharma AG in connection with our 2006 Sandoz Collaboration. As of March 31, 2012, we have received a cumulative total of $502.1 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, a $33.0 million upfront payment under the Baxter Agreement, $4.0 million from debt financing, $9.2 million from capital lease obligations and $3.2 million from our landlord for leasehold improvements related to our corporate facility and additional funds from interest income. The January 2012 launch of a third-party competitor s enoxaparin sodium injection triggered a change in the basis of our product revenue from profit share to a royalty based on net sales of enoxaparin sodium injection. This competition and the resulting contractual change has had and will have a negative impact on our near term cash generation trend. Our return to profitability, if at all, will most likely come from the commercialization of our generic Copaxone product, which is subject to FDA approval. We expect to finance our current and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2014. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources.

At March 31, 2012, we had $382.3 million in cash, cash equivalents and marketable securities and $22.4 million in accounts receivable. In addition, we also held $17.5 million in restricted cash which serves as collateral for a security bond posted in the litigation against Watson, Amphastar and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar). Our funds at March 31, 2012 were primarily invested in senior debt of government-sponsored enterprises, commercial paper, corporate debt securities and United States money market funds, directly or through managed funds, with remaining maturities of 24 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. We do not believe that our cash equivalents and marketable securities were subject to significant risk at March 31, 2012.

During the three months ended March 31, 2012, our operating activities provided cash of $41.7 million. During the three months ended March 31, 2011, our operating activities provided cash of $31.7 million. The cash provided by operating activities generally approximates our net (loss) income adjusted for non-cash items and changes in operating assets and liabilities.

For the three months ended March 31, 2012, our net loss adjusted for non-cash items was $0.3 million. For the three months ended March 31, 2012, non-cash items include share-based compensation of $3.3 million, depreciation and amortization of our property, equipment and intangible assets of $1.5 million and amortization of purchased premiums on our marketable securities of $0.5 million. In addition, the net change in our operating assets and liabilities provided cash of $41.4 million and resulted from: a decrease in accounts receivable of $5.8 million, due to a decrease in net sales of enoxaparin by Sandoz, due primarily to lower unit sales and pricing, and by a contractual change in the basis of calculating our enoxaparin product revenue, both related to the launch of a competitor s generic Lovenox in January 2012; a decrease in unbilled revenue of $1.7 million, resulting from lower first-quarter reimbursable manufacturing activities for our M356 program; an increase in prepaid expenses and other current assets of $0.5 million, primarily due to advance payments made for renewals of vendor maintenance agreements; an increase in accounts payable of $4.7 million, primarily due to the timing of payments to vendors for leasehold improvements and purchases of laboratory equipment; a decrease in accrued expenses of $2.3 million resulting from the payment of annual bonuses earned during 2011 and the timing of manufacturing activities for our M356 program; and an increase in deferred revenue of $31.9 million, primarily due to the $33.0 million upfront payment under the Baxter Agreement.

For the three months ended March 31, 2011, our net income adjusted for non-cash items was $60.2 million. For the three months ended March 31, 2011, non-cash items include share-based compensation of $1.8 million, depreciation and amortization of our property, equipment and intangible assets of $1.2 million and amortization of purchased premiums on our marketable securities of $0.2 million. In addition, the net change in our operating assets and liabilities used cash of $28.5 million and resulted from: an increase in accounts receivable of $27.9 million, due to an increase in our quarterly profit-share for sales of enoxaparin sodium injection; a decrease in unbilled revenue of $3.3 million, resulting from decreased reimbursable manufacturing activities for our M356 program; an increase in prepaid expenses and other current assets

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of $0.4 million, due to advance payments made for nonclinical program studies, the renewal of vendor maintenance agreements, and an increase in interest accrued on our available for sale marketable securities; an increase in accounts payable of $0.3 million, primarily due to the timing of payments to vendors for purchases of laboratory equipment; a decrease in accrued expenses of $3.4 million resulting from the payment of annual bonuses earned during 2010 and the timing of manufacturing activities for our M356 program; and a decrease in deferred revenue of $0.5 million, principally due to the amortization of the $13.6 million equity premium paid by Novartis Pharma AG in connection with the 2006 Sandoz Collaboration.

During the three months ended March 31, 2012, our investing activities used cash of $53.0 million. In the first three months of 2012, we used $189.4 million of cash to purchase marketable securities and we received $144.5 million from maturities of marketable securities. During the three months ended March 31, 2011, our investing activities used cash of $74.1 million. In the first three months of 2011, we used $137.3 million of cash to purchase marketable securities and we received $65.7 million from maturities of marketable securities. During the three months ended March 31, 2012 and 2011, we used $8.2 million and $2.5 million, respectively, to purchase laboratory equipment and leasehold improvements to support our programs. During the first three months 2012, we spent $6.1 million in laboratory equipment for our FOB and novel drug programs and $2.1 million in leasehold improvements, furniture and computer equipment related to additional leased laboratory and office space.

During the three months ended March 31, 2012, financing activities provided cash of $0.7 million. During the three months ended March 31, 2012, we received net proceeds of $0.7 million from stock option exercises and purchases of common shares through our employee stock purchase plan. During the three months ended March 31, 2011, financing activities provided cash of $0.4 million. During the three months ended March 31, 2011, we received net proceeds of $0.8 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $0.2 million on our capital lease agreement obligations and $0.2 million on financed leasehold improvements related to our corporate facility.

**Contractual Obligations**

Our major outstanding contractual obligations relate to license maintenance obligations including royalties payable to third parties and operating lease obligations. The disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2011 have not materially changed since we filed that report.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and share-based payments. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Please read Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our 2011 Form 10-K for a discussion of our critical accounting policies and estimates.

**Recently Issued Accounting Standards**

Please see Note 2 to our consolidated financial statements, Summary of Significant Accounting Policies, for a discussion of new accounting standards. The notes to our consolidated financial statements are contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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**Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of United States money market, government-secured, and high-grade corporate securities, directly or through managed funds, with maturities of twenty-four months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the conservative nature of our investments, low prevailing market rates and relatively short effective maturities of debt instruments, interest rate risk is mitigated. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2012, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

**Item 4. Controls and Procedures.**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2012, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, occurred during the fiscal quarter ended March 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

In August 2008, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against us, Sandoz and Novartis AG in the United Stated Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit alleges infringement by us, Sandoz and Novartis AG of Orange Book patents owned by Yeda and licensed by Teva and seeks monetary, injunctive and declaratory relief. In November 2008, we and

Sandoz each filed responsive pleadings denying the allegations of infringement, setting forth affirmative defenses based on invalidity, non-infringement and inequitable conduct and counterclaims seeking declaratory relief that the patent rights of Teva and Yeda pertaining to M356 are either not infringed, invalid or unenforceable. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against us and Sandoz. In April 2011, Teva filed a motion for summary judgment of no inequitable conduct. In June 2011, the court denied Teva s motion and granted a bench trial, which occurred in July 2011, to hear the issue of inequitable conduct only. The trial on the remaining issues occurred in September 2011 in the consolidated case. Post-trial briefs have been filed and a decision is pending. There is no defined timeframe for the court to issue a decision.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents after Teva s motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, we and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending.

While we have vigorously defended these suits, a delay in a final judgment could significantly delay, impair or prevent our ability to commercialize M356 and our business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or we will prevail in either lawsuit.

In September 2011, we sued Amphastar Pharmaceuticals Inc., or Amphastar, Watson Pharmaceuticals Inc., or Watson, and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted our motion for a preliminary injunction and entered an order enjoining prevent Amphastar, Watson and

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International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and required us and Sandoz to post a security bond of $100 million. Amphastar, Watson and International Medical Systems, Ltd. appealed the decision to the Court of Appeals for the Federal Circuit, and in January 2012 the Court of Appeals stayed the preliminary injunction pending a decision on appeal. In the event that we lose the case at the District Court and it is determined that the preliminary injunction was improvidently granted and Amphastar and Watson are able to prove they suffered damages as a result of the preliminary injunction having been in effect, we could be liable for such damages up to $35 million of the security bond.

While we intend to vigorously prosecute this action against Watson and Amphastar, and we believe that we can ultimately prove our case in court, this suit could last a number of years. As a result, absent preliminary injunctive relief, recovery of lost profits and damages could await a final judgment after an appeal of a district court decision. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz will prevail in this patent enforcement suit.

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**Item 1A. Risk Factors**

Investing in our stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to other information included or incorporated by reference in this Quarterly Report on Form 10-Q before purchasing our stock. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

**Risks Relating to Our Business**

***We have incurred a cumulative loss since inception. If we do not generate significant revenue, we may not return to profitability.***

We have incurred significant losses since our inception in May 2001. At March 31, 2012, our accumulated deficit was $108.4 million. We may incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our other drug candidates, and effectively manufacture, market and sell any drugs we successfully develop. Accordingly, we may not generate significant revenue in the longer term and, even if we do generate significant revenue, we may never achieve long term-profitability.

To be profitable, we and our collaborative partners must succeed in developing and commercializing drugs with significant market potential. This will require us and our collaborative partners to be successful in a range of challenging activities: developing product candidates; obtaining regulatory approval for product candidates through either existing or new regulatory approval pathways; clearing allegedly infringing patent rights; enforcing our patent rights; and manufacturing, distributing, marketing and selling products. Our profitability will also be dependent on the entry of competitive products and, if so, whether the entry is before or after the launch of our products. We may never succeed in these activities and may never generate revenues that are significant.

***Our current revenue is dependent on the continued successful manufacture and commercialization of enoxaparin sodium injection.***

Our near-term ability to generate revenue, in large part, depends on the continued successful commercialization of enoxaparin sodium injection. This further depends, in large part, on Sandoz s continued success in manufacturing and commercializing the product, maintaining market share and competing with Lovenox brand competition as well as other generic competition.

Under the 2003 Sandoz Collaboration, rather than paying us a profit share of 45% of contractual profits, Sandoz is now paying us a royalty on net sales. In each product year, which begins July 1, for net sales up to a pre-defined sales threshold the royalty is payable at a 10% rate, and for net sales above the sales threshold the royalty rate increases to 12%. The change in Sandoz contractual payment obligations, along with additional generic competition, has caused and will continue to cause our revenue from enoxaparin sodium injection to be significantly reduced compared to 2011.

Watson and Amphastar launched their enoxaparin product in January 2012. In addition, Teva and Hospira, Inc. have each submitted ANDAs for generic versions of Lovenox with the FDA, and other third parties may seek approval to market generic versions of Lovenox in the United States. Additional generic competition would ordinarily lead to a loss of market share as well as a significant decline in pricing.

Under these circumstances, the resulting market price for our enoxaparin sodium injection product has decreased and may decrease further, we have lost market share and may continue to lose significant market share for enoxaparin sodium injection, and significantly less favorable economic terms for us under the 2003 Sandoz Collaboration have been triggered, and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

***If our patent litigation against Amphastar or Teva related to enoxaparin sodium injection is not successful, we may be liable for damages. In addition, third parties may be able to commercialize a generic Lovenox product without risk of patent infringement damages, and our business may be materially harmed.***

In September 2011, following approval of the ANDA filed by Amphastar for enoxaparin, we sued Amphastar, Watson and International Medical Systems, Ltd. in the United States District Court for the District of Massachusetts for infringement of two of our patents that cover innovative methods of producing enoxaparin sodium which assure that the commercial product meets standards for identity and quality. Although the court granted our motion for preliminary injunction enjoining Amphastar, Watson and International Medical Systems, Ltd. from marketing a generic Lovenox product, the court required us and Sandoz to post a security bond of $100 million and Amphastar, Watson and International Medical Systems, Ltd. filed a notice to appeal the decision and an emergency motion to dissolve or stay the preliminary injunction. In January 2012, the court of appeals stayed the preliminary injunction. In January 2012, Watson and/or Amphastar began marketing their generic Lovenox. While the patent litigation is continuing in the district court, if we are not successful in the patent case and do not succeed in obtaining injunctive relief, or damages for our lost profits due to infringing sales, our revenue would be irrevocably significantly reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, may

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suffer. Furthermore, in the event that we lose the case in the District Court and it is determined that the preliminary injunction was improvidently granted, and Amphastar and Watson are able to prove they suffered damages as a result of the preliminary injunction having been in effect, then we could be liable for such damages for up to $35 million of the security bond.

In December 2010, we sued Teva in the United States District Court for the District of Massachusetts for infringement of our two patents that cover the innovative methods of producing enoxaparin sodium. If we are not successful in this patent case and do not succeed in obtaining injunctive relief, or damages for our lost profits due to infringing sales, and if Teva receives marketing approval, it will be able to commercialize a generic Lovenox. Under these circumstances, the resulting market price for our enoxaparin sodium injection product may be lower and we may lose significant market share for enoxaparin sodium injection. Consequently, our revenue would be reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

***If efforts by manufacturers of branded products to delay or limit the use of generics or FOBs are successful, our sales of generic and FOB products may suffer.***

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay competition from manufacturers of generic drugs and could be expected to use similar tactics to delay competition from FOBs. These efforts have included:

- settling patent lawsuits with generic companies, resulting in such patents remaining an obstacle for generic approval by others;

- settling paragraph IV patent litigation with generic companies to prevent the expiration of the 180-day generic marketing exclusivity period or to delay the triggering of such exclusivity period;

- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted generic drug applications;

- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of generic drug applications;

- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug standards;

- pursuing new patents for existing products or processes which could extend patent protection for a number of years or otherwise delay the launch of generic drugs; and

- attaching special patent extension amendments to unrelated federal legislation.

The FDA s practice is to rule within 180 days on Citizen Petitions that seek to prevent approval of an ANDA if the petition was filed after the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA. If, at the end of the 180-day period, the ANDA is not ready for approval or rejection, then the FDA has typically denied and dismissed the petition without acting on the petition. Teva Neuroscience, Inc. has filed several Citizen Petitions regarding M356, all of which have been denied and dismissed. However, Teva may seek to file future petitions and may also seek reversal of the denial of a Citizen Petition in federal court. Other third parties may also file Citizen Petitions requesting that the FDA adopt specific approval standards for generic products. If the FDA grants future Citizen Petitions, we and Sandoz may be delayed in obtaining, or potentially unable to obtain, approval of the ANDA for M356 which would materially harm our business.

Further, some manufacturers of branded products have engaged in state-by-state initiatives to enact legislation that restricts the substitution of some branded drugs with generic drugs. If these efforts to delay or block competition are successful, we may be unable to sell our generic products, which could have a material adverse effect on our sales and profitability.

***Our patent litigation with Teva, the manufacturer of Copaxone, may cause delays and additional expense in the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.***

In August 2008, Teva and related entities sued Sandoz, Novartis AG and us for patent infringement in the United States District Court for the Southern District of New York related to four of the seven Orange Book patents listed for Copaxone. We and Sandoz Inc. asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. Another company, Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone and in October 2010, the court consolidated the Mylan case with the case against us and Sandoz. In April 2011, Teva filed a motion for summary judgment of no inequitable conduct. In June, 2011, the court denied Teva s motion and granted a bench trial,

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which occurred in July 2011, to hear the issue of inequitable conduct only. The trial on the remaining issues occurred in September 2011 in the consolidated case. Post-trial briefs have been filed and a decision is pending. There is no defined timeframe for the court to issue a decision.

In a separate lawsuit, in December 2009, Teva and related entities sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents. We and Sandoz filed a motion to dismiss this case, and a motion to stay litigation pending resolution of the motion to dismiss. Both motions were opposed by Teva and are pending.

These lawsuits could significantly delay, impair or prevent our ability to commercialize M356, our second major generic product candidate. Litigation involves many risks and uncertainties, and there is no assurance that Sandoz or we will prevail in any lawsuit with Teva. In addition, Teva has significant resources and any litigation with Teva could last a number of years, potentially delaying or prohibiting the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.

***If other generic versions of our product candidates, including M356, are approved and successfully commercialized, our business would suffer.***

We expect that certain of our product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. For example, in September 2009, Mylan announced that the FDA had accepted for filing its ANDA for generic Copaxone. Furthermore, as patents for branded products and related exclusivity periods expire, manufacturers of generic products may receive regulatory approval for generic equivalents and may be able to achieve significant market penetration. As this happens, or as branded manufacturers launch authorized generic versions of such products, market share, revenues and gross profit typically decline, in some cases, dramatically. If any of our generic product offerings, including M356, enter markets with a number of competitors, we may not achieve significant market share, revenues or gross profit. In addition, as other generic products are introduced to the markets in which we participate, the market share, revenues and gross profit of our generic products could decline.

***If the market for a reference brand product, including Lovenox or Copaxone, significantly declines, sales or potential sales of our generic product and generic or biosimilar product candidates may suffer and our business would be materially impacted.***

Competition in the biotechnology industry is intense. Brand name products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference brand product to our generic product and generic or biosimilar product candidates, including Lovenox or Copaxone, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. If the market for the reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

***If the raw materials, including unfractionated heparin, or UFH, used in our products become difficult to obtain, significantly increase in cost or become unavailable, we may be unable to produce our products and this would have a material adverse impact on our business.***

We and our collaborative partners and vendors obtain certain raw materials, including UFH, from suppliers who in turn source the materials from other countries, including four suppliers in China. In 2008, due to the occurrence of adverse events associated with the use of UFH, there were global recalls of UFH products, including in the United States, putting our supply chain at risk. Based on investigation by the FDA into those adverse events, the FDA identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use additional tests to screen their UFH active pharmaceutical ingredient. We and our collaborative partner worked with the appropriate regulatory authorities to document and to demonstrate that our testing standards meet or exceed all requirements for testing and screening the supply of UFH active pharmaceutical ingredient. The FDA and other authorities have also placed restrictions on the import of some raw materials from China, and may in the future place additional restrictions and testing requirements on the use of raw materials, including UFH, in products intended for sale in the United States. As a result, the raw materials, including UFH, used in our products may become difficult to obtain, significantly increase in cost, or become unavailable to us. If any of these events occur, we and our collaborative partners may be unable to produce our products in sufficient quantities to meet the requirements for the commercial launch or demand for the product, which would have a material adverse impact on our business.

***If we or our collaborative partners and other third parties are unable to satisfy FDA quality standards and related regulatory requirements, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our products or product candidates, our development and commercialization efforts may be materially harmed.***

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborative partners and other third parties to provide raw materials meeting FDA quality standards and related regulatory requirements,

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manufacture the drug substance, produce the final drug product and provide certain analytical services with respect to our products and product candidates, including enoxaparin sodium injection. We, our collaborative partners or our third-party contractors may have difficulty meeting FDA manufacturing requirements, including, but not limited to, reproducibility, validation and scale-up, and continued compliance with current good manufacturing practices requirements. In addition, events such as the contamination of UFH may have an adverse impact on the supply of starting or raw materials for some of our products and product candidates, and we, our collaborative partners or our third-party contractors may have difficulty producing products in the quantities necessary to meet FDA requirements or meet anticipated market demand. If we, our collaborative partners or our third-party manufacturers or suppliers are unable to satisfy the FDA manufacturing requirements for our products and product candidates, or are unable to produce our products in sufficient quantities to meet the requirements for the launch of the product or to meet market demand, our revenue and gross margins could be adversely affected, and could have a material adverse impact on our business.

***Competition in the biotechnology and pharmaceutical industries is intense, and if we are unable to compete effectively, our financial results will suffer.***

The markets in which we intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. We expect competition to intensify as technological advances are made or new biotechnology products are introduced. New developments by competitors may render our current or future product candidates and/or technologies non-competitive, obsolete or not economical. Our competitors products may be more efficacious or marketed and sold more effectively than any of our products.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process;

- more extensive experience in commercializing generic drugs, conducting preclinical studies, conducting clinical trials, obtaining regulatory approvals, challenging patents and manufacturing and marketing pharmaceutical products;

- products that have been approved or are in late stages of development; and

- collaborative arrangements in our target markets with leading companies and/or research institutions.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on many different factors, including:

- the safety and effectiveness of our products;

- with regard to our generic product candidates, the differential availability of clinical data and experience between a brand manufacturer that conducts clinical trials and a generic manufacturer;

- the timing and scope of regulatory approvals for these products and regulatory opposition to any product approvals;

- the availability and cost of manufacturing, marketing, distribution and sales capabilities;

- the effectiveness of our marketing, distribution and sales capabilities;

- the price of our products;

- the availability and amount of third-party reimbursement for our products; and

- for our innovative products, the strength of our patent position.

Our competitors may develop or commercialize products with significant advantages in regard to any of these factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business.

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***If we or our collaborators are unable to establish and maintain key customer distribution arrangements, sales of our products, and therefore revenue, would decline.***

Generic pharmaceutical products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. As enoxaparin sodium injection is primarily a hospital-based product, a large percentage of the revenue for enoxaparin sodium injection is derived through contracts with GPOs. Currently, a relatively small number of GPOs control a substantial portion of generic pharmaceutical sales to hospital customers. In order to establish and maintain contracts with these GPOs, we believe that we, in collaboration with Sandoz, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products. The GPOs with whom we or our collaborators have established contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of enoxaparin sodium injection to certain hospital segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by our customers, including the GPOs, wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. We anticipate that M356 will be primarily distributed through retail channels and mail order services. If we or our collaborators are unable to establish and maintain distribution arrangements with all of these customers, sales of our products, our revenue and our profits would suffer.

***Even if we receive approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which could prevent us from being profitable.***

Even if our product candidates are successfully developed and approved for marketing, our success and growth will also depend upon the acceptance of our products by patients, physicians and third-party payors. Acceptance of our products will be a function of our products being clinically useful, being cost effective and demonstrating superior therapeutic effect with an acceptable side effect profile as compared to existing or future treatments. In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time.

Factors that we believe will materially affect market acceptance of our product candidates under development include:

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the competitive pricing of our products;
- physician confidence in the safety and efficacy of complex generic products;

- the success and extent of our physician education and marketing programs;

- the clinical, medical affairs, sales, distribution and marketing efforts of competitors; and

- the availability and amount of government and third-party payor reimbursement.

If our products do not achieve market acceptance, we will not be able to generate sufficient revenue from product sales to maintain or grow our business.

***We will require substantial funds and may require additional capital to execute our business plan and, if additional capital is not available, we may need to limit, scale back or cease our operations.***

As of March 31, 2012, we had cash, cash equivalents and marketable securities totaling $382.3 million and accounts receivable of $22.4 million. For the three months ended March 31, 2012, we had a net loss of $5.0 million and cash provided by operating activities of $41.7 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development. Our future capital requirements may vary depending on the following:

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- the rate of sales of enoxaparin sodium injection;

- a decision is issued in favor of Teva in its patent litigation matters against us;

- the advancement of our product candidates and other development programs, including the timing and costs of obtaining regulatory approvals;

- the timing of FDA approval of the products of our competitors;

- the cost of litigation, including with Amphastar and Watson relating to enoxaparin, that is not otherwise covered by our collaboration agreement, or potential patent litigation with others, as well as any damages, including possibly treble damages, that may be owed to third parties should we be unsuccessful in such litigation;

- the ability to enter into strategic collaborations;

- the continued progress in our research and development programs, including completion of our preclinical studies and clinical trials;

- the potential acquisition and in-licensing of other technologies, products or assets; and

- the cost of manufacturing, marketing and sales activities, if any.

We expect to finance our current and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2014. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings. Any additional capital raised through the sale of equity may dilute existing investors percentage ownership of our common stock. Capital raised through debt financing would require us to make periodic interest payments and may impose potentially restrictive covenants on the conduct of our business. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

***If we are not able to retain our current management team or attract and retain qualified scientific, technical and business personnel, our business will suffer.***

We are dependent on the members of our management team for our business success. Our employment arrangements with our executive officers are terminable by either party on short notice or no notice. We do not carry life insurance on the lives of any of our personnel. The loss of any of our executive officers would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. In addition, there is intense competition from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, for human resources, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates.

***There is a substantial risk of product liability claims in our business. If our existing product liability insurance is insufficient, a product liability claim against us that exceeds the amount of our insurance coverage could adversely affect our business.***

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in a recall of our products or a change in the approved indications for which they may be used. While we currently maintain product liability insurance coverage that we believe is adequate for our current operations, we cannot be sure that such coverage will be adequate to cover any incident or all incidents. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

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***As we evolve from a company primarily involved in drug discovery and development into one that is also involved in the commercialization of pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.***

As we advance our product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, some jurisdictions, such as the District of Columbia, have imposed licensing requirements for sales representatives. In addition, the District of Columbia and the Commonwealth of Massachusetts, as well as the Federal government by way of the Sunshine Act provisions of the Patient Protection and Affordable Care Act of 2010, have established reporting requirements that would require public reporting of consulting and research fees to health care professionals. Because the reporting requirements vary in each jurisdiction, compliance will be complex and expensive and may create barriers to entering the commercialization phase. The need to build new systems as part of our growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Such requirements may also impact our opportunities to collaborate with physicians at academic research centers as new restrictions on academic-industry relationships are put in place. In the past, collaborations between academia and industry have led to important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

***We may acquire or make investments in companies or technologies that could have an adverse effect on our business, results of operations and financial condition or cash flows.***

We may acquire or invest in companies, products and technologies. Such transactions involve a number of risks, including:

- we may find that the acquired company or assets does not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;

- difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;

- difficulty incorporating the acquired technologies;

- difficulties or failures with the performance of the acquired technologies or drug products;

- we may face product liability risks associated with the sale of the acquired company s products;

- disruption or diversion of management s attention by transition or integration issues and the complexity of managing diverse locations;

- difficulty maintaining uniform standards, internal controls, procedures and policies;

- the acquisition may result in litigation from terminated employees or third parties; and

- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

These factors could have a material adverse effect on our business, results of operations and financial condition or cash flows, particularly in the case of a larger acquisition or multiple acquisitions in a short period of time. From time to time, we may enter into negotiations for acquisitions that are not ultimately consummated. Such negotiations could result in significant diversion of management time, as well as out-of-pocket costs.

The consideration paid in connection with an acquisition also affects our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any acquisition. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted and earnings per share may decrease. In addition, acquisitions may result in the incurrence of debt, large one-time

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write-offs and restructuring charges. They may also result in goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges.

**Risks Relating to Development and Regulatory Approval**

***If we are not able to obtain regulatory approval for commercial sale of our generic product candidate, M356, as a therapeutic equivalent to Copaxone, our future results of operations will be adversely affected.***

Our future results of operations depend to a significant degree on our ability to obtain regulatory approval for and commercialize M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that M356:

- contains the same active ingredients as Copaxone;

- is of the same dosage form, strength and route of administration as Copaxone, and has the same labeling as the approved labeling for Copaxone, with certain exceptions; and

- meets compendial or other applicable standards for strength, quality, purity and identity, including potency.

In addition, approval of a generic product generally requires demonstrating that the generic drug is bioequivalent to the reference listed drug upon which it is based, meaning that there are no significant differences with respect to the rate and extent to which the active ingredients are absorbed and become available at the site of drug action. However, the FDA may or may not waive the requirements for certain bioequivalence data (including clinical data) for certain drug products, including injectable solutions that have been shown to contain the same active and inactive ingredients in the same concentration as the reference listed drug.

Determination of therapeutic equivalence of M356 to Copaxone will be based, in part, on our demonstration of the chemical equivalence of our versions to their respective reference listed drugs. The FDA may not agree that we have adequately characterized M356 or that M356 and Copaxone are chemical equivalents. In that case, the FDA may require additional information, including preclinical or clinical test results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product s safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. We cannot predict whether M356 will receive FDA approval as therapeutically equivalent to Copaxone.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Copaxone, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of M356 could be delayed or prevented or become more expensive. Delays in any part of the process or our inability to obtain regulatory approval for M356 could adversely affect our operating results

by restricting or significantly delaying our introduction of M356.

***Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of follow-on biologics has been enacted, the constitutionality of the health care reform law has been challenged and the standards for determining sameness or similarity for follow-on biologics are only just being implemented by the FDA. Therefore, substantial uncertainty remains about the potential value our proprietary technology platform can offer to FOB development programs.***

The regulatory climate in the United States for follow-on versions of biologic and complex protein products remains uncertain, even following the recent enactment of legislation establishing a regulatory pathway for the approval of follow-on biologics. The new pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing brand product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the brand product and (2) interchangeable products, which in addition to being biosimilar can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. Only interchangeable biosimilar products would be considered interchangeable at the retail pharmacy level. The new legislation authorizes but does not require the FDA to establish standards or criteria for determining biosimilarity and interchangeability, and also authorizes the FDA to use its discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis. Our competitive advantage in this area will depend on our success in demonstrating to the FDA that our analytics and protein engineering platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the agency begins to implement the new law. In addition, the FDA will likely require significant new resources and expertise to review biosimilar applications, and the timeliness of the review and approval of our future applications could be adversely affected if there were a decline or even limited growth in FDA funding.

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The new regulatory pathway also creates a number of additional obstacles to the approval and launch of biosimilar and interchangeable products, including:

- an obligation of the applicant to share, in confidence, the information in its abbreviated pathway application with the brand company s and patent owner s counsel as a condition to using the new patent clearance process;

- the inclusion of multiple potential patent rights in the patent clearance process; and

- a grant to each brand company of 12 years of marketing exclusivity following the brand approval.

Furthermore, the new regulatory pathway creates the risk that the brand company, during its 12-year marketing exclusivity period, will develop and replace its product with a modified product that qualifies for an additional 12-year marketing exclusivity period, reducing the opportunity for substitution at the retail pharmacy level for an interchangeable FOB. Finally, the new legislation also creates the risk that, as brand and FOB companies gain experience with the new regulatory pathway, subsequent FDA determinations or court rulings could create additional areas for potential disputes and resulting delays in FOB approval.

Several states have challenged the healthcare reform legislation as unconstitutional, and at least two federal courts have ruled that it is unconstitutional in whole or in part. The cases have been appealed in several circuits leading to split decisions on constitutionality. Further appeals have been filed in the United States Supreme Court and oral argument was heard in March 2012. A decision is pending and could issue in 2012. The ultimate outcome is uncertain and one outcome is that the entire health care reform law is declared unconstitutional, including the biosimilar pathway. Alternative outcomes could include a ruling upholding the legislation or declaring that portions of the legislation are unconstitutional that do not pertain to the biosimilar approval pathway. In addition, there is reconsideration and legislative debate that could lead to the repeal or amendment of the new healthcare legislation. If the legislation is declared unconstitutional, is significantly amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

***Even if we are able to obtain regulatory approval for our generic product candidates as therapeutically equivalent, state pharmacy boards or agencies may conclude that our products are not substitutable at the pharmacy level for the reference listed drug. If our generic products are not substitutable at the pharmacy level for their reference listed drugs, this could materially reduce sales of our products and our business would suffer.***

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and provide it with an A rating in the FDA s Orange Book, this designation is not binding on state pharmacy boards or agencies. As a result, in states that do not deem our product candidates therapeutically equivalent, physicians will be required to specifically prescribe a generic product alternative rather than have a routine substitution at the pharmacy level for the prescribed brand product. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states which would substantially harm our business.

***If our preclinical studies and clinical trials for our development candidates, including M402, are not successful, we will not be able to obtain regulatory approval for commercial sale of our novel or improved drug candidates.***

To obtain regulatory approval for the commercial sale of our novel drug candidates, we are required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical studies and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development candidates is high.

A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize M402 or our other drug candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- our preclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional preclinical studies or clinical trials or we may abandon projects that we previously expected to be promising;

- enrollment in our clinical trials may be slower than we anticipate, resulting in significant delays, and participants may drop out of our clinical trials at a higher rate than we anticipate;

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- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or if, in their opinion, participants are being exposed to unacceptable health risks;

- the cost of our clinical trials may be greater than we anticipate; and

- the effects of our drug candidates may not be the desired effects or may include undesirable side effects or our product candidates may have other unexpected characteristics.

The results from preclinical studies of a development candidate may not predict the results that will be obtained in human clinical trials. If we are required by regulatory authorities to conduct additional clinical trials or other testing of M402 or our other product candidates that we did not anticipate, if we are unable to successfully complete our clinical trials or other tests, or if the results of these trials are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our drug candidates or we may not be able to obtain marketing approval at all. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products. If any of these events occur, our business will be materially harmed.

***Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.***

We intend in the future to market our products, if approved, outside of the United States, either directly or through collaborative partners. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with the numerous and varying regulatory requirements of each jurisdiction. The approval procedure and requirements vary among countries, and can require, among other things, conducting additional testing in each jurisdiction. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in any other foreign country or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside of the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition, and results of operations.

***Even if we obtain regulatory approvals, our marketed products will be subject to ongoing regulatory review. If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market products and our business would be seriously harmed.***

Even after approval, any drugs or biological products we develop will be subject to ongoing regulatory review, including the review of clinical results which are reported after our products are made commercially available. Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, the manufacturer and manufacturing facilities we use to produce any of our product candidates will be subject to periodic review and inspection by the FDA, or foreign equivalent, and other regulatory agencies. We will be required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Certain changes to an approved product, including in the way it is manufactured or promoted, often require prior FDA approval before the product as modified may be marketed. If we fail to comply with applicable FDA regulatory requirements, we may be subject to fines, warning letters, civil penalties, refusal by the FDA to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions, refusal to permit the import or export of products, and/or criminal prosecutions and penalties.

Similarly, we will be subject to comprehensive compliance obligations under state and federal reimbursement, anti-kickback and government pricing regulations. If we make false price reports, fail to implement adequate compliance controls or our employees violate the laws and regulations governing relationships with health care providers, we could also be subject to substantial fines and penalties, criminal prosecution and debarment from participation in the Medicare, Medicaid, or other government reimbursement programs.

In addition, the FDA s policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from

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future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***If third-party payors do not adequately reimburse customers for any of our approved products, they might not be purchased or used, and our revenue and profits will not develop or increase.***

Our revenue and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from each government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. There is substantial uncertainty whether any particular payor will reimburse the use of any drug product incorporating new technology. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable authority. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products. The Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for our products could have a material adverse effect on our operating results and our overall financial condition.

***Federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare or may otherwise seek to limit healthcare costs, either of which could adversely affect our revenue, if any.***

The Medicare Modernization Act of 2003, or MMA, changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for drugs that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for drug purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered drugs, and provides authority for limiting the number of drugs that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered drugs. As a result of the MMA and the expansion of federal coverage of drug products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could materially adversely affect our operating results and overall financial condition. While the MMA generally applies only to

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drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payors.

Furthermore, health care reform legislation was enacted in 2010 that could significantly change the United States health care system and the reimbursement of products. A primary goal of the law is to reduce or limit the growth of health care costs, which could change the market for pharmaceuticals and biological products.

The law contains provisions that will affect companies in the pharmaceutical industry and other healthcare-related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include an increase to the mandatory rebates for drugs sold into the Medicaid program, an extension of the rebate requirement to drugs used in risk-based Medicaid managed care plans, an extension of mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities, and discounts and fees applicable to brand-name drugs. Although many of these provisions may not apply directly to us, they may change business practices in our industry and, assuming our products are approved for commercial sale, such changes could adversely impact our profitability.

Additionally, the new law establishes an abbreviated regulatory pathway for the approval of FOBs and provides that brand biologic products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new approval pathway for FOBs and adjusting reimbursement for FOBs, the new law could promote the development and commercialization of FOBs. However, given the uncertainty of how the law will be interpreted and implemented, the impact of the law on our strategy for follow-on as well as novel biologics remains uncertain. Other provisions in the law, such as the comparative effectiveness provisions, may ultimately impact positively or negatively both brand and FOB products alike depending on an applicant s clinical data, effectiveness and cost profile. If a brand product cannot be shown to provide a benefit over other therapies, then it might receive reduced coverage and reimbursement. While this might increase market share for follow-on biologics based on cost savings, it could also have the effect of reducing follow-on biologic market share.

The financial impact of this United States health care reform legislation over the next few years will depend on a number of factors, including but not limited to the issuance of implementation regulations and guidance and changes in sales volumes for products eligible for the new system of rebates, discounts and fees. Assuming our products are approved for commercial sale, the new legislation could also have a positive impact on us by increasing the aggregate number of persons with health care coverage in the United States and expanding the market for our products, but such increases, if any, are unlikely to be realized until approximately 2014 at the earliest.

The full effects of the United States health care reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the CMS and other federal and state health care agencies. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability. In addition, litigation may prevent some or all of the legislation from taking effect. Consequently, there is uncertainty regarding implementation of the new legislation.

Several states have challenged the healthcare reform legislation as unconstitutional, and at least two federal courts have ruled that it is unconstitutional in whole or in part. The cases have been appealed in several circuits leading to split decisions on constitutionality. Further appeals have been filed in the United States Supreme Court and oral argument was heard in March 2012. A decision is pending and could issue in 2012.

***Foreign governments tend to impose strict price or reimbursement controls, which may adversely affect our revenue, if any.***

In some foreign countries, particularly the countries of the European Union, the pricing and/or reimbursement of prescription pharmaceuticals are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development involves, and may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. For the years ended December 31, 2011, 2010 and 2009, we spent approximately $52,000, $57,000 and $125,000, respectively, in order to comply with environmental and waste disposal regulations. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous

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materials. Insurance may not provide adequate coverage against potential liabilities and we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in review and approval of applications. As a result, the review and potential approval of our application for M356 may be significantly delayed.***

The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in the review and approval of ANDAs and amendments or supplements due to insufficient staffing and resources. Resource constraints have also resulted in significant delays in conducting ANDA-related pre-approval inspections. The FDA has proposed legislation that would enact user fees to fund additional resources and that would be accompanied by statutory review periods to the address this backlog and the delays. Currently, the FDA is obligated to give priority to NDA and BLA applications that are subject to statutory review time periods. Until such time as resources are increased by the FDA, our applications and supplements may be subject to significant delays during their review cycles. In addition, if a user fee statute is enacted, we may become liable for fees that could be material to our earnings.

**Risks Relating to Patents and Licenses**

***If we are not able to obtain and enforce patent protection for our discoveries, our ability to successfully commercialize our product candidates will be harmed and we may not be able to operate our business profitably.***

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patent applications. As a result, we may be required to obtain licenses under third- party patents to market our proposed products. If licenses are not available to us on acceptable terms, or at all, we will not be able to market the affected products.

Assuming the other requirements for patentability are met, currently, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States will transition to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter parties* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not guarantee that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or to others.

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The allowance of broader claims may increase the incidence and cost of patent interference proceedings and/or opposition proceedings, and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage. Moreover, once they have issued, our patents and any patent for which we have licensed or may license rights may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited, other companies will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

***Third parties may allege that we are infringing their intellectual property rights, forcing us to expend substantial resources in resulting litigation, the outcome of which would be uncertain. Any unfavorable outcome of such litigation could have a material adverse effect on our business, financial position and results of operations.***

The issuance of our own patents does not guarantee that we have the right to practice the patented inventions. Third parties may have blocking patents that could be used to prevent us from marketing our own patented product and practicing our own patented technology.

If any party asserts that we are infringing its intellectual property rights or that our creation or use of proprietary technology infringes upon its intellectual property rights, we might be forced to incur expenses to respond to and litigate the claims. Furthermore, we may be ordered to pay damages, potentially including treble damages, if we are found to have willfully infringed a party s patent rights. In addition, if we are unsuccessful in litigation, or pending the outcome of litigation, a court could issue a temporary injunction or a permanent injunction preventing us from marketing and selling the patented drug or other technology for the life of the patent that we have allegedly or been deemed to have infringed. Litigation concerning intellectual property and proprietary technologies is widespread and can be protracted and expensive, and can distract management and other key personnel from performing their duties for us.

Any legal action against us or our collaborators claiming damages and seeking to enjoin any activities, including commercial activities relating to the affected products, and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive, and therefore, our competitors may have access to the same technology licensed to us.

If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

***If we become involved in patent litigation or other proceedings to determine or enforce our intellectual property rights, we could incur substantial costs which could adversely affect our business.***

We may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of third-party patent or other proprietary rights in jurisdictions where we intend to market our products, including the United States, the European Union, and many other foreign jurisdictions. The cost to us of any litigation or other proceeding relating to determining the validity of intellectual property rights, even if resolved in our favor, could be substantial and could divert our management s efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they may have substantially greater resources. Moreover, the failure to obtain a favorable outcome in any litigation in a jurisdiction where there is a claim of patent infringement could significantly delay the marketing of our products in that particular jurisdiction. Counterclaims for damages and other relief may be triggered by such enforcement actions. The costs, uncertainties and counterclaims resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

***We in-license a significant portion of our proprietary technologies and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to develop our product candidates.***

We are a party to and rely on a number of in-license agreements with third parties, such as those with the Massachusetts Institute of Technology, that give us rights to intellectual property that is necessary for our business. In addition, we expect to enter into additional licenses in the future. Our current in-license arrangements impose various diligence, development, royalty and other obligations on us. If we breach our obligations with regard to our exclusive in-licenses, they could be converted to non-exclusive licenses or the agreements could be terminated, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology.

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**Risks Relating to Our Dependence on Third Parties**

***The 2003 Sandoz Collaboration and 2006 Sandoz Collaboration are important to our business. If Sandoz fails to adequately perform under either collaboration, or if we or Sandoz terminate all or a portion of either collaboration, the development and commercialization of some of our drug candidates, including enoxaparin sodium injection, would be delayed or terminated and our business would be adversely affected.***

*2003 Sandoz Collaboration*

Either we or Sandoz may terminate the 2003 Sandoz Collaboration for material uncured breaches or certain events of bankruptcy or insolvency by the other party. Sandoz may also terminate the 2003 Sandoz Collaboration if the enoxaparin sodium injection product or the market lacks commercial viability, if new laws or regulations are passed or court decisions rendered that substantially diminish our legal avenues for commercialization of enoxaparin sodium injection, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If the 2003 Sandoz Collaboration is terminated other than due to our uncured breach or bankruptcy, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize enoxaparin sodium injection in the United States. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from commercializing enoxaparin sodium injection. If Sandoz terminates the 2003 Sandoz Collaboration due to our uncured breach or bankruptcy, Sandoz would retain the exclusive right to commercialize enoxaparin sodium injection in the United States. In that event, we would no longer have any influence over the commercialization strategy of enoxaparin sodium injection in the United States. In addition, Sandoz would retain its rights of first negotiation with respect to certain of our other products in certain circumstances and its rights of first refusal outside of the United States and the European Union. Accordingly, if Sandoz terminates the 2003 Sandoz Collaboration, we may decide to discontinue the enoxaparin sodium injection project, or our revenue may be reduced, any one of which could have a material adverse effect on our business.

*2006 Sandoz Collaboration*

Either we or Sandoz may terminate the Second Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. In addition, either we or Sandoz may terminate some of the products, on a product-by-product basis, if clinical trials are required. For some of the products, for any termination of the Second Sandoz Collaboration Agreement other than a termination by Sandoz due to our uncured breach or bankruptcy, or a termination by us alone due to the need for clinical trials, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize the particular product. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. For some products, if Sandoz terminates the Second Sandoz Collaboration Agreement due to our uncured breach or bankruptcy, or if there is a termination by us alone due to the need for clinical trials, Sandoz would retain the exclusive right to develop and commercialize the applicable product. In that event, we would no longer have any influence over the development or commercialization strategy of such product. In addition, for other products, if Sandoz terminates due to our uncured breach or bankruptcy, Sandoz retains a right to license certain of our intellectual property without the obligation to make any additional payments for such licenses. For certain products, if the Second Sandoz Collaboration Agreement is terminated other than due to our uncured breach or bankruptcy, neither party will have a license to the other party s intellectual property. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. Accordingly, if the Second Sandoz Collaboration Agreement is terminated, our introduction of certain products may be significantly delayed, or our revenue may be significantly reduced either of which could have a material adverse effect on our business.

***The Baxter Agreement is important to our business. If we or Baxter fail to adequately perform under the Agreement, or if we or Baxter terminate all or a portion of the Agreement, the development and commercialization of some of our FOB candidates would be delayed or terminated and our business would be adversely affected.***

The Baxter Agreement may be terminated:

- by either party for breach by the other party (in whole or on a product by product or country-by-country basis);

- by either party for bankruptcy of the other party;

- by us in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;

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- by Baxter for its convenience (in whole or on a product by product basis);

- by us in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided, that we also have certain rights to directly commercialize such product, as opposed to terminating the Baxter Agreement, in event of such a breach by Baxter; or

- by either party in the event there is a condition constituting force majeure for more than a certain consecutive number of days.

If the Baxter Agreement were terminated by Baxter for convenience or if Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products in the specified time frame or if we terminate the Baxter Agreement for breach by Baxter, while we would have the right to research, develop, manufacture or commercialize the terminated products or license a third party to do so, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from commercializing our FOB candidates. In addition, we may need to seek additional financing to support the research, development and commercialization of the terminated products or alternatively we may decide to discontinue the terminated products, which could have a material adverse effect on our business. If Baxter terminates the Baxter Agreement due to our uncured breach, Baxter would retain the exclusive right to commercialize the terminated products on a world-wide basis, subject to certain payment obligations to us as outlined in the Agreement. In addition, depending upon the timing of the termination, we would no longer have any influence over or input into the clinical development strategy or/and the commercialization strategy or/and the legal strategy of the products in the territory.

***We and our collaborative partners depend on third parties for the manufacture of products. If we encounter difficulties in our supply or manufacturing arrangements, our business may be materially adversely affected.***

We have a limited number of personnel with experience in, and we do not own facilities for, manufacturing products. In addition, we do not have, and do not intend to develop, the ability to manufacture material for our clinical trials or at commercial scale. To develop our product candidates, apply for regulatory approvals and commercialize any products, we or our collaborative partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. In order to generate revenue from the sales of enoxaparin sodium injection, sufficient quantities of such product must also be produced in order to satisfy demand. If these contract manufacturers are unable to manufacture sufficient quantities of product, comply with regulatory requirements, or breach or terminate their manufacturing arrangements with us, the development and commercialization of the affected products or drug candidates could be delayed, which could have a material adverse effect on our business. In addition, any change in these manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

We have relied upon third parties to produce material for preclinical and clinical studies and may continue to do so in the future. We cannot be certain that we will be able to obtain and/or maintain long-term supply and supply arrangements of those materials on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

In addition, the FDA and other regulatory authorities require that our products be manufactured according to current good manufacturing practices, or cGMP, regulations and that proper procedures are implemented to assure the quality of our sourcing of raw materials and the

manufacture of our products. Any failure by us, our collaborative partners or our third-party manufacturers to comply with cGMP, and/or our failure to scale-up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action, including product recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions. To the extent we rely on a third-party manufacturer, the risk of non-compliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.***

We do not have a sales organization and have no experience as a company in the sale, marketing or distribution of pharmaceutical products. There are risks involved with establishing our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, developing a sales force is expensive and time consuming and could delay any product launch. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing or distribution services, we will have less control over sales of our products and our future revenue would depend heavily on the success of the efforts of these third parties.

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**General Company Related Risks**

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and our by-laws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified board of directors;
- a prohibition on actions by our stockholders by written consent; and
- limitations on the removal of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

***Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.***

The stock market in general and the market prices for securities of biotechnology companies in particular have experienced extreme volatility that often has been unrelated or disproportionate to the operating performance of these companies. The trading price of our common stock has been, and is likely to continue to be, volatile. Furthermore, our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure of enoxaparin sodium injection to sustain commercial success or to meet expectations of securities analysts;

- failure to obtain FDA approval for the M356 ANDA;

- other adverse FDA decisions relating to our enoxaparin sodium injection product or M356 program, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M356 ANDA approval;

- announcements by other companies regarding the status of their ANDAs for generic versions of Lovenox or Copaxone;

- FDA approval of other companies ANDAs for generic versions of Lovenox or Copaxone;

- marketing and/or launch of other companies generic versions of Lovenox or Copaxone;

- litigation involving our company or our general industry or both, including litigation pertaining to the launch of our, our collaborative partners or our competitors products;

- a decision in favor of or against Amphastar and Watson in the current patent litigation matters, or a settlement related to any case;

- adverse FDA decisions regarding the development requirements for one or our FOB development candidates or failure of our other product applications to meet the requirements for regulatory review and/or approval;

- results or delays in our or our competitors clinical trials or regulatory filings;

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- a ruling by the United States Supreme Court that the health care reform law is unconstitutional to the extent that the biosimilar regulatory pathway is no longer in effect; or legislation is enacted that repeals the law enacting the biosimilar regulatory approval pathway;

- failure to demonstrate therapeutic equivalence, biosimilarity or interchangeability with respect to our technology-enabled generic product candidates or FOBs;

- demonstration of or failure to demonstrate the safety and efficacy for our novel development product candidates;

- our inability to manufacture any products in conformance with cGMP or in sufficient quantities to meet the requirements for the commercial launch of the product or to meet market demand;

- failure of any of our product candidates, if approved, to achieve commercial success;

- the discovery of unexpected or increased incidence in patients adverse reactions to the use of our products or product candidates or indications of other safety concerns;

- developments or disputes concerning our patents or other proprietary rights;

- changes in estimates of our financial results or recommendations by securities analysts;

- termination of any of our collaborations;

- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- investors general perception of our company, our products, the economy and general market conditions;

- rapid or disorderly sales of stock by holders of significant amounts of our stock; or

- significant fluctuations in the price of securities generally or biotech company securities specifically.

If any of these factors causes an adverse effect on our business, results of operations or financial condition, the price of our common stock could fall and investors may not be able to sell their common stock at or above their respective purchase prices.

***We could be subject to class action litigation due to stock price volatility, which, if it occurs, will distract our management and could result in substantial costs or large judgments against us.***

The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of companies in the biotechnology industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. We may be the target of similar litigation in the future. Securities litigation could result in substantial costs and divert our management s attention and resources, which could cause serious harm to our business, operating results and financial condition.

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**Item 6.** **Exhibits.**

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| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101+ | The following materials from Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Comprehensive (Loss) Income, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Unaudited, Condensed Consolidated Financial Statements. |

+In accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall be deemed to be furnished and not filed.

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**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.

Momenta Pharmaceuticals, Inc.

Date: May 9, 2012

By: /s/ Craig A. Wheeler
Craig A. Wheeler, President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2012

By: /s/ Richard P. Shea
Richard P. Shea, Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)