

MOMENTA PHARMACEUTICALS INC
Form 10-Q
November 08, 2010
Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended September 30, 2010

- 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)

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

04-3561634
(I.R.S. Employer Identification No.)

675 West Kendall Street, Cambridge, MA
(Address of Principal Executive Offices)

02142
(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 No

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 No

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

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

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

Indicate the number of shares outstanding of each of the Registrant's classes of Common Stock as of November 1, 2010.

Class	Number of Shares
Common Stock \$0.0001 par value	45,461,418

Table of Contents

MOMENTA PHARMACEUTICALS, INC.

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	2
<u>Item 1.</u>	
<u>Financial Statements (unaudited)</u>	2
<u>Condensed Consolidated Balance Sheets as of September 30, 2010 and December 31, 2009 (unaudited)</u>	2
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2010 and 2009 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2010 and 2009 (unaudited)</u>	4
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	5
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures about Market Risk</u>	25
<u>Item 4.</u>	
<u>Controls and Procedures</u>	25
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	27
<u>Item 1A.</u>	
<u>Risk Factors</u>	27
<u>Item 5.</u>	
<u>Other Information</u>	45
<u>Item 6.</u>	
<u>Exhibits</u>	46
<u>SIGNATURES</u>	47

Our logo, trademarks and service marks are the property of Momenta Pharmaceuticals, Inc. Other trademarks or service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****MOMENTA PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

(unaudited)

	September 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,636	\$ 21,934
Marketable securities	35,050	73,716
Accounts receivable	44,188	
Unbilled revenue	1,866	4,750
Prepaid expenses and other current assets	2,448	1,693
Total current assets	114,188	102,093
Property and equipment, net of accumulated depreciation	9,622	11,795
Intangible assets, net	2,560	2,785
Restricted cash	1,778	1,778
Total assets	\$ 128,148	\$ 118,451
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,210	\$ 4,225
Accrued expenses	6,019	6,114
Deferred revenue	2,192	2,850
Capital lease obligations	2,577	2,344
Lease financing liability	447	737
Deferred rent	41	70
Total current liabilities	13,486	16,340
Deferred revenue, net of current portion	4,305	5,913
Capital lease obligations, net of current portion	75	1,729
Lease financing liability, net of current portion		258
Other long term liabilities	51	49
Total liabilities	17,917	24,289

Stockholders Equity:

Preferred stock, \$0.01 par value; 5,000 shares authorized at September 30, 2010 and December 31, 2009, 100 shares of Series A Junior Participating Preferred Stock, \$0.01 par value designated and no shares issued and outstanding

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

Common stock, \$0.0001 par value; 100,000 shares authorized, 45,395 and 44,627 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	5	4
Additional paid-in capital	430,238	415,214
Accumulated other comprehensive income (loss)	5	(7)
Accumulated deficit	(320,017)	(321,049)
Total stockholders' equity	110,231	94,162
Total liabilities and stockholders' equity	\$ 128,148	\$ 118,451

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

Table of Contents**MOMENTA PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Collaboration revenues:				
Product revenue	\$ 44,188	\$	\$ 44,188	\$
Research and development revenue	7,773	4,008	14,258	14,603
Total collaboration revenue	51,961	4,008	58,446	14,603
Operating expenses:				
Research and development*	12,488	12,912	36,521	46,380
General and administrative*	7,325	5,633	20,759	17,743
Total operating expenses	19,813	18,545	57,280	64,123
Operating income (loss)	32,148	(14,537)	1,166	(49,520)
Other income (expense):				
Interest income	46	131	132	748
Interest expense	(74)	(136)	(266)	(447)
Other expense		(104)		(104)
Total other income (expense)	(28)	(109)	(134)	197
Net income (loss)	\$ 32,120	\$ (14,646)	\$ 1,032	\$ (49,323)
Net income (loss) per share:				
Basic	\$ 0.72	\$ (0.38)	\$ 0.02	\$ (1.27)
Diluted	\$ 0.70	\$ (0.38)	\$ 0.02	\$ (1.27)
Weighted average shares outstanding:				
Basic	44,719	39,014	44,183	38,855
Diluted	46,032	39,014	45,708	38,855

*Includes the following share-based compensation expense:

Research and development	\$ 808	\$ 1,117	\$ 3,291	\$ 3,305
General and administrative	\$ 1,392	\$ 1,568	\$ 5,462	\$ 4,935

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

Table of Contents**MOMENTA PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2010	2009
Cash Flows from Operating activities:		
Net income (loss)	\$ 1,032	\$ (49,323)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	3,279	3,370
Share-based compensation expense	8,753	8,240
Amortization of premium (accretion of discount) on investments	664	(445)
Amortization of intangible assets	225	251
Loss on disposal of assets	6	109
Changes in operating assets and liabilities:		
Accounts receivable	(44,188)	411
Unbilled revenue	2,884	(1,033)
Prepaid expenses and other current assets	(755)	(511)
Other assets		12
Accounts payable	(2,015)	(1,766)
Accrued expenses	(95)	(2,283)
Deferred rent	(52)	(52)
Deferred revenue	(2,266)	(1,608)
Other current liabilities		(1,000)
Other long term liabilities	25	
Net cash used in operating activities	(32,503)	(45,628)
Cash Flows from Investing activities:		
Purchases of property and equipment	(1,112)	(1,113)
Purchases of marketable securities	(48,087)	(47,978)
Proceeds from maturities of marketable securities	86,101	64,985
Net cash provided by investing activities	36,902	15,894
Cash Flows from Financing activities:		
Proceeds from public offering of common stock, net of issuance costs		46,773
Proceeds from issuance of common stock under stock plans	6,272	560
Payments on financed leasehold improvements	(548)	(511)
Principal payments on capital lease obligations	(1,421)	(1,369)
Principal payments on line of credit		(17)
Net cash provided by financing activities	4,303	45,436
Increase in cash and cash equivalents	8,702	15,702
Cash and cash equivalents, beginning of period	21,934	55,070
Cash and cash equivalents, end of period	\$ 30,636	\$ 70,772

Supplemental Cash Flow Information:

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

Cash paid for interest	\$	266	\$	447
Supplemental Non-Cash Information:				
Issuance of common stock for payment of Parivid milestone	\$		\$	1,000

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

Table of Contents

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 collaboration agreements with pharmaceutical companies.

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 nine months ended September 30, 2010 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, 2009, which was filed with the SEC on March 12, 2010.

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 financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

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 September 30, 2010 and December 31, 2009.

Concentration of Credit Risks

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

The Company invests its cash in bank deposits, money market accounts, corporate debt securities, 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.

Table of Contents

Marketable Securities

Available-for-sale debt securities are recorded at fair market value. Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive income (loss), which is reported as a separate component of stockholders' equity. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is transferred from other comprehensive loss to the consolidated statements of operations. There were no charges taken for other-than-temporary declines in fair value of marketable securities during the three and nine months ended September 30, 2010 and 2009. Realized gains and losses are reported in interest income on a specific identification basis. There were no realized gains or losses on marketable securities during the three and nine months ended September 30, 2010 and 2009.

Accounts Receivable and Unbilled Revenue

Accounts receivable represents amounts due to the Company at September 30, 2010 from one collaborative partner related to sales of enoxaparin sodium injection. Unbilled revenue represents amounts owed at September 30, 2010 and December 31, 2009 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 results 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 September 30, 2010.

Revenue Recognition

The Company receives revenue from collaboration agreements. 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.

Revenue from non-refundable, up-front license fees is reported as research and development revenue and is recognized on a straight-line basis over the contracted or estimated period of performance, which is typically the development term. Research and development funding is recognized as earned over the period of effort.

Any milestone payments are recognized as 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.

Table of Contents

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, which could be adjusted based on actual results in the future.

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, 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 the requisite 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 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 concluded that a blended volatility rate based upon its own historical performance, as well as the implied volatilities of its own currently traded options, appropriately reflects the expected volatility of its stock going forward. The Company uses a blend of its own historical data and peer data to estimate option exercise and employee termination behavior, adjusted for known trends, to arrive at the estimated expected life of an option.

For purposes of identifying peer entities, the Company considers characteristics such as industry, stage of life cycle and financial leverage. The Company updates these assumptions as needed 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 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.

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 nine months ended September 30, 2010, 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 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.

Table of Contents

For the three and nine months ended September 30, 2010, the Company had income before taxes of \$32.1 million and \$1.0 million, respectively. The Company did not record a tax provision as the effective income tax rate was 0%. The effective tax rate and the statutory tax rate are the same due to the special carryback and carryforward of the alternative minimum tax operating loss from calendar year 2009 allowing the use of 100% of the net operating loss carryforward.

Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) as of September 30, 2010 and December 31, 2009 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive income (loss) for the three months ended September 30, 2010 and 2009 was \$32.1 million and \$(14.7) million, respectively. Comprehensive income (loss) for the nine months ended September 30, 2010 and 2009 was \$1.0 million and \$(49.7) 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 September 30, 2010 have come from one collaborative partner.

Recently Issued Accounting Standards

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements (Topic 605)*, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of Accounting Standards Codification Subtopic 605-25. The consensus in ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The present standard requires that the fair value of the undelivered item be either the price of the item sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. In addition, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied retrospectively for all periods presented. The Company does not believe this standard will have a material impact on its financial position or results of operations.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition - Milestone Method*, or ASU 2010-017. ASU 2010-017 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. ASU 2010-017 is effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require the Company to apply this guidance retrospectively effective as of January 1, 2010

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. As the Company plans to implement ASU 2010-17 prospectively, the effect of this guidance will be limited to future transactions. The Company does not expect adoption of this standard to have a material impact on its financial position or results of operations.

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 September 30, 2010	For the Three Months Ended September 30, 2009	For the Nine Months Ended September 30, 2010	For the Nine Months Ended September 30, 2009
Numerator:				
Net income (loss)	\$ 32,120	\$ (14,646)	\$ 1,032	\$ (49,323)
Denominator:				
Basic weighted average common shares outstanding	44,719	39,014	44,183	38,855
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock awards	1,313		1,525	
Diluted weighted average common shares outstanding	46,032	39,014	45,708	38,855
Basic net income (loss) per common share	\$ 0.72	\$ (0.38)	\$ 0.02	\$ (1.27)
Diluted net income (loss) per common share	\$ 0.70	\$ (0.38)	\$ 0.02	\$ (1.27)
Weighted-average anti-dilutive shares related to:				
Outstanding stock options	1,960	3,881	2,186	3,956
Restricted stock awards		641	72	584

Table of Contents

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 common stock equivalents that have either an exercise price above the average stock price for the period or average unrecognized share-based compensation expense related to the common stock equivalents is sufficient to buy back the entire amount of shares. In those reporting periods in which the Company has a net loss, anti-dilutive shares comprise the impact of those number of shares that would have been dilutive had the Company had net income plus the number of common stock equivalents that would be anti-dilutive had the Company had net income.

4. Fair Value Measurements

In January 2010, the Company adopted a newly issued accounting standard that requires additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. As this newly issued accounting standard only requires enhanced disclosure, the adoption of this standard did not impact the Company's financial position or results of operations. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard will require additional disclosure and require an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount.

The tables below present information about the Company's assets that are measured at fair value on a recurring basis as of September 30, 2010 and December 31, 2009 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 September 30, 2010 and December 31, 2009.

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

Table of Contents

The following tables set forth the Company's financial assets that were recorded at fair value at September 30, 2010 and December 31, 2009 (in thousands):

Description	Balance as of September 30, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	\$ 22,661	\$ 22,661	\$	\$
U.S. Treasury obligations	6,009	6,009		
Marketable securities:				
U.S. Government-sponsored enterprise obligations	35,050		35,050	
Total	\$ 63,720	\$ 28,670	\$ 35,050	\$

Description	Balance as of December 31, 2009	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Cash equivalents	\$ 20,201	\$ 19,700	\$ 501	\$
Marketable securities:				
U.S. Treasury obligations	15,181	15,181		
U.S. Government-sponsored enterprise obligations	58,535		58,535	
Total	\$ 93,917	\$ 34,881	\$ 59,036	\$

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.

5. Cash, Cash Equivalents and Marketable Securities

The following table summarizes the Company's cash, cash equivalents and marketable securities as of September 30, 2010 and December 31, 2009 (in thousands):

As of September 30, 2010	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	\$ 24,627	\$	\$	\$ 24,627
U.S. Treasury obligations due in one year or less	6,009			6,009
U.S. Government-sponsored enterprise obligations due in one year or less	35,045	8	(3)	35,050

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

Total	\$	65,681	\$	8	\$	(3)	\$	65,686
Reported as:								
Cash and cash equivalents	\$	30,636	\$		\$		\$	30,636
Marketable securities		35,045		8		(3)		35,050
Total	\$	65,681	\$	8	\$	(3)	\$	65,686

Table of Contents

As of December 31, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	\$ 21,433	\$	\$	\$ 21,433
U.S. Treasury obligations due in one year or less	15,184	1	(4)	15,181
U.S. Government-sponsored enterprise obligations due in one year or less	59,040	11	(15)	59,036
Total	\$ 95,657	\$ 12	\$ (19)	\$ 95,650
Reported as:				
Cash and cash equivalents	\$ 21,934	\$	\$	\$ 21,934
Marketable securities	73,723	12	(19)	73,716
Total	\$ 95,657	\$ 12	\$ (19)	\$ 95,650

At September 30, 2010, one marketable security was in an unrealized loss position for less than one year. At December 31, 2009, 18 marketable securities were in an unrealized loss position for less than one year. The unrealized losses were caused by fluctuations in interest rates. The following tables summarize the aggregate fair value of these securities at September 30, 2010 and December 31, 2009 (in thousands):

	As of September 30, 2010	
Security Type	Aggregate Fair Value	Unrealized Losses
U.S. Government-sponsored enterprise obligations due in one year or less	\$ 6,212	\$ (3)

	As of December 31, 2009	
Security Type	Aggregate Fair Value	Unrealized Losses
U.S. Treasury bonds due in one year or less	\$ 9,122	\$ (4)
U.S. Government-sponsored enterprise obligations due in one year or less	\$ 22,857	\$ (15)

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 September 30, 2010, 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 September 30, 2010 and December 31, 2009, intangible assets, net of accumulated amortization, are as follows (in thousands):

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

	Estimated Life	September 30, 2010		December 31, 2009	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Core technology	12 years	\$ 3,593	\$ (1,033)	\$ 3,593	\$ (808)
Non-compete agreement	2 years	170	(170)	170	(170)
Total intangible assets		\$ 3,763	\$ (1,203)	\$ 3,763	\$ (978)

Table of Contents

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets. The non-compete agreement was fully amortized as of April 30, 2009. Amortization expense was \$75,000 for the three months ended September 30, 2010 and 2009. Amortization expense was \$0.2 million and \$0.3 million for the nine months ended September 30, 2010 and 2009, respectively.

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

7. Collaboration 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, formerly known as M-Enoxaparin, 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 includes 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 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 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 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 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 Revenues

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

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 three months ended September 30, 2010. Because no third-party competitors marketed a Lovenox-Equivalent Product during the three months ended September 30, 2010, the Company earned \$44.2 million, net of \$35.2 million of development and legal expenses, in profit-share product revenue from Sandoz.

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.

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

Table of Contents

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 and \$1.6 million for the three and nine months ended September 30, 2010, respectively. 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 the products.

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.

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, 2009, the Company was authorized to issue up to 9,420,445 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, 2010, the Company's Board of Directors increased the number of authorized shares by 1,974,303 shares. At September 30, 2010, the Company had 5,845,242 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 September 30, 2010 and 2009 was \$2.2 million and \$2.7 million, respectively. 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 nine months ended September 30, 2010 and 2009 was \$8.8 million and \$8.2 million, respectively.

In the nine month period ended September 30, 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

Table of Contents

to calculate share-based compensation expense during the years ending December 31, 2006, 2007 and 2008. In accordance with SEC Staff Accounting Bulletin, or SAB, No. 99, *Materiality*, and SAB No. 108, the Company assessed the materiality of these charges to its 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 financial statements for the years ended December 31, 2006, 2007 and 2008 and, as such, those 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 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 \$1.7 million and \$2.0 million for the three months ended September 30, 2010 and 2009, respectively. Share-based compensation expense related to outstanding employee stock option grants and the Company's employee stock purchase plan was \$7.0 million and \$6.1 million for the nine months ended September 30, 2010 and 2009, respectively. During the nine months ended September 30, 2010, 752,533 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 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 September 30, 2010 and 2009 was \$11.35 and \$8.16 per option, respectively. The weighted-average grant date fair value of option awards granted during the nine months ended September 30, 2010 and 2009 was \$9.56 and \$8.05 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	For the Three Months Ended	For the Three Months Ended	For the Three Months Ended
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Expected volatility	81%	98%	71%	98%
Expected dividends				
Expected life (years)	6.5	7	0.5	0.5
Risk-free interest rate	2.0%	3.2%	0.1%	0.3%

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Nine Months Ended	For the Nine Months Ended	For the Nine Months Ended	For the Nine Months Ended
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Expected volatility	71%	98%	82%	95%
Expected dividends				
Expected life (years)	5.7	6	0.5	0.5
Risk-free interest rate	3.1%	2.6%	0.2%	0.6%

At September 30, 2010, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to \$9.2 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.2 years.

During the nine months ended September 30, 2010, holders of options issued under the Company's stock plans exercised their right to acquire an aggregate of 574,576 shares of common stock. Additionally, during the nine months ended September 30, 2010, the Company issued 55,002 shares of common stock to employees under the Company's employee stock purchase plan.

Restricted Stock Awards

The Company has also made awards of restricted common stock to certain employees, officers and directors. During the nine months ended September 30, 2010, the Company awarded 147,638 shares of restricted common stock to certain employees and officers in connection with annual merit awards. Awards generally fully vest four years from the grant date, although certain awards granted in prior periods have performance conditions, such as the commercial launch of enoxaparin sodium injection in the United States. At September 30, 2010, nonvested shares of restricted stock that have time-based vesting schedules totaled 339,618 shares.

Table of Contents

9. Subsequent Events

The Company evaluated events and transactions after the date of the balance sheet but prior to the issuance of the financial statements for potential recognition or disclosure in its financial statements. The Company did not identify any material subsequent events requiring adjustment (recognized subsequent events). Those items requiring disclosure (unrecognized subsequent events) are described below.

On October 29, 2010, the Company received notification from the Internal Revenue Service that it has been awarded four separate grants in the aggregate amount of \$1.0 million pursuant to the qualifying therapeutic discovery grant program established by the Internal Revenue Service and the Secretary of Health and Human Services under the Patient Protection and Affordable Care Act of 2010. The grants have been made with respect to certain of the Company's qualifying research and development programs. The Company expects to record the grants as other income in its financial statements for the year ending December 31, 2010.

10. 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 court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the international affiliates of Sandoz. 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. In September 2010, the court denied Sandoz and the Company's 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 the Company and Sandoz.

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. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the international affiliates of Sandoz. 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.

Table of Contents

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.

Business Overview

Momenta is 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 pipeline of complex generic, follow-on biologic, and novel drugs. These product opportunities are 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 product candidates, we tailor that approach for each specific product candidate. 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 innovator'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, and as required by the United States Food and Drug Administration, or FDA, we will supplement an application 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 two advanced complex generic product programs target marketed products which 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. Enoxaparin sodium injection, formerly known as M-Enoxaparin, received FDA marketing approval in July 2010 as a generic version of Lovenox®, a low molecular weight heparin, or LMWH, 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. 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.

In addition to our two complex generic product programs, our follow-on biologics 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

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

enoxaparin sodium injection and M356 and pursue the development and commercialization of multiple biogeneric (designated by FDA to be substitutable with the marketed product) or biosimilar (designated by FDA not to be directly substitutable with the marketed drug) products.

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 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, formerly known as M118, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed products 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

Table of Contents

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 profits from the sale of enoxaparin sodium injection. Profits on sales of enoxaparin sodium injection are calculated by deducting from net sales 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, 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, but the amount of any future payment due to the annual adjustment is not expected to be material. Because no third-party competitor has marketed a Lovenox-Equivalent Product, we earned \$44.2 million, net of \$35.2 million repayment to Sandoz of our full contractual pre-launch development and legal expenses, in profit-share product revenue from Sandoz during the three months ended September 30, 2010. In addition to the profit-share earned, we achieved a regulatory milestone defined in the 2003 Sandoz Collaboration as a result of the FDA's approval of the ANDA and received an additional \$5.0 million in research and development revenue from Sandoz.

The future revenues 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 the lawsuit filed by Sanofi-Aventis in July 2010 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.

Since our inception in May 2001, we have incurred annual net losses. As of September 30, 2010, we had an accumulated deficit of \$320.0 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 revenues had been derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and, until the quarter ended September 30, 2010, primarily consisted of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for certain programs. 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 revenues to maintain profitability.

Financial Operations Overview

Revenue

We have recognized, in the aggregate, \$153.1 million of revenue from our inception through September 30, 2010. 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. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of payments we receive upon the sale of our products by Sandoz and the timing and amount of research and development and other payments received under our collaborative or strategic relationships.

Table of Contents

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 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. We believe that Sanofi-Aventis's claims are without merit and are cooperating with Sandoz to vigorously oppose the lawsuit.

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 has not been obtained in the specified timeframe of 30 months, the 180-day exclusivity period for which Sandoz's ANDA is eligible will be forfeited unless certain conditions enumerated in the statute apply. Sandoz and we will not know whether such conditions apply, or whether the 180-exclusivity is forfeited, 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.

Table of Contents

Adomiparin (M118)

Adomiparin (M118) 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 provide baseline anticoagulant therapy for patients diagnosed with ACS who are medically managed and who may or may not require coronary intervention in order to treat their condition, as well as for patients diagnosed with stable angina who require a coronary intervention. 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. 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 adomiparin 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 play a role in the conversion of normal cells

into cancerous cells, and present growth factors, cytokines, and chemokines necessary for tumor cell growth, migration, and survival. M402 is designed to exploit this biology. Data from preclinical studies have shown that M402 has the potential to modulate angiogenesis and tumor metastasis through a variety of HSPG-binding proteins. We currently are conducting non-clinical research with the goal of advancing M402 into human clinical trials in the first half of 2011.

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.

Table of Contents**Results of Operations*****Three Months Ended September 30, 2010 and 2009******Collaboration revenue***

Collaboration revenue for the three months ended September 30, 2010 and 2009 was \$52.0 million and \$4.0 million, respectively, representing an increase of approximately \$48.0 million, or greater than 100%.

Our collaboration revenue for the three months ended September 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended September 30,		
	2010	2009	\$ Change
Product revenue	\$ 44,188	\$	\$ 44,188
Milestone	\$ 5,000	\$	\$ 5,000
Research and development revenue	2,773	4,008	(1,235)
Total Research and development revenue	7,773	4,008	3,765
Total collaboration revenue	\$ 51,961	\$ 4,008	\$ 47,953

The increase in collaboration revenue was primarily due to product revenue we earned from Sandoz representing our profit-share on Sandoz sales of enoxaparin sodium injection following its commercial launch in July 2010. Due to the achievement of a regulatory milestone defined in the 2003 Sandoz Collaboration, specifically the FDA's approval of the enoxaparin sodium injection ANDA, Sandoz made a non-refundable payment of \$5.0 million to us. Research and development revenues for the three months ended September 30, 2010 and 2009 consist of (i) amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs and (ii) amounts earned by us under the 2006 Sandoz Collaboration for reimbursement of research and development services, reimbursement of development costs and amortization of the equity premium paid by Novartis Pharma AG in connection with the 2006 Sandoz Collaboration. Research and development revenues for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 decreased by \$1.2 million primarily due to a decrease in reimbursable expenses associated with our enoxaparin sodium injection program as the ANDA review process for the syringe form was completed in July 2010.

Research and Development

Research and development expense for the three months ended September 30, 2010 was \$12.5 million compared to \$12.9 million for the three months ended September 30, 2009. The decrease of \$0.4 million, or 3%, from the 2009 period to the 2010 period resulted from decreases of: \$1.0 million related to the timing of manufacturing, process development and third-party research costs primarily in support of both our M356

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

program and enoxaparin sodium injection program; \$0.5 million in consultant expenses as a result of shifting activities to internal resources; \$0.4 million in laboratory equipment depreciation and other facility related costs; \$0.3 million in share-based compensation expense and \$0.1 million in laboratory supplies. These decreases were offset by an increase of \$1.1 million in personnel and related costs, primarily due to performance payments made in connection with the July 2010 regulatory approval of enoxaparin sodium injection, and \$0.8 million in development costs principally related to our M402 preclinical activities.

The lengthy process of securing FDA approvals 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.

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 September 30, 2010 and 2009, and 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.

Table of Contents

Commercial and Development Programs (Status)	Research and Development Expense (in thousands)		
	Three Months Ended September 30, 2010	Three Months Ended September 30, 2009	Project Inception to September 30, 2010
Enoxaparin Sodium Injection (ANDA Approved July 2010)	\$ 443	\$ 1,113	\$ 45,694
M356 (ANDA Filed)	1,602	1,763	29,829
Adomiparin (Phase 2a)	78	87	35,708
Other development programs	841	463	
Discovery programs	49	100	
Research and development internal costs	9,475	9,386	
Total research and development expense	\$ 12,488	\$ 12,912	

The decrease of \$0.7 million in enoxaparin external expenditures from the 2009 period to the 2010 period was primarily due to decreased manufacturing activity and commercial activity being contracted directly with Sandoz. The decrease of \$0.2 million in M356 external expenditures from the 2009 period to the 2010 period was primarily related to the timing of process development activities, manufacturing and third-party research costs. The increase of \$0.4 million in external expenditures related to our other development programs from the 2009 period to the 2010 period was principally due to increased M402 preclinical activities.

The research and development internal costs, which include compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation, were consistent from the 2009 period to the 2010 period.

General and Administrative

General and administrative expense for the three months ended September 30, 2010 was \$7.3 million, compared to \$5.6 million for the three months ended September 30, 2009. General and administrative expense increased by \$1.7 million, or 30%, from the 2009 period to the 2010 period due to: an increase of \$0.6 million in royalty and license fees payable to Massachusetts Institute of Technology based on the product sales of enoxaparin sodium injection; an increase of \$0.8 million in personnel and related costs primarily due to performance payments made in connection with the July 2010 regulatory approval of enoxaparin sodium injection; and an increase of \$0.5 million in professional fees. These increases were offset by a decrease of \$0.2 million in share-based compensation expense.

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 \$46,000 and \$0.1 million for the three months ended September 30, 2010 and 2009, respectively. The decrease from the 2009 period to the 2010 period was due to lower average investment balances and lower interest rates.

Interest expense was \$0.1 million for each of the three months ended September 30, 2010 and 2009. We have not drawn any additional amounts from our equipment capital lease obligation since December of 2007.

Nine Months Ended September 30, 2010 and 2009

Collaboration revenue

Collaboration revenue for the nine months ended September 30, 2010 and 2009 was \$58.4 million and \$14.6 million, respectively, representing an increase of approximately \$43.8 million, or greater than 100%.

Table of Contents

Our collaboration revenue for the nine months ended September 30, 2010 and 2009 consisted of the following (in thousands):

	Nine Months Ended September 30,		\$ Change
	2010	2009	
Product revenue	\$ 44,188	\$	\$ 44,188
Milestone	\$ 5,000	\$	\$ 5,000
Research and development revenue	9,258	14,603	(5,345)
Total Research and development revenue	14,258	14,603	(345)
Total collaboration revenue	\$ 58,446	\$ 14,603	\$ 43,843

The increase in collaboration revenue was primarily due to product revenue we earned from Sandoz representing our profit-share on Sandoz sales of enoxaparin sodium injection following its commercial launch in July 2010. Due to the achievement of a regulatory milestone defined in the 2003 Sandoz Collaboration, specifically the FDA's approval of the enoxaparin sodium injection ANDA, Sandoz made a non-refundable payment of \$5.0 million to us. Research and development revenues for the three months ended September 30, 2010 and 2009 consist of (i) amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs and (ii) amounts earned by us under the 2006 Sandoz Collaboration for reimbursement of research and development services, reimbursement of development costs and amortization of the equity premium paid by Novartis Pharma AG in connection with the 2006 Sandoz Collaboration. Research and development revenues for the nine month period ended September 30, 2010 compared to the nine months ended September 30, 2009 decreased by \$5.3 million primarily due to a decrease of \$2.3 million in reimbursable manufacturing expenses associated with our M356 program and a decrease of \$3.0 million in reimbursable expenses associated with our enoxaparin sodium injection program as the ANDA review process was completed in July 2010.

Research and Development

Research and development expense for the nine months ended September 30, 2010 was \$36.5 million compared to \$46.4 million for the nine months ended September 30, 2009. The decrease of \$9.9 million, or 21%, from the 2009 period to the 2010 period resulted from decreases of: \$6.6 million related to the timing of manufacturing, process development and third-party research costs primarily in support of both our M356 program and enoxaparin sodium injection program; \$2.3 million in clinical trial costs due to the completion of our adomiparin Phase 2a clinical trial in June 2009; \$2.0 million in consultants principally related to our adomiparin Phase 2a clinical trial completed in June 2009; \$1.0 million in laboratory supplies; and \$0.7 million in laboratory equipment depreciation. These decreases were offset by increases of \$2.2 million in personnel and related costs primarily due to performance payments made in connection with the regulatory approval of enoxaparin sodium injection in July 2010 and a \$0.5 million credit in the 2009 period to research and development expense as a result of a revision to an accrued milestone liability.

The lengthy process of securing FDA approvals 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.

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

The following table summarizes the primary components of our research and development expenditures for our principal commercial and development programs for the nine months ended September 30, 2010 and 2009, and 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.

Table of Contents

Commercial and Development Programs (Status)	Research and Development Expense (in thousands)		
	Nine Months	Nine Months	Project Inception to
	Ended, September 30 2010	Ended September 30, 2009	
Enoxaparin Sodium Injection (ANDA Approved July 2010)	\$ 1,592	\$ 2,951	\$ 45,694
M356 (ANDA Filed)	3,146	8,415	29,829
Adomiparin (Phase 2a)	439	5,074	35,708
Other development programs	2,666	1,064	
Discovery programs	159	261	
Research and development internal costs	28,519	28,615	
Total research and development expense	\$ 36,521	\$ 46,380	

The decrease of \$1.4 million in enoxaparin external expenditures from the 2009 period to the 2010 period was primarily due to decreased manufacturing activity and commercial activity being contracted directly with Sandoz. The decrease of \$5.3 million in M356 external expenditures from the 2009 period to the 2010 period was primarily related to the timing of process development activities, manufacturing and third-party research costs. The decrease of \$4.6 million in external expenditures on our adomiparin program from the 2009 period to the 2010 period was due to the completion our Phase 2a clinical trial in June 2009. The increase of \$1.6 million in external expenditures related to our other development programs from the 2009 period to the 2010 period was principally due to increased M402 preclinical activities.

The research and development internal costs, which include compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation, were consistent from the 2009 period to the 2010 period.

General and Administrative

General and administrative expense for the nine months ended September 30, 2010 was \$20.8 million, compared to \$17.7 million for the nine months ended September 30, 2009. General and administrative expense increased by \$3.1 million, or 17%, from the 2009 period to the 2010 period due to: an increase of \$1.4 million in personnel and related costs primarily due to performance payments made in connection with the July 2010 regulatory approval of enoxaparin sodium injection; an increase of \$0.6 million in royalty and license fees payable to Massachusetts Institute of Technology based on the product sales of enoxaparin sodium injection; an increase of \$0.6 million in professional fees; and an increase of \$0.5 million in share-based compensation expense principally due to a modification in the application of our forfeiture rate assumption.

Interest Income and Expense

Interest income was \$0.1 million and \$0.7 million for the nine months ended September 30, 2010 and 2009, respectively. The decrease of \$0.6 million from the 2009 period to the 2010 period was primarily due to lower average investment balances and lower interest rates.

Interest expense was \$0.3 million and \$0.4 million for the nine months ended September 30, 2010 and 2009, respectively. We have not drawn any additional amounts from our equipment capital lease obligation since December of 2007.

Liquidity and Capital Resources

We finance our operations 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 borrowings from our lines of credit and capital lease obligations. We believe that these funds will be sufficient to meet our operating requirements through at least 2012. 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 September 30, 2010, we had \$65.7 million in cash, cash equivalents and marketable securities. 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 September 30, 2010 were invested in senior debt of government-sponsored enterprises and United States money market funds, directly or through managed funds, with remaining maturities of one year or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The

Table of Contents

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 are subject to significant risk at September 30, 2010.

During the nine months ended September 30, 2010 and 2009, our operating activities used \$32.5 million and \$45.6 million, respectively. The use of cash for operating activities generally approximates our net income (loss) adjusted for non-cash items and changes in operating assets and liabilities. For the nine months ended September 30, 2010, the Company's net income adjusted for non-cash items was \$14.0 million including net income of \$1.0 million and non-cash items including share-based compensation expense of \$8.8 million, amortization of purchased premiums on our marketable securities of \$0.7 million, and depreciation and amortization expense of \$3.5 million. In addition, the net change in our operating assets and liabilities used \$46.5 million and resulted from: an increase in accounts receivable of \$44.2 million, due to the timing of cash receipts from Sandoz related to the profit-share payments for the sales of enoxaparin sodium injection; a decrease in unbilled revenue of \$2.9 million, resulting from decreased reimbursable commercial activities for our M356 program as well as decreased reimbursable activities for our enoxaparin sodium injection program; an increase in prepaid expenses and other current assets of \$0.8 million, due to the timing of payroll tax payments; a decrease in accounts payable of \$2.0 million, primarily due to the timing of commercial activities for our M356 program; and a decrease in deferred revenue of \$2.3 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 nine months ended September 30, 2009, our net loss adjusted for non-cash items was \$37.8 million. In addition, the net change in our operating assets and liabilities used \$7.8 million and resulted from: a decrease in accounts receivable of \$0.4 million, due to the timing of cash receipts from Sandoz; an increase in unbilled revenue of \$1.0 million, due to the timing of reimbursable manufacturing, process development and third-party research costs for our enoxaparin sodium injection program; an increase in prepaid expenses and other current assets of \$0.5 million, primarily due to a vendor credit for manufacturing raw materials; a decrease in accounts payable of \$1.8 million, primarily due to the timing of manufacturing costs for M356 manufacturing batches; a decrease in deferred revenue of \$1.6 million, due to the amortization of the \$13.6 million equity premium paid by Novartis AG in connection with the 2006 Sandoz Collaboration; a decrease in accrued expenses of \$2.3 million, due primarily to a decrease in accrued compensation and a decrease in clinical accruals associated with the completion in June 2009 of our Phase 2a clinical trial for our adomiparin program; and a decrease in other current liabilities of \$2.0 million. Of the \$2.0 million decrease in other current liabilities, \$0.5 million relates to a revision to an accrued milestone liability, \$0.5 million was paid in cash and \$1.0 million of common stock was issued as consideration for the completion and satisfaction of milestones achieved under our asset purchase agreement with Parivid LLC.

During the nine months ended September 30, 2010 and 2009, our investing activities provided \$36.9 million and \$15.9 million, respectively. In the first nine months of 2010, we received \$86.1 million from maturities of marketable securities and we used \$48.1 million of cash to purchase marketable securities. In the first nine months of 2009, we received \$65.0 million from the maturities of marketable securities and we used \$48.0 million of cash to purchase marketable securities. During both the nine months ended September 30, 2010 and 2009, we used \$1.1 million to purchase laboratory equipment and leasehold improvements.

During the nine months ended September 30, 2010 and 2009, financing activities provided \$4.3 million and \$45.4 million, respectively. During the nine months ended September 30, 2010, we received net proceeds of \$6.3 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of \$1.4 million on our capital lease agreement obligations and \$0.5 million on financed leasehold improvements related to our corporate facility. During the nine months ended September 30, 2009, we received net proceeds of \$46.8 million from our public offering of common stock in September 2009 and \$0.5 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These activities were offset by principal payments of \$1.4 million on our line of credit and lease agreement obligations and \$0.5 million on financed leasehold improvements related to our corporate facility.

Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations and capital and operating lease obligations. On April 22, 2010, we exercised our right to extend the lease for our Cambridge facility by four years, through April 30, 2015. During the extension term, beginning on May 1, 2011, our annual rent will increase by \$1.2 million per year over our current annual rental rate.

Table of Contents

The following table summarizes our contractual obligations at September 30, 2010 (in thousands):

Contractual Obligations	Total	October 1, 2010 through December 31, 2010	2011 through 2012	2013 through 2014	2015	After 2015
License maintenance obligations	\$ 984	\$ 39	\$ 315	\$ 315	\$ 315	*
Capital lease obligations	2,795	978	1,817			
Operating lease obligations	21,021	913	9,125	9,414	1,569	
Total contractual obligations	\$ 24,800	\$ 1,930	\$ 11,257	\$ 9,729	\$ 1,884	\$

*After 2015, the annual obligations, which extend indefinitely, are approximately \$0.2 million per year.

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 and related allowances, accrued expenses and certain equity instruments. 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 2009 Form 10-K for a discussion of our critical accounting policies and estimates.

Recently Issued Accounting Standards

Please see Note 2 to our Consolidated Financial Statements, *Summary of Significant Accounting Policies*, for a discussion of recently issued accounting standards.

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 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 September 30, 2010, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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 September 30, 2010. 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

Table of Contents

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 September 30, 2010, 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.

In July 2010, Sandoz began the commercial sale of enoxaparin sodium injection. Under the 2003 Sandoz Collaboration agreement, Sandoz is responsible for commercial activities. We began recognizing revenue related to such sales during the quarter and, as a result, established internal controls with respect to such revenue. There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended), during the fiscal quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the foreign affiliates of Sandoz. We and Sandoz asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. 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.

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. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the foreign affiliates of Sandoz.

Item 1A. Risk Factors

Statements contained or incorporated by reference in this Quarterly Report on 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. 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. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

Risks Relating to our Business

We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenue, we may not remain profitable.

We have incurred significant losses since our inception in May 2001. At September 30, 2010, our accumulated deficit was \$320.0 million. Even with revenue from the sales by Sandoz of enoxaparin sodium injection, which commenced in July 2010, 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 receive significant revenue, including from the sales by Sandoz of enoxaparin sodium injection. Although our first quarter 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 other drugs we successfully develop. Accordingly, we may not generate significant revenues in the longer term and, even if we do generate significant revenues, we may never achieve long term-profitability.

Table of Contents

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.

If we receive insufficient revenue for enoxaparin sodium injection, we may have to curtail our product development programs and our business would be materially harmed.

Our near-term ability to generate revenue and our future success, in large part, depend 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 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.

In addition, the 2003 Sandoz Collaboration contains terms which specify the sharing of commercial revenues 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. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues 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 efforts by Sanofi-Aventis or others to delay, limit, or prevent the use of our enoxaparin sodium injection product are successful, our business may suffer.

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

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. 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. The case remains on-going.

If Sanofi-Aventis is able to obtain an injunction blocking sales of enoxaparin sodium injection during the period of the litigation, our revenues will be significantly impacted and our business will suffer. Furthermore, if Sanofi-Aventis is successful in its lawsuit against the FDA, approval of the ANDA may be reversed, which would materially harm our business.

Table of Contents

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;
- 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.

In November 2009, Teva Neuroscience, Inc. (on behalf of Teva Pharmaceutical Industries Ltd.) filed a Citizen Petition with the FDA requesting that the FDA neither approve nor accept for filing any ANDA for a generic version of Copaxone because the complexity of Copaxone makes it impossible to demonstrate that the active ingredient in the generic version is the same as Copaxone. The FDA dismissed the petition in May 2010. 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 dismissed the petition without acting on the petition. Teva Neuroscience, Inc. may seek to file another petition, and other third parties may also file Citizen Petitions requesting the FDA to adopt specific approval standards for generic products. For example, in October, 2010, Peptimmune, Inc. filed a Citizen Petition requesting that certain pharmacokinetic and

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

pharmacodynamic tests be adopted by the FDA as sameness standards for generic Copaxone. While we believe that our technology and methods will demonstrate the equivalence of M356 without the use of Peptimmune's technology, 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. The court subsequently dismissed all claims in the case against Sandoz GmbH and Novartis AG the foreign affiliates of Sandoz. We and Sandoz asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. 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.

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. The court subsequently dismissed all claims in the case against Sandoz GmbH and Novartis AG the foreign affiliates of Sandoz.

Table of Contents

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 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 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 of 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

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

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

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 September 30, 2010, we had cash, cash equivalents and marketable securities totaling \$65.7 million. For the nine months ended September 30, 2010, we had a net income of \$1.0 million and used cash in operating activities of \$32.5 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

Table of Contents

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 of growth in 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;
- 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;

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

- 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.

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.

Table of Contents

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 revenues, would decline.

Generic pharmaceutical products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. As enoxaparin sodium injection is primarily a hospital-based product, a large percentage of the revenue for enoxaparin sodium injection is derived through contracts with GPOs. Currently, a relatively small number of GPOs control a substantial portion of generic

pharmaceutical sales to hospital customers. In order to establish and maintain contracts with these GPOs, we believe that we, in collaboration with Sandoz, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products. The GPOs with whom we or our collaborators have established contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of enoxaparin sodium injection to certain hospital segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by our customers, including the GPOs, wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. We anticipate that M356 will be primarily distributed through retail channels and mail order services. If we or our collaborators are unable to establish and maintain distribution arrangements with all of these customers, sales of our products, our revenues 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;

Table of Contents

- 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 revenues 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 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 law 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:

Table of Contents

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

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

- difficulty incorporating the acquired technologies;

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

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

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

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

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

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

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

The consideration paid in connection with an acquisition also affects our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any acquisition. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted and earnings per share may decrease. In addition, acquisitions may result in the incurrence of debt, large one-time 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 candidates, including M356, as therapeutic equivalents to their corresponding reference listed drugs, 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 generic versions of complex drugs, such as M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products:

- contain the same active ingredients as the branded products upon which they are based;
- are of the same dosage form, strength and route of administration as the branded products upon which they are based, and have the same labeling as the approved labeling for the branded products, with certain exceptions; and
- meet 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 our generic versions of complex drugs to the reference listed drugs 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

Table of Contents

have adequately characterized our products or that our products and their respective branded drugs 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 any of our generic product candidates will receive FDA approval as therapeutically equivalent to its reference branded product.

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

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, including enoxaparin sodium injection, are not substitutable at the pharmacy level for the 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.

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 established by the FDA, and therefore there remains substantial uncertainty 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 contemplates that the FDA will establish standards or criteria for determining biosimilarity and interchangeability, and expressly 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.

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

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 connection with the new patent clearance process; the inclusion of multiple potential patent rights in the patent clearance process; a grant to each brand company of 12 years of marketing exclusivity following 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 follow-on biologic. Finally, the new legislation also creates the risk that, as brand and follow-on biologic 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 follow-on biologic approval.

Table of Contents

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:

- 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 to conduct additional clinical trials or other testing of adomiparin, M402 or our future product candidates, 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

Table of Contents

safety and efficacy of the product candidate. In addition, the manufacturer and manufacturing facilities we use to produce any of our product candidates will be subject to periodic review and inspection by the FDA, or foreign equivalent, and other regulatory agencies. We will be required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Certain changes to an approved product, including in the way it is manufactured or promoted, often require prior FDA approval before the product as modified may be marketed. If we fail to comply with applicable FDA regulatory requirements, we may be subject to fines, warning letters, civil penalties, refusal by the FDA to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions, refusal to permit the import or export of products and/or criminal prosecutions and penalties.

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

- neither experimental nor investigational.

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

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products. The Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, the health

Table of Contents

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 revenues, 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 this year 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 a regulatory pathway for the approval of follow-on biologics and provides that biologic products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new regulatory approval pathway for follow-on biologic products and adjusting reimbursement for follow-on biologic products, the new law could promote the development and commercialization of follow-on biologics. 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 follow-on biologics 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 profitability.

Foreign governments tend to impose strict price or reimbursement controls, which may adversely affect our revenues, 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

Table of Contents

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, 2009, 2008 and 2007, we spent approximately \$125,000, \$65,000 and \$64,000, respectively, in order to comply with environmental and waste disposal regulations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. 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. Although we maintain workers compensation insurance as prescribed by the Commonwealth of Massachusetts and, for claims not covered by workers compensation insurance, employer's liability insurance, to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. 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.

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.

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.

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

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

Table of Contents

will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

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

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

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

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

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

If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues 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. The costs and uncertainties 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.

Table of Contents

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 develop and 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 revenues may be reduced, any one of which could have a material adverse effect on our business.

2006 Sandoz Collaboration

Either we or Sandoz may terminate the 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 revenues 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;

Table of Contents

- 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 revenues, which may substantially harm our business.

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

Table of Contents

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 revenues.

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 revenues 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 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

Table of Contents

- 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 achieve 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;
- 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;

Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form 10-Q

- 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;
- 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;

Table of Contents

- 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.

Item 5. Other Information

In conjunction with the resignation of Steven Brugger as our chief operating officer, effective as of November 5, 2010, we entered into a letter agreement with Mr. Brugger regarding his termination of employment and entry into a consulting agreement. Pursuant to the terms of the consulting agreement, we will pay Mr. Brugger \$270 per hour during the consulting term which begins November 6, 2010 and continues through June 30, 2011 (or such earlier date as may be determined by the parties).

Table of Contents

Item 6. Exhibits.

- 10.1* Letter Agreement dated November 5, 2010 between Steven B. Brugger and the Registrant.
- 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

Table of Contents

SIGNATURES

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

Date: November 8 , 2010

Momenta Pharmaceuticals, Inc.

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

Date: November 8, 2010

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