MOMENTA PHARMACEUTICALS INC
Form 10-Q
May 05, 2011
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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, 2011

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 o 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 o	Accelerated filer x
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, 2011.

Class	**Number of Shares**
Common Stock $0.0001 par value	50,852,549

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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, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 58,658	$ 100,681
Marketable securities	123,364	52,078
Accounts receivable	82,354	54,485
Unbilled revenue	1,928	5,265
Prepaid expenses and other current assets	2,176	1,793
Total current assets	268,480	214,302
Property and equipment, net of accumulated depreciation	10,365	9,003
Intangible assets, net	2,411	2,486
Restricted cash	1,778	1,778
Total assets	$ 283,034	$ 227,569
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 4,728	$ 4,394
Accrued expenses	5,687	9,098
Deferred revenue	2,156	2,150
Capital lease obligations	1,514	1,729
Lease financing liability	65	258
Deferred rent	6	23
Total current liabilities	14,156	17,652
Deferred revenue, net of current portion	3,227	3,763
Other long term liabilities	51	51
Total liabilities	17,434	21,466
Stockholders Equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized at March 31, 2011 and December 31, 2010, 100 shares of Series A Junior Participating Preferred Stock, $0.01 par value designated and no shares issued and outstanding		
	5	5

Common stock, $0.0001 par value; 100,000 shares authorized at March 31, 2011 and December 31, 2010, 50,809 and 49,747 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively				
Additional paid-in capital		492,417		489,873
Accumulated other comprehensive loss		(69)		(16)
Accumulated deficit		(226,753)		(283,759)
Total stockholders equity		265,600		206,103
Total liabilities and stockholders equity	$	283,034	$	227,569

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 OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Collaboration revenues:		
Product revenue	$ 75,761	$
Research and development revenue	2,411	3,690
Total collaboration revenue	78,172	3,690
Operating expenses:		
Research and development*	12,943	12,255
General and administrative*	8,310	7,475
Total operating expenses	21,253	19,730
Operating income (loss)	56,919	(16,040)
Other income (expense):		
Interest income	128	60
Interest expense	(41)	(104)
Total other income (expense)	87	(44)
Net income (loss)	$ 57,006	$ (16,084)
Net income (loss) per share:		
Basic	$ 1.15	$ (0.37)
Diluted	$ 1.13	$ (0.37)
Weighted average shares outstanding:		
Basic	49,532	43,752
Diluted	50,334	43,752

*Includes the following share-based compensation expense:		
Research and development	$ 837	$ 1,539
General and administrative	$ 929	$ 2,529

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,	
	2011	**2010**
Cash Flows from Operating activities:		
Net income (loss)	$ 57,006	$ (16,084)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,117	1,100
Share-based compensation expense	1,766	4,068
Amortization of premium on investments	245	368
Amortization of intangibles	75	75
Loss on disposal of assets		6
Changes in operating assets and liabilities:		
Accounts receivable	(27,869)	
Unbilled revenue	3,337	2,138
Prepaid expenses and other current assets	(383)	(897)
Accounts payable	334	(1,735)
Accrued expenses	(3,411)	(1,632)
Deferred rent	(17)	(17)
Deferred revenue	(530)	(563)
Other long term liabilities		25
Net cash provided by (used in) operating activities	31,670	(13,148)
Cash Flows from Investing activities:		
Purchases of property and equipment	(2,479)	(323)
Purchases of marketable securities	(137,316)	(8,989)
Proceeds from maturities of marketable securities	65,732	24,960
Net cash (used in) provided by investing activities	(74,063)	15,648
Cash Flows from Financing activities:		
Proceeds from issuance of common stock under stock plans	778	670
Payments on financed leasehold improvements	(193)	(180)
Principal payments on capital lease obligations	(215)	(579)
Net cash provided by (used in) financing activities	370	(89)
(Decrease) increase in cash and cash equivalents	(42,023)	2,411
Cash and cash equivalents, beginning of period	100,681	21,934
Cash and cash equivalents, end of period	$ 58,658	$ 24,345
Supplemental Cash Flow Information:		
Cash paid for interest	$ 41	$ 104

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 one collaborative partner. Collaboration revenue includes product revenue related to sales of enoxaparin sodium injection and reimbursement of research and development expenses.

Basis of Presentation

The accompanying unaudited, condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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, 2011 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, 2010, which was filed with the SEC on March 10, 2011.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The Company s condensed 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 generally accepted accounting principles, or GAAP, in the United States requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses. Actual results could differ materially from those estimates.

Reclassifications

Certain prior year amounts in marketable securities have been reclassified to conform to the current year presentation.

Revenue Recognition

Product Revenue

Profit share and/or royalty revenue is reported as product revenue and is recognized based upon net sales of licensed products in licensed territories as provided by the collaboration agreement in the period the sales occur. 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.

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Research and Development Revenue

The Company receives revenue from collaboration agreements with one collaborative partner. Under the terms of collaboration agreements entered into by the Company, the Company may receive non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales. Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is then allocated among the separate units based on either their respective fair values or the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

In October 2009, the Financial Accounting Standards Board issued a new accounting standard which amends the guidance on the accounting for arrangements involving the delivery of more than one element. This standard 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. The Company adopted this new accounting standard on a prospective basis 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.

Pursuant to the new standard, each required deliverable is evaluated 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 limited to the consideration not contingent upon future deliverables.

For multiple-element arrangements entered into prior to January 1, 2011 and not materially modified thereafter, the Company continues to apply its prior accounting policy with respect to such arrangements. Under this policy, in general, revenue from non-refundable, upfront fees related to intellectual property rights/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. This requirement with respect to the fair value of undelivered items was eliminated in the newly issued accounting standard. Research and development funding is recognized as earned over the period of effort. In general, the consideration with respect to the other deliverables is recognized when the goods or services are delivered.

Milestone payments are recognized as research and development revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payment is deferred and recognized as revenue over the estimated remaining period of performance under the contract as the Company completes its performance obligations.

Cash and Cash Equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash and that mature within three months from date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and were primarily comprised of money market funds at March 31, 2011 and December 31, 2010.

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

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included in accumulated other comprehensive 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. 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 during the three months ended March 31, 2011. There were no realized gains or losses on marketable securities during the three months ended March 31, 2011 and 2010.

Accounts Receivable and Unbilled Revenue

Accounts receivable represents amounts due to the Company at March 31, 2011 and December 31, 2010 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, 2011 and December 31, 2010 from one 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.

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 undiscounted future cash flows of such assets or businesses. No impairment charges have been recognized through March 31, 2011.

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

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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 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 Income (Loss) Per Share

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted average number of shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) 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. For the three months ended March 31, 2010, the effect of all potentially dilutive securities is anti-dilutive as the Company had a net loss in that period. Accordingly, basic and diluted net loss per share is the same in that period.

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. For the three months ended March 31, 2011, the Company had no material unrecognized tax benefits and no adjustments to its deferred tax assets. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense. The Company expects to generate U.S. taxable income during 2011. However, the Company s U.S. taxable income is expected to be offset by net operating loss carryforwards and other deferred tax attributes resulting in an estimated tax rate of zero for the year ended December 31, 2011.

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 carryforwards that originated before 2004. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

Comprehensive Income (Loss)

Accumulated other comprehensive loss as of March 31, 2011 and December 31, 2010 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive income (loss) for the three months ended March 31, 2011 and 2010 was $56.9 million and $(16.1) million, respectively.

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, 2011 have come from one collaborative partner and are based solely on activities in the United States.

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3. Net Income (Loss) 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, 2011	For the Three Months Ended March 31, 2010
Numerator:		
Net income (loss)	$ 57,006	$ (16,084)
Denominator:		
Basic weighted average shares outstanding	49,532	43,752
Weighted average stock equivalents from assumed exercise of stock options and restricted stock awards	802	
Diluted weighted average shares outstanding	50,334	43,752
Basic net income (loss) per share	$ 1.15	$ (0.37)
Diluted net income (loss) per share	$ 1.13	$ (0.37)
Weighted average anti-dilutive shares related to:		
Outstanding stock options	2,324	3,135
Restricted stock awards	37	774

The weighted average anti-dilutive shares shown in the foregoing table were not included in the computation of diluted net income (loss) per share. In those reporting periods in which the Company has reported net income, anti-dilutive shares comprise those 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 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 stock equivalents that would be anti-dilutive had the Company had net income.

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, 2011 and December 31, 2010 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value.

Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets. Fair values determined by Level 2 inputs utilize data points from active markets that are observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

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 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, 2011 and December 31, 2010.

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

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The following tables set forth the Company s financial assets that were recorded at fair value at March 31, 2011 and December 31, 2010 (in thousands):

Description	Balance as of March 31, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 57,670	$ 57,670	$	$
Marketable securities:				
U.S. Government-sponsored enterprise obligations	71,465		71,465	
Corporate debt securities	33,901		33,901	
Commercial paper obligations	16,993		16,993	
U.S. Treasury obligation	1,005	1,005		
Total	$ 181,034	$ 58,675	$ 122,359	$

Description	Balance as of December 31, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 99,911	$ 99,911	$	$
Marketable securities:				
U.S. Government-sponsored enterprise obligations	48,557		48,557	
Corporate debt securities	3,521		3,521	
Total	$ 151,989	$ 99,911	$ 52,078	$

In the tables above, as of March 31, 2011 and December 31, 2010, corporate debt securities include $9.3 million and $3.5 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 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.

The Company did not have any non-recurring fair value measurements on any assets or liabilities at March 31, 2011 and December 31, 2010.

5. Cash, Cash Equivalents and Marketable Securities

The following table summarizes the Company s cash, cash equivalents and marketable securities as of March 31, 2011 and December 31, 2010 (in thousands):

As of March 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 58,658	$	$	$ 58,658
U.S. Government-sponsored enterprise obligations				
Due in one year or less	29,608	6	(1)	29,613
Due in two years or less	41,906	4	(58)	41,852
Corporate debt securities				
Due in one year or less	30,585	2	(19)	30,568
Due in two years or less	3,348		(15)	3,333
Commercial paper obligations due in one year or less	16,982	11		16,993
U.S. Treasury obligations due in one year or less	1,004	1		1,005
Total	$ 182,091	$ 24	$ (93)	$ 182,022
Reported as:				
Cash and cash equivalents	$ 58,658	$	$	$ 58,658
Marketable securities	123,433	24	(93)	123,364
Total	$ 182,091	$ 24	$ (93)	$ 182,022

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As of December 31, 2010	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 100,681	$	$	$ 100,681
U.S. Government-sponsored enterprise obligations				
Due in one year or less	37,574	2	(15)	37,561
Due in two years or less	10,996	3	(3)	10,996
Corporate debt securities due in one year or less	3,524		(3)	3,521
Total	$ 152,775	$ 5	$ (21)	$ 152,759
Reported as:				
Cash and cash equivalents	$ 100,681	$	$	$ 100,681
Marketable securities	52,094	5	(21)	52,078
Total	$ 152,775	$ 5	$ (21)	$ 152,759

At March 31, 2011, the Company held 16 marketable securities that were in an unrealized loss position for less than one year. At December 31, 2010, the Company held 13 marketable securities that were in an unrealized loss position for less than one year. The unrealized losses were caused by fluctuations in interest rates. The following table summarizes the aggregate fair value of these securities at March 31, 2011 and December 31, 2010 (in thousands):

	As of March 31, 2011		As of December 31, 2010	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
U.S. Government-sponsored enterprise obligations	$ 41,618	$ (59)	$ 37,316	$ (18)
Corporate debt securities	$ 24,291	$ (34)	$ 3,521	$ (3)

No marketable securities were in an 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, 2011 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, 2011 and December 31, 2010, intangible assets, net of accumulated amortization, are as follows (in thousands):

		March 31, 2011		December 31, 2010	
	Estimated Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Core technology	12 years	$ 3,593	$ (1,182)	$ 3,593	$ (1,107)
Non-compete agreement	2 years	170	(170)	170	(170)
Total intangible assets		$ 3,763	$ (1,352)	$ 3,763	$ (1,277)

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Amortization is computed using the straight-line method over the useful lives of the respective intangible assets. Amortization expense was $75,000 for each of the three months ended March 31, 2011 and 2010.

The Company expects to incur amortization expense of approximately $0.3 million per year for each of the next five years.

7. Collaboration and License Agreements

2003 Sandoz Collaboration

In November 2003, the Company entered into a collaboration and license agreement (the 2003 Sandoz Collaboration) with Sandoz N.V. and Sandoz Inc. to jointly develop and commercialize enoxaparin sodium injection, a generic version of Lovenox®, a low molecular weight heparin or LMWH. Sandoz N.V. later assigned its rights and obligations under the 2003 Sandoz Collaboration to Sandoz AG. Sandoz AG and Sandoz Inc. are collectively referred to as Sandoz. 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 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 including: (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 has determined that a single unit of accounting exists with respect to the 2003 Sandoz Collaboration.

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. In addition, in the event no third-party competitors are marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), Sandoz will pay the Company 45% of the contractual profits from the sale of enoxaparin sodium injection. If a third-party competitor begins marketing a Lovenox-Equivalent Product, Sandoz will instead pay the Company a royalty based on net sales of enoxaparin sodium injection. If the only Lovenox-Equivalent Product being marketed by a third-party competitor is Lovenox being marketed by Sanofi-Aventis, which distributes Lovenox, as a generic drug or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, Sandoz will pay the Company a combination of a royalty payment based on net sales and a share of profits. If certain milestones are achieved with respect to enoxaparin sodium injection under certain circumstances, Sandoz will make payments to the Company which would reach $55 million if all such milestones are achieved.

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.

Collaboration Revenue

On July 23, 2010, the FDA granted marketing approval of the ANDA for enoxaparin sodium injection filed by Sandoz. As a result of the FDA s approval, the Company achieved a regulatory milestone defined in the 2003 Sandoz Collaboration and recorded $5.0 million in research and development revenue from Sandoz in the year ended December 31, 2010. Because no third-party competitors marketed a Lovenox-Equivalent Product during the three months ended March 31, 2011, the Company earned $75.8 million in profit-share product revenue from Sandoz during the three months ended March 31, 2011.

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

In July 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 Definitive Agreement). Together, this series of agreements is referred to as the 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 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 in each of the three months ended March 31, 2011 and 2010. 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 three other follow-on and complex generic products for sale in specified regions of the world. In December 2008, the Company and Sandoz AG terminated the collaborative program with regard to one of the follow-on products, M249, primarily due to the commercial prospects for M249. In December 2009, the Company and Sandoz AG terminated the collaborative program with regard to the other follow-on product, M178. 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. For the remaining products under the collaboration, 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 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 including: (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 Definitive 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 Definitive 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 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 if all milestones are achieved for the products remaining under collaboration. None of these payments, once received, is refundable and there are no general rights of return in the 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 are 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.

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.

In exchange for these rights, the Company paid M.I.T. a license issue fee, and pays annual license maintenance fees. The Company, upon commercialization, is also required to pay M.I.T. royalties on 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. M.I.T. and certain contributing individuals were also issued shares of the Company s common stock. The Company recorded license fee expense of approximately $39,000 related to these agreements for each of the three months ended March 31, 2011 and 2010, and royalty fee expense of $1.4 million for the three months ended March 31, 2011, related to these agreements.

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8. 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, 2010, the Company was authorized to issue up to 11,394,748 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, 2011, the Company s Board of Directors increased the number of authorized shares by 1,974,393 shares. At March 31, 2011, the Company had 5,637,256 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, 2011 and 2010 was $1.8 million and $4.1 million, respectively.

In the three month period ended March 31, 2010, the Company recorded a charge to research and development expense of $0.6 million and a charge to general and administrative expense of $1.0 million, due to a correction in the application of the stock option forfeiture rates used to calculate share-based compensation during the years ending December 31, 2006, 2007 and 2008. In accordance with SEC Staff Accounting Bulletin (SAB) No. 99, *Materiality,* and SAB No. 108, the Company assessed the materiality of these charges to its consolidated financial statements for the years ended December 31, 2006, 2007 and 2008, using both the roll-over method and iron-curtain method as defined in SAB No. 108. The Company concluded the effect of understating share-based compensation was not material to its consolidated financial statements for the years ended December 31, 2006, 2007 and 2008 and, as such, those consolidated financial statements are not materially misstated. The Company also concluded that providing for the correction of the understatement in 2010 would not have a material effect on its consolidated financial statements for the year ending December 31, 2010.

Share-based compensation expense related to outstanding employee stock option grants and the Company s employee stock purchase plan was $1.5 million and $3.3 million for the three months ended March 31, 2011 and 2010, respectively. During the three months ended March 31, 2011, 667,884 stock options were granted in connection with annual merit, new hire and Board of Director awards. The weighted average grant date fair value of options granted to employees and members of the Company s Board of Directors 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, 2011 and 2010 was $8.75 and $9.93 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, 2011	For the Three Months Ended March 31, 2010	For the Three Months Ended March 31, 2011	For the Three Months Ended March 31, 2010
Expected volatility	69%	71%	78%	86%
Expected dividends				
Expected life (years)	6.5	5.9	0.5	0.5
Risk-free interest rate	2.9%	3.1%	0.2%	0.2%

At March 31, 2011, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $11.0 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.6 years.

During the three months ended March 31, 2011, holders of options issued under the Company s stock plans exercised their right to acquire an aggregate of 65,109 shares of common stock. Additionally, during the three months ended March 31, 2011, the Company issued 26,134 shares of common stock to employees under the Company s employee stock purchase plan.

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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, 2011, the Company awarded 136,907 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. In addition, during the three months ended March 31, 2011, the Company awarded 835,800 shares of performance-based restricted common stock to its employees and officers. 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. The awards of restricted common stock are generally forfeited if the employment relationship terminates with the Company prior to vesting.

The Company recorded share-based compensation expense related to outstanding restricted stock awards, including the performance based shares as the Company determined that it was probable the performance condition would be achieved, of $0.4 million and $0.7 million for the three months ended March 31, 2011 and 2010, respectively. As of March 31, 2011, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $14.8 million, which is expected to be recognized over the weighted average remaining requisite service period of 2.5 years.

A summary of the status of nonvested shares of restricted stock as of March 31, 2011, and the changes during the three months then ended, is presented below:

	Number of Shares (in thousands)		Weighted Average Grant Date Fair Value
Nonvested at January 1, 2011	284	$	12.22
Granted	972		14.37
Vested	(56)		12.75
Forfeited	(2)		7.41
Nonvested at March 31, 2011	1,198	$	13.95

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of March 31, 2011 are summarized below:

Vesting Schedule	Nonvested Shares (in thousands)
Time-based	362
Performance-based	836
Nonvested at March 31, 2011	1,198

9. Legal Contingencies

In July 2008, the FDA accepted for review the ANDA containing a paragraph IV certification for generic Copaxone submitted by Sandoz. Subsequently, in August 2008, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and the Company for patent infringement related to four of the seven Orange Book patents listed for Copaxone in the United States District Court for the Southern District of New York. The Company 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. In January 2010, the court heard arguments from the parties on the meaning of certain disputed claim terms in a claim construction hearing (also known as a Markman hearing). There is no defined timeline for the judge to issue a decision on claim construction and such a decision could be issued at any time Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva Pharmaceutical Industries Ltd. 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. A trial has been scheduled for September 2011 in the consolidated case. On April 4, 2011 Teva filed a motion for summary judgment of no inequitable conduct.

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In a separate lawsuit, in December 2009, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and the Company for patent infringement related to certain non-Orange Book patents. In January 2010, the Company 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.

While it is not possible to determine with any degree of certainty the ultimate outcome of the legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. In addition, under the terms of the 2006 Sandoz Collaboration, Sandoz AG agreed to indemnify the Company for various claims, including patent infringement claims based on the Company s activities related to partnered programs. The Company has not recorded any accrual for such matter as it is not probable that a loss has been incurred nor is a loss estimable.

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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

We are a biotechnology company specializing in the characterization and process engineering of complex molecules. These complex molecules include proteins, polypeptides, and cell surface polysaccharides, like heparan-sulfate proteoglycans, or HSPGs. This results in a diversified product portfolio and pipeline of complex generic, follow-on biologic, and novel drugs derived from our proprietary, innovative technology platform which we leverage to study the structure (thorough characterization of chemical components), structure-process (understand, design and control of manufacturing process), and structure-activity (understand and relate structure to biological and clinical activity) of complex molecule drugs.

Our complex generics and follow-on biologics activities are focused on building a thorough understanding of the structure-process-activity of complex molecule drugs to develop generic versions of marketed products. While we use a similar analytical and development approach across all of our programs, we tailor that approach for each specific program. Our first objective is to apply our core analytical technology to thoroughly characterize the structure of the marketed product. By defining the chemical composition of multiple batches of the marketed product, we are able to develop an equivalence window which captures the inherent variability of the brand company s manufacturing process. Using this information, we then build an extensive understanding of the structure-process relationship to thoroughly understand, design and control our manufacturing process to reproducibly manufacture an equivalent version of the marketed product. Where necessary or appropriate, and as required by the U.S. Food and Drug Administration, or FDA, we will provide regulators with additional supportive structure-activity data (e.g., immunogenicity, pharmacodynamics). Our goal is to obtain FDA approval for and commercialize, either directly or with collaborative partners, complex generic and follow-on biologic products thereby providing high quality, effective, safe and affordable medicines to patients in

need.

Our complex generic programs target marketed products that were originally approved by the 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. Enoxaparin sodium injection received FDA marketing approval in July 2010 as a generic version of Lovenox®, which is used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. Lovenox is a complex mixture of polysaccharide chains derived from naturally sourced heparin. Our second major generic product program, 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 complex mixture of polypeptide chains. With M356, we have extended our core characterization and process engineering capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures. The ANDA for M356 is currently under FDA review.

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In addition to our two complex generic programs, our follow-on biologics, or FOB, program further extends our proprietary technology platform to include the characterization and engineering of therapeutic protein products. By thoroughly characterizing these molecules, which are derived from natural or cell-based manufacturing processes, we seek to gain a deeper understanding of the relationship between the multiple steps involved in their manufacturing processes and the final product compositions. Our goal is to replicate our development approach with enoxaparin sodium injection and M356 to pursue the development and commercialization of follow on, or biosimilar (including interchangeable), biologics.

Our novel drug program leverages our characterization and process engineering capabilities to develop novel drugs by studying the structure-activity of complex mixtures. We are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex molecule drug candidates. Our goal is to capitalize on the structural diversity and/or the multi-targeting potential of these complex molecules to engineer novel drug candidates that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex molecule drug candidates can be applied across several product categories with significant therapeutic potential, our most advanced efforts have been in the area of HSPGs. Our lead novel HSPG-based 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. M402, our second novel HSPG-based drug candidate, is in early development as a potential anti-cancer agent. We also are seeking to discover and develop additional novel HSPG-based drugs, as well as improved and novel protein drug candidates by applying our technology to better understand the function of these complex molecules in biological processes.

In November 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. 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 Definitive Agreement, with Sandoz AG, an affiliate of Novartis Pharma AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Definitive 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.

In July 2010, Sandoz began the commercial sale of enoxaparin sodium injection. Under the 2003 Sandoz Collaboration, in the event no third-party competitors are marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), Sandoz will pay us 45% of the contractual profits from the sale of enoxaparin sodium injection. Because no third-party competitors marketed a Lovenox-Equivalent Product during the three months ended March 31, 2011, we earned $75.8 million in profit-share product revenue from Sandoz during the three months ended March 31, 2011. 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. If a third-party competitor begins marketing a Lovenox-Equivalent Product, Sandoz will instead pay us a royalty based on net sales of enoxaparin sodium injection at royalty rates ranging from high single digit to low double digits. If the only Lovenox-Equivalent Product being marketed by a third-party competitor is Lovenox being marketed by Sanofi-Aventis U.S. LLC, or Sanofi-Aventis, which distributes Lovenox, as a generic drug, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, Sandoz will pay us a combination of a royalty payment based on net sales and a share of profits. 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 five years. The first adjustment will be calculated at the end of the fourth quarter following the commercial launch of enoxaparin sodium injection, which is as of June 30, 2011. We will record this adjustment as a reduction in collaboration product revenue for the quarter ended June 30, 2011 and estimate that it will be in the range of $3.0 million to $4.0 million.

The future revenue that we recognize from the sale of enoxaparin sodium injection will depend on, among other things, whether any other generic versions of Lovenox are approved by the FDA, whether any litigation is partially or wholly successful at limiting Sandoz s sales of enoxaparin sodium injection and whether Sandoz is able to continue commercialization of enoxaparin sodium injection.

In the event no third-party competitor has marketed a Lovenox-Equivalent Product through July 23, 2011, the first anniversary of FDA approval of enoxaparin sodium injection, we will be obligated to make a milestone payment to Parivid, LLC in the form of issuing approximately 332,000 shares of our common stock, but in no event in a number of shares exceeding a value of $12.0 million, pursuant to the terms of the Asset Purchase Agreement we entered into with Parivid, LLC in April 2007.

As of March 31, 2011, we had an accumulated deficit of $226.8 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. Prior to the launch of enoxaparin sodium injection, our revenue had been derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and primarily consisted of amounts earned by us for

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reimbursement by Sandoz of research and development services and development costs for certain programs. During the second half of 2010, we began to derive revenue from our profit share on the commercial sale of enoxaparin sodium injection. We may still 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 maintain profitability.

Financial Operations Overview

Revenue

We have recognized, in the aggregate, $289.6 million of revenue from our inception through March 31, 2011. This revenue was derived entirely from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. We will seek to generate revenue from a combination of research and development payments, profit sharing payments, milestone payments and royalties in connection with our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and similar future collaborative or strategic relationships. In the near term, our current and future revenues are dependent upon the continued sale of enoxaparin sodium injection. 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 profit share and royalty payments we receive and the timing and amount of research and development and other payments received 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.

Commercial and Development Programs

The following summarizes our primary commercial and development programs:

Enoxaparin Sodium Injection

Enoxaparin sodium injection, our first product to receive marketing approval under an ANDA, is a generic version of Lovenox, a complex drug consisting of a mixture of polysaccharide chains. Lovenox is a widely-prescribed low molecular weight heparin, or LMWH, used for the prevention and treatment of DVT and to support the treatment of ACS. Lovenox is distributed worldwide by 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 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.

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. The FDA is currently reviewing the ANDA for the vial form of enoxaparin sodium injection.

In July 2010, Sanofi-Aventis filed a lawsuit in the United States District Court for the District of Columbia against the FDA, Margaret A. Hamburg, Commissioner of Food and Drugs, and Kathleen Sebelius, Secretary of Health and Human Services. The complaint alleged, among other things, that FDA s approval of the ANDA filed by Sandoz for enoxaparin sodium injection was arbitrary and capricious and exceeded FDA s statutory authority by requiring additional data for the purpose of demonstrating the safety or effectiveness of a generic version of Lovenox and departing from its own precedent governing the approval of generic drugs that have not been fully characterized. The lawsuit sought, among other things, a temporary restraining order and preliminary injunction directing the FDA to suspend and withdraw its approval of the ANDA filed by Sandoz for enoxaparin sodium injection. In August 2010, the court denied the motion for a temporary restraining order and preliminary injunction. In December 2010, Sanofi-Aventis filed a motion for summary judgment seeking a reversal of the FDA approval and the defendants have each filed responses opposing the motion and filed cross-motions seeking to affirm the approval of Sandoz s ANDA for enoxaparin sodium injection. We believe that Sanofi-Aventis s claims are without merit and are cooperating with Sandoz to vigorously oppose the lawsuit and uphold the FDA approval.

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In December 2010, we sued Teva Pharmaceutical Industries Ltd., or 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 sodium having specified quality attributes. We will continue to prosecute this case and enforce our patents.

M356

M356 is designed to be a generic version of Copaxone, a complex drug consisting of a mixture of polypeptide chains. Copaxone is indicated for reduction of the frequency of relapses in patients with RRMS. Multiple sclerosis is a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. In North America, Copaxone is marketed by Teva Neuroscience LLC, a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. In Europe, Copaxone is marketed by Teva Pharmaceutical Industries Ltd. and Sanofi-Aventis.

In December 2007, our collaborative partner, Sandoz, submitted to the FDA an ANDA in its name containing a Paragraph IV certification seeking approval to market M356 in the United States. 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.

Follow-On Biologics (FOBs) Program

We are also applying our technology platform to the development of FOBs, including both generic (designated by FDA to be interchangeable) and biosimilar versions of marketed therapeutic proteins. Therapeutic proteins represent a sizable segment of the U.S. drug industry, with sales expected to be approximately $57 billion in 2011. 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 glycoprotein drug 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.

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 their similarity to 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.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.

Adomiparin

Adomiparin is a novel anticoagulant that is a complex drug consisting of a mixture of polysaccharide chains. Adomiparin was rationally designed to capture, in a single therapy, the positive attributes of both unfractionated heparin (reversibility, monitorability and broad inhibition of the coagulation cascade) and LMWH (adequate bioavailability and predictable pharmacokinetics to allow for convenient subcutaneous administration). We believe that adomiparin has the potential to replace these agents and provide a safer, more effective and easier to use baseline anticoagulant therapy for the medical management of patients diagnosed with ACS who may or may not require coronary intervention

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in order to treat their condition. We believe that the properties of adomiparin observed to date in both preclinical and clinical investigations continue to support the design hypothesis and may provide physicians with a more flexible treatment option than is currently available. ACS includes several diseases ranging from unstable angina, which is characterized by chest pain at rest, to acute myocardial infarction, or heart attack, which is caused by a complete blockage of a coronary artery. Currently, a majority of patients are initially medically managed with an anti-clotting agent, such as LMWH or unfractionated heparin, or UFH, in combination with other therapies. Neither LMWH nor UFH were developed specifically for patients with ACS, and both have numerous clinical disadvantages. An increasing proportion of ACS patients are also proceeding to early intervention with procedures such as angioplasty or coronary artery bypass grafting, or CABG. Both angioplasty and CABG require anticoagulant therapy to prevent clot formation during and immediately following the procedure. Adomiparin is designed to be a LMWH that could be used in multiple settings, including initial medical management, angioplasty or CABG.

In July 2006, we filed an Investigational New Drug Application, or IND, with the FDA for our adomiparin intravenous injection product candidate and in October 2006 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In June 2009, we completed a Phase 2a clinical trial to evaluate the feasibility of utilizing adomiparin intravenous injection as an anticoagulant in patients with stable coronary artery disease undergoing percutaneous coronary intervention. This trial, known as EMINENCE (Evaluation of M118 in Percutaneous Coronary Intervention), enrolled approximately 500 patients with stable coronary artery disease undergoing elective percutaneous coronary intervention. Patients were randomly assigned to receive treatment with one of three doses of intravenous adomiparin or a standard dose of UFH. The primary endpoint of the study was the combined incidence of clinical events defined as the composite of death, myocardial infarction, repeat revascularization, and stroke (over thirty days); incidence of bleeding and thrombocytopenia (over the first 24 hours); and bailout use of glycoprotein IIb/IIIa inhibitors and catheter thrombus (during the procedure). The primary analysis in the study provided evidence of non-inferiority of the combined adomiparin group (combining all three doses) as compared to the UFH group within the parameters of the prospectively defined analysis. The observed incidence of the primary endpoint was lower in all adomiparin treatment groups than in the UFH group; however it should be noted that the study was not designed or powered to detect statistically significant differences between treatments. The incidence of serious and non-serious adverse events was comparable in all treatment groups.

In March 2007, we submitted an IND for our adomiparin subcutaneous injection product candidate and in May 2007 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. These trials have been completed.

We believe that the results of clinical trials conducted to date support continuing the evaluation of adomiparin in patients diagnosed with ACS who are medically managed with or without an intervention. We are seeking a collaborative partner to finance and support the further clinical development of adomiparin. We will not start additional clinical trials until we have a partner or funding available, but we remain committed to the product and its continued development.

M402

M402 is our next most advanced novel HSPG-based product candidate and is engineered to have potent anti-cancer properties and low anticoagulant activity. HSPGs 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 HSPG-binding proteins.

A preclinical study, conducted 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, the standard of care chemotherapeutic drug for

pancreatic cancer, significantly improved survival and substantially lowered the incidence of metastasis compared to mice treated with gemcitabine alone.

We currently have plans to advance M402 into human clinical trials in 2011. It is anticipated that M402 will be used in combination with standard-of-care cytotoxic regimens for the treatment of advanced malignancies.

Discovery Program HSPG s and Proteins

Our most advanced discovery research efforts have been in the area of HSPGs. We believe our 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. With HSPGs, our goal is to leverage the multi-targeting nature of these molecules to develop novel HSPG-based therapeutics each of which we could positively affect multiple pathways in a disease with a single drug. Because of the broad role of HSPGs in biology, we plan to target multiple disease areas with this therapeutic approach. While not yet as advanced as our HSPG program, we also are extending these biological systems insights into the development of improved and more targeted protein therapeutics.

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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, 2011 and 2010

Collaboration Revenue

Collaboration revenue for the three months ended March 31, 2011 was $78.2 million, compared with $3.7 million for the three months ended March 31, 2010.

Collaboration revenues are summarized as follows (in thousands):

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
Product revenue	$ 75,761	$
Research and development revenue	2,411	3,690
Total collaboration revenue	$ 78,172	$ 3,690

The increase in collaboration revenue for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 was due primarily to product revenue we earned from Sandoz representing our profit-share on Sandoz sales of enoxaparin sodium injection which launched in July 2010. Sandoz reported $246.9 million in net sales of enoxaparin sodium injection for the three month period ended March 31, 2011. Research and development revenue for the three months ended March 31, 2011 and 2010 consists of amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs, and 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. Research and development revenue for the three month period ended March 31, 2011 compared to the three month period ended March 31, 2010 decreased by $1.3 million primarily due to a decrease in reimbursable manufacturing expenses associated with our M356 program.

There are a number of factors that make it difficult to predict the magnitude of future enoxaparin sodium injection product revenue, including how long we will remain the sole generic competitor to the brand product receiving 45% of the contractual profits compared to receiving a royalty based on net sales of enoxaparin sodium injection ranging from high single digit to low double digits, the inventory levels of enoxpaparin sodium injection maintained by wholesalers, distributors and other customers, the frequency of re-orders by existing customers, the change in estimates for product reserves, the pricing of products that compete with enoxaparin sodium injection and other actions taken by our competitors. Accordingly, our enoxaparin sodium injection collaboration revenue in previous quarters may not be indicative of future enoxaparin sodium injection collaboration revenue. As a result of these and other factors, future enoxaparin sodium injection collaboration revenue could decline or could vary significantly from quarter to quarter.

Research and Development Expense

Research and development expense for the three months ended March 31, 2011 was $12.9 million, compared with $12.3 million for the three months ended March 31, 2010. The increase of $0.6 million, or 5%, from the 2010 period to the 2011 period resulted from increases of: $0.6 million in process development, manufacturing and third-party research costs in support of our development programs, principally our M356 program; $0.4 million in general consulting costs; $0.3 million in personnel and related costs associated with our headcount growth and $0.2 million in depreciation expense and facility related expense. These increases were offset by decreases of $0.7 million in share-based compensation expense due primarily to a modification in 2010 in the application of our forfeiture rate assumption and $0.2 in laboratory expenses related to our enoxaparin sodium injection program.

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. 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, 2011 and 2010, and it shows the total external costs 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, 2011**	**Three Months Ended March 31, 2010**	**Project Inception to March 31, 2011**
Enoxaparin Sodium Injection (ANDA Approved July 2010)	$ 642	$ 695	$ 46,537
M356 (ANDA Filed)	1,187	560	35,251
Adomiparin (Phase 2a)	38	266	35,769
Other development programs	843	758	
Discovery programs	289	90	
Research and development internal costs	9,944	9,886	
Total research and development expense	$ 12,943	$ 12,255	

The increase of $0.6 million in M356 external expenditures from the 2010 period to the 2011 period was primarily due to the timing of process development activities, manufacturing and third-party research costs. The decrease of $0.2 million in adomiparin external expenditures from the 2010 period to the 2011 period was due to the residual costs, incurred in 2010, related to our Phase 2a clinical trial which was completed in June 2009. The increase of $0.1 million in the other development programs from the 2010 period to the 2011 period primarily related to an increase in M402 manufacturing, preclinical and toxicology work. The increase of $0.2 million in the discovery programs relates to our efforts to advance our research and development in the area of HSPGs.

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 $0.1 million from the 2010 period to the 2011 period was due to additional research and development headcount and related costs in support of our development programs.

General and Administrative

General and administrative expense for the three months ended March 31, 2011 was $8.3 million, compared to $7.5 million for the three months ended March 31, 2010. General and administrative expense increased by $0.8 million, or 11%, from the 2010 period to the 2011 period due to increases of: $1.4 million in royalty and license fees payable to Massachusetts Institute of Technology associated with the sales of enoxaparin sodium injection and $1.0 million in professional and other fees primarily due to a increase in legal and consulting activities. These increases were offset by a decrease of $1.6 million in share-based compensation expense due to a modification in 2010 in the application of our forfeiture rate assumption.

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.

Interest Income and Expense

Interest income was $0.1 million and $60,000 for the three months ended March 31, 2011 and 2010, respectively. The increase from the 2010 period to the 2011 period was primarily due to higher average investment balances.

Interest expense was $41,000 and $0.1 million for the three months ended March 31, 2011 and 2010, respectively. The decrease from the 2010 period to the 2011 period was primarily due to the completion of repayment schedules on our equipment line of credit.

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 payments related to product sales of enoxaparin sodium injection, and

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borrowings from our lines of credit and capital lease obligations. The length of time we remain the sole generic competitor to Lovenox, and therefore continue to receive a profit share compared to a royalty based on net sales of enoxaparin sodium injection, will have a notable impact on our near term cash trend. 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 2013. 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, 2011, we had $182.0 million in cash, cash equivalents and marketable securities and $82.4 million in accounts receivable. In addition, we also hold $1.8 million in restricted cash which serves as collateral for a letter of credit related to our facility lease. Our funds at March 31, 2011 were primarily invested in senior debt of government-sponsored enterprises, United States money market funds, commercial paper and corporate debt securities directly or through managed funds, with remaining maturities of 21 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, 2011.

During the three months ended March 31, 2011, our operating activities provided cash of $31.7 million. During the three months ended March 31, 2010, our operating activities used $13.1 million of cash. The cash provided by or used for operating activities generally approximates our net income (loss) adjusted for non-cash items and changes in operating assets and liabilities.

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 of $0.4 million, due to advance payments made for non-clinical 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.

For the three months ended March 31, 2010, our net loss adjusted for non-cash items was $10.5 million. In addition, the net change in our operating assets and liabilities used cash of $2.7 million and resulted from: a decrease in unbilled revenue of $2.1 million, resulting from decreased commercial activities for our M356 program; an increase in prepaid expenses and other current assets of $0.9 million, related to advance payments made for non-clinical program studies and the renewal of vendor maintenance agreements; a decrease in accounts payable of $1.7 million, primarily due to the timing of commercial activities for our M356 program; a decrease in accrued expenses of $1.6 million, resulting from the payment of annual bonuses earned during 2009 and the timing of development manufacturing for our M402 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, 2011, our investing activities used cash of $74.1 million. In the first three months of 2011, we received $65.7 million from maturities of marketable securities and we used $137.3 million of cash to purchase marketable securities. During the three months ended March 31, 2010, our investing activities provided cash of $15.6 million. In the first three months of 2010, we received $25.0 million from maturities of marketable securities and we used $9.0 million of cash to purchase marketable securities. During the three months ended March 31, 2011 and 2010, we used $2.5 million and $0.3 million, respectively, to purchase laboratory equipment and leasehold improvements.

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. During the three months ended March 31, 2010, financing activities used $0.1 million. During the three months ended March 31, 2010, we received net proceeds of $0.7 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $0.6 million on our capital lease agreement obligations and $0.2 million on financed leasehold improvements related to our corporate facility.

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Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations and capital 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, 2010 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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 on-going 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 2010 Form 10-K for a discussion of our critical accounting policies and estimates.

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, 2011, 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, 2011. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under

the Securities Exchange Act of 1934, as amended, means controls and other procedures of a company that are 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 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 the evaluation of our disclosure controls and procedures as of March 31, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On August 28, 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 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 addition, Teva and Yeda alleged additional claims against Sandoz and Novartis AG seeking monetary, injunctive and declaratory relief for alleged misappropriation of trade secrets and unfair competition. On November 3, 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. Sandoz s answer also denied the allegations made by Teva and Yeda alleging misappropriation of trade secrets and unfair competition. In addition, we filed a counterclaim seeking damages for false patent marking under the applicable United States patent law. In November 2009, Teva amended its complaint to remove the trade secrets and unfair competition claims against Sandoz and Novartis AG. On December 23, 2009, we and Sandoz filed a motion for summary judgment as a matter of law in the case. In September 2010, the court denied Sandoz and our motion for summary judgment, stating that fact finding was necessary to render a ruling. 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. The Mylan-related Markman hearing was held in January 2011 and a trial has been scheduled for September 2011 in the consolidated case. On April 4, 2011, Teva filed a motion for summary judgment of no inequitable conduct.

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.

While we intend to vigorously defend these suits and prosecute our counterclaims, and we believe that we can ultimately prove our case in court, each of these litigations could last a number of years. As a result, one or both of these litigations 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 any lawsuit with Teva.

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.

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Risks Relating to our Business

We have incurred a cumulative loss since inception. If we do not continue to generate significant revenue, we may not remain profitable, and approval of another generic enoxaparin product will significantly affect our revenue.

We have incurred significant losses since our inception in May 2001. At March 31, 2011, our accumulated deficit was $226.8 million. Until the sales by Sandoz of enoxaparin sodium injection, which commenced in July 2010, we had never received any revenue from the sale of products and we may still incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. To remain profitable, we must continue to receive significant revenue, including from the sales by Sandoz of enoxaparin sodium injection. Although our first three quarters of enoxaparin sodium injection-related revenue was significant, revenue of that magnitude is highly dependent on Sandoz product remaining the sole generic competitor to the brand product, and could significantly decline with the competitive entry of an additional generic enoxaparin product. 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 remain 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; 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 or our collaborative partners products. We may never succeed in these activities and may never generate revenues that are significant. We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would cause the market price of our common stock to decrease and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

Our success is highly dependent on the successful commercialization of enoxaparin sodium injection.

Our near-term ability to generate revenue and our future success, in large part, depends on the successful commercialization of enoxaparin sodium injection. This success further depends, in large part, on Sandoz continued success in commercializing the product, capturing market share and in competing with Lovenox brand competition as well as potential other generic competition. Additional generic competition could lead to a significant loss of market share and a significant decline in pricing, resulting in a significant decline in revenue. Because enoxaparin sodium injection was only approved by the FDA in late July 2010, we cannot be certain the sales will continue to be successful and sustained. If the commercialization of enoxaparin sodium injection is not successful we may have to curtail our product development programs and our business would be materially harmed.

If other generic versions of Lovenox are approved and successfully commercialized, our business would suffer due to a substantial change in the revenue we receive from Sandoz under our collaboration agreement.

In March 2003, Amphastar Pharmaceuticals, Inc. and Teva each submitted ANDAs for generic versions of Lovenox with the FDA. In 2007, Hospira, Inc. submitted ANDAs for generic versions of Lovenox with the FDA. In addition, other third parties, including, without limitation,

Sanofi-Aventis, may seek approval to market generic versions of Lovenox in the United States. If a competitor obtains FDA approval or if Sanofi-Aventis decides to market its drug as a generic or license it to another company to be sold as a generic, both known as authorized generics, the financial returns to us from the sale of enoxaparin sodium injection would be significantly less than if no other generics are approved. Under these circumstances, the resulting market price for our enoxaparin sodium injection product may be lower. Also, we may lose significant market share for enoxaparin sodium injection if one or more third parties market generic versions of Lovenox.

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In addition, the 2003 Sandoz Collaboration contains terms which specify the sharing of commercial revenue of enoxaparin sodium injection between us and Sandoz. Under circumstances when one or more third parties successfully commercialize a generic version of Lovenox, significantly less favorable economic terms for us would be triggered. Specifically, rather than a 45% profit share, we would receive a royalty in the high single to low double digits if a third-party competitor starts marketing a generic Lovenox equivalent or a combination of a royalty and a profit share in the case of an authorized generic. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenue from enoxaparin sodium injection would be reduced and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, would suffer.

If our patent litigation against Teva Pharmaceutical Industries Ltd. related to enoxaparin sodium injection is not successful, Teva Pharmaceutical Industries Ltd., may be able to commercialize a generic enoxaparin product, and our business would be materially harmed.

In December 2010, we sued Teva Pharmaceutical Industries Ltd. in the United States District Court for the District of Massachusetts for infringement of two of our patents that cover the innovative methods of producing enoxaparin sodium, which assure that the commercial product meets standards for identity and quality. If we are not successful in this patent litigation, and if Teva Pharmaceutical Industries Ltd. receives marketing approval, it may be able to commercialize a generic enoxaparin. Under these circumstances, the resulting market price for our enoxaparin sodium injection product may be lower, we may lose significant market share for enoxaparin sodium injection and significantly less favorable economic terms for us under the 2003 Sandoz Collaboration would be triggered. Consequently, if Teva commercialized a generic enoxaparin, our revenue would be reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, would suffer.

If efforts by Sanofi-Aventis or others to limit or prevent the use of our enoxaparin sodium injection product are successful, our business may suffer.

In February 2003, Sanofi-Aventis filed a Citizen Petition with the FDA requesting that the FDA withhold approval of any ANDA for a generic version of Lovenox until and unless the FDA determines that the manufacturing process used by the generic applicant is equivalent to the process used to make Lovenox, or until the generic applicant demonstrates through clinical trials that its product is equally safe and effective as Lovenox. The Citizen Petition also requested that the FDA require the generic product to contain a specific molecular structure. In July 2010, the FDA denied Sanofi-Aventis Citizen Petition and approved the ANDA filed by Sandoz for enoxaparin sodium injection. In July 2010, Sanofi-Aventis filed a lawsuit in the United States District Court for the District of Columbia against the FDA, Margaret A. Hamburg, Commissioner of Food and Drugs, and Kathleen Sebelius, Secretary of Health and Human Services. The complaint alleged, among other things, that FDA s approval of the ANDA filed by Sandoz was arbitrary and capricious and exceeded FDA s statutory authority by requiring additional data for the purpose of demonstrating the safety or effectiveness of a generic version of Lovenox and departing from its own precedent governing the approval of generic drugs that have not been fully characterized. In December 2010, Sanofi-Aventis filed a motion for summary judgment seeking a reversal of the FDA approval and the defendants have each filed responses opposing the motion and filed cross-motions seeking to affirm the approval of Sandoz s ANDA for enoxaparin sodium injection.

If Sanofi-Aventis is successful in its lawsuit against the FDA, approval of the ANDA may be reversed. A reversal may block continued sales of enoxaparin sodium injection, which would materially harm our business.

If efforts by manufacturers of branded products to delay or limit the use of generics are successful, our sales of technology-enabled generic products may suffer.

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay competition from manufacturers of generic drugs. 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;

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- appealing denials of Citizens 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, two of which have been denied and dismissed and one of which is pending. Teva may seek to file future petitions if the current petition is denied and Teva 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 Teva s or a third party s Citizen Petition, 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 Pharmaceutical Industries Ltd., 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 July 2008, the FDA accepted for review the ANDA containing a paragraph IV certification for generic Copaxone submitted by Sandoz. Subsequently, in August 2008, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and us for patent infringement related to four of the seven Orange Book patents listed for Copaxone in the United States District Court for the Southern District of New York. 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. In January 2010, the court heard arguments from the parties on the meaning of certain disputed claim terms in a claim construction hearing (also known as a Markman hearing). There is no defined timeline for the judge to issue a decision on claim construction and such a decision could be issued at any time. In September 2010, the court denied Sandoz and our motion for summary judgment to rule that the Orange Book patents were invalid as a matter of law, stating that fact finding was necessary to render a ruling. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva Pharmaceutical Industries Ltd. 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. While discovery in the consolidated cases is complete, and a trial date is scheduled for September 2011, there is a risk that Teva will seek to use legal procedures to delay the trial, to appeal a decision and to delay clearance of the patents prior to approval of the ANDA for generic Copaxone. On April 4, 2011 Teva filed a motion for summary judgment of no inequitable conduct.

In a separate lawsuit, in December 2009, Teva Pharmaceutical Industries Ltd. 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 Pharmaceutical Industries Ltd. In addition, Teva Pharmaceutical Industries Ltd. has significant resources and any litigation with Teva

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Pharmaceutical Industries Ltd. 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 Inc. 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 candidate, 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 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, 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

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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.

We will require substantial additional funds 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, 2011, we had cash, cash equivalents and marketable securities totaling $182.0 million and accounts receivable of $82.4 million. For the quarter ended March 31, 2011, we had a net income of $57.0 million and cash provided by operating activities of $31.7 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:

- the rate sales of enoxaparin sodium injection and the timeliness with which enoxaparin sodium injection is accepted by patients, physicians and third- party payors as an alternative to Lovenox;

- if Sanofi-Aventis is able to obtain an injunction blocking sales of enoxaparin sodium injection;

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

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

- the timing of FDA approval of the products of our competitors, such as Teva Pharmaceuticals Industries Ltd. s generic enoxaparin product candidate;

- the cost of litigation, including with Teva Pharmaceuticals Industries Ltd. relating to Copaxone, 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 time and costs involved in obtaining regulatory approvals;

- 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 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.

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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.

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

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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.

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

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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.

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

As we advance our drug 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 health care reform legislation, 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.

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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 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.

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.

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Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of follow-on biologics has recently been enacted, the standards for determining sameness or similarity for follow-on biologics have not yet been implemented by the FDA. Therefore, substantial uncertainty remains about the potential value our proprietary technology platform can offer to follow-on biologic 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 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, non-clinical 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.

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 in order to utilize 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. These cases have been appealed and the ultimate outcome may not be known for several years. 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, our opportunity to develop biosimilar (including interchangeable) biologics could be lost and our business could be materially and adversely affected.

If our preclinical studies and clinical trials for our development candidates, including adomiparin and 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 adomiparin, M402 or our other drug candidates, including:

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- 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;

- 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 adomiparin, M402 or our future 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 drug 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

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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 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

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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 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 U.S. 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 new 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 follow-on biologics 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 U.S. 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 U.S. 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 U.S. 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

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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.

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 is 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, 2010, 2009 and 2008, we spent approximately $57,000, $125,000 and $65,000, 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 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.

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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.

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.

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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.

Risks Relating to Our Dependence on Third Parties

Our 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.

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2006 Sandoz Collaboration

Either we or Sandoz may terminate the collaboration and license agreement, or Definitive Agreement, we executed with Sandoz in June 2007, as amended, 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 Definitive 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 Definitive 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 Definitive 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 Definitive 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.

We may need or elect to enter into alliances or collaborations with other companies to fund our development efforts or to supplement and enhance our own capabilities. If we are unsuccessful in forming or maintaining these alliances on favorable terms, or if any collaborative partner terminates or fails to perform its obligations, our business could be adversely affected.

Because we have limited or no capabilities for manufacturing, sales, marketing and distribution, and because we have limited resources, we may need to enter into alliances or collaborations with other companies that can assist with the development and commercialization of our product candidates, such as adomiparin. In those situations, we would expect our alliance or collaborative partners to provide substantial capabilities in manufacturing, sales, marketing and distribution. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them.

Factors that may affect the success of our collaborations include the following:

- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;

- our collaborators may pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, that may be competitive with the products on which they are collaborating with us or which could affect our collaborators commitment to our collaborations;

- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;

- our collaborators may pursue higher-priority programs or change the focus of their development programs, which could affect the collaborators commitment to us; and

- our collaborators with marketing rights may choose to devote fewer resources to the marketing of our product candidates, if any are approved for marketing, than to products from their own development programs.

In addition to relying on a third party for its capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our drug candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop particular drug candidates internally, or to bring drug candidates to market. Failure or delays in bringing our drug candidates to market will reduce their competitiveness and prevent us from generating sales revenue, which may substantially harm our business.

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Furthermore, in an effort to continually update and enhance our proprietary technology platform, we enter into agreements with other companies to develop, license, acquire and/or collaborate on various technologies. If we are unable to enter into the desired agreements, if the agreements do not yield the intended results or if the agreements terminate, we may need to find alternative approaches to such technology needs. If any of these occur, the development and commercialization of one or more drug candidates could be delayed, curtailed or terminated, any of which may adversely affect our business.

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.

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

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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;

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

- a decision in favor of or against Teva Pharmaceutical Industries Ltd. in the current patent litigation matters, or a settlement related to either case;

- 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;

- failure to demonstrate therapeutic equivalence with respect to our technology-enabled generic product candidates;

- 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;

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- 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 strategic partnerships;

- 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.**

10.1	Form of Restricted Stock Agreement (incorporated by reference to the Registrant s Current Report on Form 8-K filed with the Securities and Exchange Commission on April, 2011).
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.

* Management contract or compensatory plan or arrangement

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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 5, 2011

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

Date: May 5, 2011

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