MOMENTA PHARMACEUTICALS INC
Form 10-Q
November 07, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended September 30, 2014

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

For the Transition Period from to

Commission File Number 000-50797

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(617) 491-9700

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

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

Indicate the number of shares outstanding of each of the Registrant s classes of Common Stock as of October 31, 2014.

Class	**Number of Shares**
Common Stock $0.0001 par value	53,050,634

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MOMENTA PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

MOMENTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

(unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 54,876	$ 29,766
Marketable securities	121,581	215,916
Accounts receivable	7,649	13,095
Unbilled receivables	3,056	3,413
Prepaid expenses and other current assets	3,701	3,401
Total current assets	190,863	265,591
Property and equipment, net	24,943	24,699
Restricted cash	20,719	20,719
Intangible assets, net	4,854	5,650
Other long-term assets	156	156
Total assets	$ 241,535	$ 316,815
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,150	$ 6,307
Accrued expenses	11,908	11,447
Deferred revenue	3,065	3,692
Other current liabilities	492	496
Total current liabilities	18,615	21,942
Deferred revenue, net of current portion	21,863	24,024
Other long-term liabilities	701	1,012
Total liabilities	41,179	46,978
Commitments and contingencies (Note 9)		
Stockholders Equity:		
Preferred stock, $0.01 par value per share; 5,000 shares authorized at September 30, 2014 and December 31, 2013, 100 shares of Series A Junior Participating Preferred Stock, $0.01 par value per share designated and no shares issued and outstanding		
Common stock, $0.0001 par value per share; 100,000 shares authorized at September 30, 2014 and December 31, 2013, 52,816 and 52,357 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	5	5

Additional paid-in capital		553,409		540,266
Accumulated other comprehensive income		20		25
Accumulated deficit		(353,078)		(270,459)
Total stockholders equity		200,356		269,837
Total liabilities and stockholders equity	$	241,535	$	316,815

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

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MOMENTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Collaboration revenues:				
Product revenue	$ 4,714	$ 4,774	$ 15,216	$ 11,798
Research and development revenue	4,622	5,977	15,855	10,918
Total collaboration revenue	9,336	10,751	31,071	22,716
Operating expenses:				
Research and development*	27,508	27,435	80,289	71,771
General and administrative*	11,103	8,977	34,039	30,202
Total operating expenses	38,611	36,412	114,328	101,973
Operating loss	(29,275)	(25,661)	(83,257)	(79,257)
Other income:				
Interest income	112	224	452	736
Other income	62	55	186	174
Total other income	174	279	638	910
Net loss	$ (29,101)	$ (25,382)	$ (82,619)	$ (78,347)
Basic and diluted net loss per share	$ (0.56)	$ (0.50)	$ (1.61)	$ (1.54)
Weighted average shares used in computing basic and diluted net loss per share	51,545	51,055	51,456	50,813
Comprehensive loss:				
Net loss	$ (29,101)	$ (25,382)	$ (82,619)	$ (78,347)
Net unrealized holding (losses) gains on available-for-sale marketable securities	(26)	98	(5)	9
Comprehensive loss	$ (29,127)	$ (25,284)	$ (82,624)	$ (78,338)

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

Research and development	$ 1,509	$ 1,359	$ 4,755	$ 3,969
General and administrative	$ 1,890	$ 1,796	$ 5,760	$ 5,387

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

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MOMENTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Cash Flows from Operating Activities:		
Net loss	$ (82,619)	$ (78,347)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash items:		
Depreciation and amortization	5,663	4,545
Share-based compensation expense	10,515	9,356
Amortization of premium on investments	1,855	2,627
Amortization of intangibles	796	796
Impairment of equity investment		244
Changes in operating assets and liabilities:		
Accounts receivable	5,446	4,409
Unbilled revenue	357	(4,545)
Prepaid expenses and other current assets	(300)	302
Restricted cash		(748)
Accounts payable	(3,157)	2,614
Accrued expenses	461	2,133
Deferred revenue	(2,788)	(2,997)
Other current liabilities	(4)	(284)
Other long-term liabilities	(311)	(116)
Net cash used in operating activities	(64,086)	(60,011)
Cash Flows from Investing Activities:		
Purchases of property and equipment	(5,907)	(6,560)
Purchases of marketable securities	(68,805)	(178,162)
Proceeds from maturities of marketable securities	161,280	220,569
Proceeds from sales of marketable securities		3,822
Net cash provided by investing activities	86,568	39,669
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock under stock plans	2,628	4,483
Net cash provided by financing activities	2,628	4,483
Increase (decrease) in cash and cash equivalents	25,110	(15,859)
Cash and cash equivalents, beginning of period	29,766	52,990
Cash and cash equivalents, end of period	$ 54,876	$ 37,131

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

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MOMENTA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED, CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company

Business

Momenta Pharmaceuticals, Inc. (the Company or Momenta) was incorporated in the state of Delaware in May 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the detailed structural analysis, process engineering and biologic systems analysis of complex molecules in three product areas complex generics, biosimilars and novel drugs. The Company presently derives all of its revenue from collaborations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company s accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, applicable to interim periods and, in the opinion of management, include all normal and recurring adjustments that are necessary to state fairly the results of operations for the reported periods. The Company s condensed consolidated financial statements have also been prepared on a basis substantially consistent with, and should be read in conjunction with, the Company s audited consolidated financial statements for the year ended December 31, 2013, which were included in the Company s Annual Report on Form 10-K that was filed with the Securities and Exchange Commission, or SEC, on February 28, 2014. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The results of the Company s operations for any interim period are not necessarily indicative of the results of the Company s operations for any other interim period or for a full fiscal year.

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements

and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and judgments, including those related to revenue recognition, accrued expenses, and share-based payments. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

Net Loss Per Common Share

The Company computes basic net loss per common share by dividing net loss by the weighted average number of common shares outstanding, which includes common stock issued and outstanding and excludes unvested shares of restricted common stock. The Company computes diluted net loss per common share by dividing net loss by the weighted average number of common shares and potential shares from outstanding stock options and unvested restricted stock determined by applying the treasury stock method.

The following table presents anti-dilutive shares for the three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Weighted-average anti-dilutive shares related to:				
Outstanding stock options	6,572	4,719	5,763	4,799
Restricted stock awards	822	910	860	928

Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per share is the same for the three and nine months ended September 30, 2014 and 2013. Anti-dilutive shares comprise the impact of the number of shares that would have been dilutive had the Company had net income plus the number of common stock equivalents that would be anti-dilutive had the Company had net income. Furthermore, performance-based restricted common stock awards which vest based

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upon U.S. Food and Drug Administration, or FDA, approval for M356 in the United States were excluded from diluted shares outstanding as the vesting condition had not been met as of September 30, 2014.

Fair Value Measurements

The tables below present information about the Company s assets that are measured at fair value on a recurring basis at September 30, 2014 and December 31, 2013, and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices (adjusted), interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The fair value hierarchy level is determined by the lowest level of significant input. Financial assets measured at fair value on a recurring basis are summarized as follows (in thousands):

Description	Balance as of September 30, 2014	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	$ 51,339	$ 51,339	$	$
Corporate debt securities	27,262		27,262	
Commercial paper obligation	1,350		1,350	
Marketable securities:				
Corporate debt securities	48,485		48,485	
Commercial paper obligations	12,500		12,500	
Foreign government bonds	20,187		20,187	
Asset-backed securities	13,147		13,147	
Total	$ 174,270	$ 51,339	$ 122,931	$

Description	Balance as of December 31, 2013	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 24,841	$ 24,841	$	$
Marketable securities:				
U.S. Government-sponsored enterprise obligations	22,309		22,309	
Corporate debt securities	110,158		110,158	
Commercial paper obligations	20,996		20,996	
Foreign government bonds	26,793		26,793	
Asset-backed securities	35,660		35,660	
Total	$ 240,757	$ 24,841	$ 215,916	$

During the nine months ended September 30, 2014, there were no transfers between Level 1 and Level 2 financial assets. The Company did not have any non-recurring fair value measurements on any assets or liabilities at September 30, 2014 and December 31, 2013. The carrying amounts reflected in the Company s condensed consolidated balance sheets for cash, accounts receivable, unbilled receivables, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Cash, Cash Equivalents and Marketable Securities

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

The Company invests its excess cash balances in short-term and long-term marketable debt securities. The Company classifies its investments in marketable debt securities as available-for-sale based on facts and circumstances present at the time it purchased the securities. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of stockholders equity. Realized gains and losses are determined using the specific identification method and are included in interest income. 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

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September 30, 2014 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. The Company did not record any impairment charges related to its marketable securities during the three and nine months ended September 30, 2014 and 2013. There were no realized gains or losses on marketable securities for the three months ended September 30, 2014 and 2013, or the nine months ended September 30, 2014. Realized gains on marketable securities for the nine months ended September 30, 2013 were immaterial. The Company s marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is 90 days or less, and as marketable securities if the original maturity, from the date of purchase, is in excess of 90 days. The Company s cash equivalents are primarily composed of money market funds.

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, 2014 and December 31, 2013.

The following tables summarize the Company s cash, cash equivalents and marketable securities at September 30, 2014 and December 31, 2013 (in thousands):

As of September 30, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 53,526	$	$	$ 53,526
Corporate debt securities due in one year or less	75,752	7	(12)	75,747
Commercial paper obligations due in one year or less	13,841	9		13,850
Foreign government bonds due in one year or less	20,173	14		20,187
Asset-backed securities due in one year or less	13,145	3	(1)	13,147
Total	$ 176,437	$ 33	$ (13)	$ 176,457
Reported as:				
Cash and cash equivalents	$ 54,876	$	$	$ 54,876
Marketable securities	121,561	33	(13)	121,581
Total	$ 176,437	$ 33	$ (13)	$ 176,457

As of December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 29,766	$	$	$ 29,766
U.S. Government-sponsored enterprise obligations				
Due in one year or less	11,000	3		11,003
Due in two years or less	11,303	3		11,306
Corporate debt securities				
Due in one year or less	94,659	13	(14)	94,658
Due in two years or less	15,498	9	(7)	15,500

Commercial paper obligations due in one year or less	20,978	18		20,996
Foreign government bonds due in one year or less	26,782	13	(2)	26,793
Asset-backed securities				
Due in one year or less	26,550	2	(4)	26,548
Due in two years or less	9,121		(9)	9,112
Total	$ 245,657	$ 61	$ (36)	$ 245,682
Reported as:				
Cash and cash equivalents	$ 29,766	$	$	$ 29,766
Marketable securities	215,891	61	(36)	215,916
Total	$ 245,657	$ 61	$ (36)	$ 245,682

At September 30, 2014 and December 31, 2013, the Company held 16 and 28 marketable securities, respectively, that were in a continuous unrealized loss position for less than one year. At September 30, 2014, one marketable security was in a continuous unrealized loss position for greater than one year. At December 31, 2013, no marketable securities were in a continuous unrealized loss position for greater than one year.

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The unrealized losses were caused by fluctuations in interest rates. The following table summarizes the aggregate fair value of these securities at September 30, 2014 and December 31, 2013 (in thousands):

	As of September 30, 2014		As of December 31, 2013	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities:				
Due in one year or less	$ 37,416	$ (12)	$ 38,508	$ (14)
Due in two years or less	$	$	$ 11,696	$ (7)
Foreign government bonds due in one year or less	$	$	$ 6,203	$ (2)
Asset-backed securities:				
Due in one year or less	$ 3,848	$ (1)	$ 16,977	$ (4)
Due in two years or less	$	$	$ 9,112	$ (9)
U.S. Government-sponsored enterprise obligations due in two years or less	$	$	$ 7,303	$ *

* Less than $1,000

Income Taxes

The Company generated U.S. taxable income during the years ended December 31, 2011 and 2010, and as a result, utilized $190.9 million and $26.3 million, respectively, of its available federal net operating loss carryforwards to offset this income.

At December 31, 2013, the Company had federal and state net operating loss carryforwards of $142.1 million and $132.1 million, respectively, available to reduce future taxable income and which will expire at various dates through 2033. Of this amount, approximately $13.1 million of federal and state net operating loss carryforwards relate to stock option deductions for which the related tax benefit will be recognized in equity when realized. At December 31, 2013, the Company had federal and state research and development and other credit carryforwards of $12.8 million and $7.1 million, respectively, available to reduce future tax liabilities. The federal and state research and development credit carryforwards will expire at various dates beginning in 2024 through 2033 and 2019 through 2028, respectively. The Company completed a research and development credit study and qualified its research activities under the tax code for the tax years 2004 through 2013. Ownership changes, as defined in Tax Reform Act of 1986, in future periods may place limits on the Company s ability to utilize its net operating loss carryforwards and tax credit carryforwards. As the Company has a full valuation allowance on its net deferred tax assets, there is no financial statement impact for any differences between the credits claimed on its tax returns versus credits substantiated as part of the study.

Comprehensive Loss

Comprehensive income (loss) is the change in equity of a company during a period from transactions and other events and circumstances, excluding transactions resulting from investments by owners and distributions to owners. Comprehensive income (loss) includes net (loss) income and the change in accumulated other comprehensive income (loss) for the period. Accumulated other comprehensive income (loss)

consists entirely of unrealized gains and losses on available-for-sale marketable securities for all periods presented. See the consolidated statements of comprehensive loss for relevant disclosures.

The following tables summarize the changes in accumulated other comprehensive income during the three and nine months ended September 30, 2014 and 2013 (in thousands):

		Unrealized Gains (Losses) on Securities Available for Sale
Balance as of June 30, 2014	$	46
Other comprehensive income (loss) before reclassifications		(26)
Amounts reclassified from accumulated other comprehensive income (loss)		
Net current period other comprehensive income (loss)		(26)
Balance as of September 30, 2014	$	20

		Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2014	$	25
Other comprehensive income (loss) before reclassifications		(5)
Amounts reclassified from accumulated other comprehensive income (loss)		
Net current period other comprehensive income (loss)		(5)
Balance as of September 30, 2014	$	20

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	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of June 30, 2013	$ 22
Other comprehensive income (loss) before reclassifications	98
Amounts reclassified from accumulated other comprehensive income (loss)	
Net current period other comprehensive income (loss)	98
Balance as of September 30, 2013	$ 120

	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2013	$ 111
Other comprehensive income (loss) before reclassifications	12
Amounts reclassified from accumulated other comprehensive income (loss)	(3)
Net current period other comprehensive income (loss)	9
Balance as of September 30, 2013	$ 120

The amounts reclassified from accumulated other comprehensive income (loss) represents realized gains on sales of marketable securities and are included in interest income in the consolidated statements of comprehensive loss.

New Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-15, a new going concern standard, which requires management to assess, at each interim and annual reporting period, whether substantial doubt exists about a company s ability to continue as a going concern. Substantial doubt exists if it is probable (the same threshold that is used for contingencies) that a company will be unable to meet its obligations as they become due within one year after the date the financial statements are issued or available to be issued (assessment date). Management needs to consider known (and reasonably knowable) events and conditions at the assessment date. If management determines there is substantial doubt, it should consider whether the doubt is overcome by management s plans. If it is probable that management s plans can be both effectively implemented and mitigate the conditions or events that raise substantial doubt, those plans, along with the principal conditions or events that gave rise to that doubt and management s evaluation of the significance of those conditions or events, must be disclosed. The new standard is effective for all entities for fiscal years beginning after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is evaluating the impact of the new guidance.

In May 2014, the FASB issued ASU No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. This guidance is effective for fiscal years beginning after December 15, 2016, with early adoption not permitted. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its consolidated financial statements.

3. Intangible Assets

As of September 30, 2014 and December 31, 2013, intangible assets, net of accumulated amortization, were as follows (in thousands):

	Weighted-Average Amortization Period (in years)	September 30, 2014 Gross Carrying Amount	September 30, 2014 Accumulated Amortization	December 31, 2013 Gross Carrying Amount	December 31, 2013 Accumulated Amortization
Core and developed technology	10	$ 10,257	$ (5,403)	$ 10,257	$ (4,607)
Non-compete agreement	2	170	(170)	170	(170)
Total intangible assets	10	$ 10,427	$ (5,573)	$ 10,427	$ (4,777)

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Amortization is computed using the straight-line method over the useful lives of the respective intangible assets as there is no other pattern of use that is reasonably estimable. Amortization expense was approximately $0.3 million for each of the three months ended September 30, 2014 and 2013. Amortization expense was approximately $0.8 million for each of the nine months ended September 30, 2014 and 2013.

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

4. Restricted Cash

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Amphastar Pharmaceuticals Inc., or Amphastar, Actavis, Inc., or Actavis (formerly Watson Pharmaceuticals Inc.), and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar), as discussed within Note 9, *Commitments and Contingencies*. The $17.5 million is held in an escrow account by Hanover Insurance. The Company classified this restricted cash as long-term as the timing of a final decision in the Enoxaparin Sodium Injection patent litigation is not known.

The Company designated $2.5 million as collateral for a letter of credit related to the lease of office and laboratory space located at 675 West Kendall Street in Cambridge, Massachusetts. This balance will remain restricted through the remaining term of the lease which ends in April 2015. The Company will earn interest on the balance.

The Company designated $0.7 million as collateral for a letter of credit related to the lease of office and laboratory space located at 320 Bent Street in Cambridge, Massachusetts. This balance will remain restricted through the lease term and during any lease term extensions. The Company will earn interest on the balance.

5. Collaboration and License Agreements

The following tables provide amounts by year and by line item included in the Company s consolidated statements of comprehensive (loss) income attributable to transactions arising from its collaborative arrangements, as defined in the Financial Accounting Standards Board s Accounting Standards Codification Topic 808, *Collaborative Arrangements*. The Company does not have any insignificant collaborative arrangements.

	For the Three Months Ended September 30, 2014 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 4,714	$	$	$ 4,714
Research and development revenue:				
Amortization of upfront payments		121	767	888

Research and development services and external costs	195	944	2,595	3,734
Total research and development revenue	$ 195	$ 1,065	$ 3,362	$ 4,622
Total collaboration revenues	$ 4,909	$ 1,065	$ 3,362	$ 9,336
Operating expenses:				
Research and development expense (1)	$ 50	$ 444	$ 3,639	$ 4,133
General and administrative expense (1)	$ 15	$ 84	$ 242	$ 341
Total operating expenses	$ 65	$ 528	$ 3,881	$ 4,474

	For the Three Months Ended September 30, 2013 (in thousands)			
	2003 Sandoz Collaboration	**2006 Sandoz Collaboration**	**Baxter Agreement**	**Total Collaborations**
Collaboration revenues:				
Product revenue	$ 4,774	$	$	$ 4,774
Research and development revenue:				
Amortization of upfront payments		244	705	949
Research and development services and external costs	606	(325)	4,747	5,028
Total research and development revenue	$ 606	$ (81)	$ 5,452	$ 5,977
Total collaboration revenues	$ 5,380	$ (81)	$ 5,452	$ 10,751
Operating expenses:				
Research and development expense (1)	$ 72	$ 362	$ 7,539	$ 7,973
General and administrative expense (1)	$ 5	$	$ 140	$ 145
Total operating expenses	$ 77	$ 362	$ 7,679	$ 8,118

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	For the Nine Months Ended September 30, 2014 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 15,216	$	$	$ 15,216
Research and development revenue:				
Amortization of upfront payments		480	2,309	2,789
Research and development services and external costs	796	1,738	10,532	13,066
Total research and development revenue	$ 796	$ 2,218	$ 12,841	$ 15,855
Total collaboration revenues	$ 16,012	$ 2,218	$ 12,841	$ 31,071
Operating expenses:				
Research and development expense (1)	$ 134	$ 973	$ 11,868	$ 12,975
General and administrative expense (1)	$ 110	$ 315	$ 399	$ 824
Total operating expenses	$ 244	$ 1,288	$ 12,267	$ 13,799

	For the Nine Months Ended September 30, 2013 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 11,798	$	$	$ 11,798
Research and development revenue:				
Amortization of upfront payments		884	2,115	2,999
Research and development services and external costs	2,411	135	5,373	7,919
Total research and development revenue	$ 2,411	$ 1,019	$ 7,488	$ 10,918
Total collaboration revenues	$ 14,209	$ 1,019	$ 7,488	$ 22,716
Operating expenses:				
Research and development expense (1)	$ 571	$ 1,238	$ 12,924	$ 14,733
General and administrative expense (1)	$	$ 131	$ 370	$ 501
Total operating expenses	$ 571	$ 1,369	$ 13,294	$ 15,234

(1) The amounts represent external expenditures, including amortization of an intangible asset, and exclude salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies, as these costs are not directly charged to programs.

2003 Sandoz Collaboration

In November 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz AG and Sandoz Inc., collectively, Sandoz, to jointly develop and commercialize Enoxaparin Sodium Injection, a generic version of Lovenox®, a low molecular weight heparin, or LMWH.

Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell Enoxaparin Sodium Injection in the United States. The Company agreed to provide development and related services on a commercially reasonable basis, which included developing a manufacturing process to make Enoxaparin Sodium Injection, scaling up the process, contributing to the preparation of an Abbreviated New Drug Application, or ANDA, in Sandoz s name to be filed with the FDA, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product.

In July 2010, the FDA granted marketing approval of the ANDA for Enoxaparin Sodium Injection filed by Sandoz. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents, or FTEs, performing development and related services. Sandoz is obligated to pay the Company a royalty on net sales in each post-launch contract year, which for net sales up to a pre-defined sales threshold is payable at a 10% rate, and for net sales above the sales threshold increases to 12%. See Product revenue in the tables above for royalties earned by the Company on Sandoz s net sales of Enoxaparin Sodium Injection.

The Company is no longer eligible to receive milestones under the 2003 Sandoz Collaboration because the remaining milestones were contingent upon there being no third-party competitors marketing an interchangeable generic version of a Lovenox-Equivalent Product.

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A portion of the development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, are offset against profit-sharing amounts, royalties and milestone payments. Sandoz also may offset a portion of any product liability costs and certain other expenses arising from patent litigation against any profit-sharing amounts, royalties and milestone payments. The contractual share of these development and other expenses is subject to an annual adjustment at the end of each product year, and ends with the product year ending June 2015. Annual adjustments are recorded as a reduction in product revenue in the second quarter of the Company s fiscal year. The annual adjustment of $2.2 million for the product year ending June 30, 2014 was decreased by $2.1 million to reflect an adjustment to royalties earned in the product year ended June 30, 2012. The annual adjustment was $3.8 million for the product year ended June 30, 2013.

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. See tables above for research and development revenue earned by the Company under the 2003 Sandoz Collaboration.

2006 Sandoz Collaboration

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

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, which is being recognized in revenue on a straight-line basis over the estimated development period. In September 2014, the Company revised the estimate of the development period due to a change in the period over which the Company s remaining performance obligations will occur. The impact of this change in estimate on the Company s net loss and net loss per share for the three months ended September 30, 2014 was immaterial. See Amortization of upfront payments in the tables above for research and development revenue earned by the Company relating to this paid premium. The equity premium has been earned as of September 30, 2014.

Under the 2006 Sandoz Collaboration, the Company and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356 for sale in specified regions of the world. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions. The Company has agreed to provide development and related services which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market any products covered by the 2006 Sandoz Collaboration. The Company identified two significant deliverables in this arrangement consisting of (i) a license and (ii) the development and related services. The Company determined that the license did not meet the criteria for separation as it does not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company has determined that a single unit of accounting exists with respect to the 2006 Sandoz Collaboration.

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

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization costs will be borne by Sandoz AG as they are incurred for all products. Under the 2006 Sandoz Collaboration, the Company is paid at cost for any external costs incurred in the development of products at the same proportion that Sandoz is responsible for development costs. The Company also is paid at a contractually specified rate for FTEs performing development services at the same proportion that Sandoz is responsible for development costs. Upon commercialization, the Company will earn a 50% profit share on worldwide net sales of M356. Profits on net sales of M356 will be calculated by deducting from net sales the costs of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. Additionally, the Company is eligible to receive up to $163.0 million in milestone payments upon the achievement of certain regulatory, commercial and sales-based milestones for the products under the collaboration, which include: a $10.0 million regulatory milestone payment related to the approval by the FDA of M356, and $153.0 million in sales-based and commercial milestone payments, of which up to $140.0 million (including the M356 regulatory milestone) are U.S.-based milestones. The Company has concluded that the regulatory milestone pursuant to its 2006 Sandoz Collaboration is substantive. In making this assessment the Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. Revenues from the non-refundable regulatory milestone are recognized as research and development revenue upon successful accomplishment of the milestone. Sales-based and commercial milestones are accounted for as royalties and are recorded as

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revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services, except with respect to any amounts due Sandoz for shared development costs, which are recorded on a net basis. See Research and development services and external costs in the tables above for research and development revenue earned by the Company from FTE services and external development costs under the 2006 Sandoz Collaboration.

Baxter Agreement

In December 2011, the Company entered into a global collaboration and license agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, Baxter) to develop and commercialize biosimilar product candidates. The Company refers to this agreement as the Baxter Agreement. The Baxter Agreement became effective in February 2012.

Under the Baxter Agreement, the Company agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilar products, M923 and M834, both indicated in the inflammatory and autoimmune therapeutic areas, referred to as the initial products. M923 is a biosimilar product candidate for HUMIRA® (adalimumab). In addition to M923 and M834, both parties are evaluating additional products for biosimilar development under the Agreement. Baxter has the right, until February 2015, to select up to three additional biosimilars to be included in the collaboration.

The process for achieving milestones under the Baxter Agreement is as follows:

- Baxter selects an additional product to the collaboration and the Company initiates development.

- If the Company achieves pre-defined minimum development criteria related to the additional product, Baxter is given an option to exercise exclusive license rights.

- If Baxter exercises its exclusive license option to advance the additional product under the Baxter Agreement, the Company will earn a license payment.

- If the Company achieves pre-defined technical development criteria related to an initial product or additional product, the Company will earn a milestone payment.

- For an initial and additional product, if the Company either (a) submits an Investigational New Drug application, or IND, to the FDA or equivalent application in the European Union, and application is subsequently accepted by the regulatory authority, or (b) is not required to file an IND, either referred to as the Transition Period, the Company will earn a milestone payment.

- Following the Transition Period, Baxter will assume responsibility for development of each biosimilar, and the Company has the potential to receive up to $250 million in regulatory milestone payments. These milestones are designed to reward the Company, on a sliding scale, for reducing the scope of the clinical activities required to develop each biosimilar.

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

In addition, the Company has agreed, for a period commencing six months following the effective date and ending on the earlier of (i) three years from the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement) or

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

Under the terms of the Baxter Agreement, the Company received an initial cash payment of $33.0 million. The Company is eligible to receive from Baxter license payments totaling $21.0 million for the exercise of options with respect to the additional three product candidates that can be named under the Baxter Agreement, payments of $5.0 million each for extensions of the period during which such additional products may be selected, and a $7.0 million license payment for M834 upon the achievement of pre-defined minimum development criteria, as defined in the agreement. The Company is also eligible to receive from Baxter an aggregate of approximately $316.0 million in potential milestone payments, comprised of (i) up to $66.0 million in substantive milestone payments upon achievement of specified technical and development milestone events across the five product candidates, and (ii) regulatory milestone payments totaling up to $250.0 million, on a sliding scale, across the five product candidates where, based on the products regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval. Two of the technical and development milestones were time-based and the total eligible milestones have been adjusted to correspond to current development plans. There are no other time-based milestones included in the Baxter Agreement. The technical and development milestones include (i) achievement of certain criteria that will ultimately drive commercial feasibility for manufacturing the products and (ii) acceptance by the FDA of an IND or acceptance in the European Union of an equivalent application.

The Company continues to advance development of its two biosimilar products under development with Baxter. In October 2014, the Company achieved pre-defined minimum development criteria for M834 and earned (and collected from Baxter) the $7.0 million license payment in the fourth quarter of 2014. Also in October 2014, Baxter submitted a clinical trial application for M923 to support the initiation of a Phase 1 clinical trial in the European Union. Acceptance of the clinical trial application triggers technical and development milestone payments totaling $12.0 million.

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

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

The Baxter Agreement may be terminated by:

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

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

- Baxter for its convenience; or

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

In accordance with FASB s ASU No. 2009-13: Multiple-Deliverable Revenue Arrangements (Topic 615), the Company identified all of the deliverables at the inception of the Baxter Agreement. The deliverables were determined to include (i) the development and product licenses to the two initial biosimilars and the four additional biosimilars, (ii) the research and development services related to the two initial biosimilars and the four additional biosimilars and (iii) the Company s participation in a joint steering committee. The Company has determined that each of the license deliverables do not have stand-alone value apart from the related research and development services deliverables as there are no other vendors selling similar, competing products on a stand-alone basis, Baxter does not have the contractual right to resell the license, and Baxter is unable to use the license for its intended purpose without the Company s performance of research and development services. As such, the Company determined that separate units of accounting exist for each of the six licenses together with the related research and development services, as well as the joint steering committee with respect to this arrangement. The estimated selling prices for these units of accounting were determined based on similar license arrangements and the nature of the research and development services to be performed for Baxter and market

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rates for similar services. At the inception of the Baxter Agreement, the arrangement consideration of $61.0 million, which included the $33.0 million upfront payment and aggregate option payments for the four additional biosimilars of $28.0 million, was allocated to the units of accounting based on the relative selling price method. Of the $61.0 million, $10.3 million was allocated to the first initial product license together with the related research and development services, $10.3 million to each of the four additional product licenses with the related research and development services, $9.4 million has been allocated to the second initial product license together with the related research and development services due to that product s stage of development at the time the license was delivered, and $114,000 was allocated to the joint steering committee unit of accounting. In December 2013, Baxter terminated its option to license M511, a named product under the Baxter Agreement. Accordingly, the expected consideration to be received under the arrangement has been reduced by $7.0 million (M511 option payment) and there is now one less deliverable. The Company determined that the change in expected consideration to be received under the arrangement represents a change in estimate and, as a result, the Company reallocated the revised expected consideration of $54.0 million to the remaining deliverables under the agreement using the original best estimate of selling price. The Company will recognize the resulting change in revenue on a prospective basis. Of the $54.0 million, $11.0 million was allocated to the first initial product license together with the related research and development services, $11.0 million to each of the three additional product licenses with the related research and development services, $10.0 million has been allocated to the second initial product license together with the related research and development services due to that product s stage of development at the time the license was delivered, and $122,000 was allocated to the joint steering committee unit of accounting.

The Company will commence revenue recognition for each of the five units of accounting related to the products upon delivery of the related development and product license and will record this revenue on a straight-line basis over the applicable performance period during which the research and development services will be delivered. The $7.0 million license payment for M834 will be combined with the $10.0 million consideration previously allocated to that product and will be recognized on a straight line basis over the period research and development services will be provided. The Company will recognize the revenue related to the joint steering committee deliverable over the applicable performance period during which the research and development services will be delivered. The Company has determined that the performance period for each of the combined five units of accounting consisting of the products and related research and development services, begins upon delivery of the related development and product license and ends upon FDA approval of the related product. The Company has also determined that the applicable performance period for the joint steering committee deliverable begins upon delivery of the first development and product license and ends upon the latest date of FDA approval. The Company currently estimates that the performance period for the two initial products, considering their respective stage of development, is approximately five and eight years, respectively, and the period of performance for the joint steering committee is approximately eleven years.

In 2012, the Company commenced recognition of the revenue allocated to the two initial products but not for the three additional products as those licenses have not been delivered. 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. Beginning in the second quarter of 2013, the Company commenced billing to Baxter external development costs for reimbursable activities related to M923. Beginning in the second half of 2013, the Company commenced billing to Baxter FTE fees related to M923. See tables above for research and development revenue earned by the Company under the Baxter Agreement. The portion of the upfront payment that is unearned at September 30, 2014 is included in deferred revenue.

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

The Company has concluded that certain of the technical and development milestones and all of the regulatory milestones pursuant to the Baxter Agreement are substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve these milestones, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and

payment terms in the arrangement in making this assessment. Revenues from non-refundable technical, development and regulatory milestones will be recognized upon successful accomplishment of the milestones as research and development revenue. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

Massachusetts Institute of Technology

The Company has an agreement dated November 1, 2002 with the Massachusetts Institute of Technology, or M.I.T., granting the Company various exclusive and non-exclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to:

- methods and technologies for characterizing polysaccharides;
- certain heparins, heparinases and other enzymes; and
- carbohydrate synthesis methods.

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In exchange for the licenses granted in the agreement, the Company has paid M.I.T. license maintenance fees, royalties on certain products and services covered by the licenses and sold by the Company or its affiliates or sublicensees, a percentage of certain other income received by the Company from corporate partners and sublicensees, and certain patent prosecution and maintenance costs.

The following table summarizes the license maintenance fees and royalties paid to M.I.T. and recorded in the three and nine months ended September 30, 2014 and 2013 (in thousands):

	For the Three Months Ended September 30, 2014	For the Three Months Ended September 30, 2013	For the Nine Months Ended September 30, 2014	For the Nine Months Ended September 30, 2013
License maintenance fees	$ 22	$ 21	$ 63	$ 62
Royalties	71	75	241	174
Total	$ 93	$ 96	$ 304	$ 236

The annual license maintenance obligations, which extend through the life of the patents, are approximately $0.1 million per year. The annual payments may be applied towards royalties payable to M.I.T. for that year for product sales, sublicensing of the patent rights or joint development revenue. A portion of the annual license payments was applied against cumulative royalties due for the three and nine months ended September 30, 2014 and 2013.

The Company is obligated to indemnify M.I.T. and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements, unless the losses result from the indemnified parties gross negligence or willful misconduct.

The agreement expires upon the expiration or abandonment of all patents that issue and are licensed to the Company by M.I.T. under such agreement. The issued patents include over 40 United States patents and foreign counterparts of some of those. Any such patent will have a term of 20 years from the filing date of the underlying application. M.I.T. may terminate the agreement immediately if the Company ceases to carry on its business, if any nonpayment by the Company is not cured within 60 days of written notice or the Company commits a material breach that is not cured within 90 days of written notice. The Company may terminate the agreement for any reason upon six months notice to M.I.T., and it can separately terminate the license under a certain subset of patent rights upon three months notice.

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

The Company previously had an exclusive patent license agreement dated October 31, 2002 with M.I.T. granting the Company various licenses under certain patents solely related to the commercial sale or leasing of sequencing machines, including the performance of sequencing services.

The Company terminated that agreement in January 2013. Nothing in the notice of termination impacts the agreement between the Company and M.I.T. dated November 1, 2002.

6. Share-Based Payments

Incentive Award Plans

In March 2013, the Company s Board of Directors adopted the 2013 Incentive Award Plan, or the 2013 Plan. The 2013 Plan became effective on June 11, 2013, the date the Company received shareholder approval for the plan. Also on June 11, 2013, the 2004 Stock Incentive Plan terminated except with respect to awards previously granted under that plan. No further awards will be granted under the 2004 Stock Incentive Plan.

The 2013 Plan allows for the granting of stock options (both incentive stock options and nonstatutory stock options), restricted stock, stock appreciation rights, performance awards, dividend equivalents, stock payments and restricted stock units to employees, consultants and members of the Company s board of directors.

Incentive stock options will be granted only to employees of the Company. Incentive stock options granted to employees who own more than 10% of the total combined voting power of all classes of stock will be granted with exercise prices no less than 110% of the fair market value of the Company s common stock on the date of grant. Incentive stock options generally vest ratably over four years. Non-statutory stock options and restricted stock awards may be granted to employees, consultants and members of the Company s board of directors. Restricted stock awards

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generally vest ratably over four years. Non-statutory stock options granted have varying vesting schedules. Incentive and non-statutory stock options generally expire ten years after the date of grant. Restricted stock awards are granted only to employees of the Company.

Under the 2013 Plan, the aggregate number of shares reserved for issuance is equal to the sum of: (a) 3,300,000 shares reserved for issuance under the 2013 Plan, plus (b) one share for each share subject to a stock option that was granted through December 31, 2012 under the 2004 Stock Incentive Plan and the Amended and Restated 2002 Stock Incentive Plan (together, the Prior Plans) that subsequently expires, is forfeited or is settled in cash (up to a maximum of 5,386,094 shares), plus (c) 1.35 shares for each share subject to an award other than a stock option that was granted through December 31, 2012 under the Prior Plans and that subsequently expires, is forfeited, is settled in cash or repurchased (up to a maximum of 1,137,394 shares). On April 14, 2014, the compensation committee of the board of directors approved an amendment and restatement of the 2013 Plan to increase the shares of common stock available for grant under the 2013 Plan by 1,800,000 shares. The amended and restated 2013 Plan became effective on June 11, 2014, the date the Company received stockholder approval. At September 30, 2014, 3,301,068 shares were available for issuance under the 2013 Plan.

Each share issued in connection with an award granted under the 2013 Plan, other than stock options and stock appreciation rights, will be counted against the 2013 Plan s share reserve as 1.35 shares for every one share issued in connection with such award, while each share issued in connection with an award of stock options or stock appreciation rights will count against the share reserve as one share for every one share granted.

In 2004, the Company s Board of Directors adopted the 2004 Employee Stock Purchase Plan, or ESPP. Since adoption of the ESPP through February 2014, an aggregate of 524,652 shares of common stock have been reserved for issuance under the ESPP. In March 2014, the board of directors approved the amendment and restatement of the ESPP to increase the shares of common stock available for grant under the ESPP by 500,000 shares. The amended and restated ESPP became effective on June 11, 2014, the date the Company received approval by its stockholders. As of September 30, 2014, 527,968 shares of common stock have been issued to the Company s employees under the ESPP, and 496,684 shares remain available for future issuance.

Share-Based Compensation

The Company recognizes the fair value of share-based compensation in its consolidated statements of comprehensive (loss) income. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under its stock option plans and the ESPP. For stock options, the Company recognizes share-based compensation expense equal to the fair value of the stock options on a straight-line basis over the requisite service period. For time-based restricted stock awards, the Company records share-based compensation expense equal to the market value on the date of the grant on a straight-line basis over each award s explicit service period. For performance-based restricted stock, each reporting period the Company assesses the probability that the performance condition(s) will be achieved. The Company then expenses the awards over the implicit service period based on the probability of achieving the performance conditions. The Company estimates an award s implicit service period based on its best estimate of the period over which an award s vesting condition(s) will be achieved. The Company reviews and evaluates these estimates on a quarterly basis and will recognize any remaining unrecognized compensation as of the date of an estimate revision over the revised remaining implicit service period. The Company issues new shares upon stock option exercises, upon the grant of restricted stock awards and under its ESPP.

Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the ESPP for the three months ended September 30, 2014 and 2013 was $3.4 million and $3.2 million, respectively. Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the ESPP for the nine

months ended September 30, 2014 and 2013 was $10.5 million and $9.4 million, respectively.

Share-based compensation expense related to outstanding employee stock option grants and the ESPP was $2.6 million and $2.2 million for the three months ended September 30, 2014 and 2013, respectively. Share-based compensation expense related to outstanding employee stock option grants and the ESPP was $7.5 million and $6.2 million for the nine months ended September 30, 2014 and 2013, respectively. During the nine months ended September 30, 2014, the Company granted 1,363,172 stock options, of which 1,164,922 were granted in connection with annual merit awards, 142,000 were granted to the Company s board of directors, and 56,250 were granted to new hires. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended September 30, 2014 and 2013 was $6.90 per option and $9.52 per option, respectively. The weighted average grant date fair value of option awards granted during the nine months ended September 30, 2014 and 2013 was $10.62 per option and $7.33 per option, respectively.

The following tables summarize 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 September 30, 2014	For the Three Months Ended September 30, 2013	For the Three Months Ended September 30, 2014	For the Three Months Ended September 30, 2013
Expected volatility	61%	65%	63%	63%
Expected dividends				
Expected life (years)	6.3	6.2	0.5	0.5
Risk-free interest rate	2.2%	2.2%	0.1%	0.1%

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	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Nine Months Ended September 30, 2014	For the Nine Months Ended September 30, 2013	For the Nine Months Ended September 30, 2014	For the Nine Months Ended September 30, 2013
Expected volatility	66%	62%	63%	64%
Expected dividends				
Expected life (years)	6.1	6.0	0.5	0.5
Risk-free interest rate	2.2%	1.4%	0.1%	0.1%

At September 30, 2014, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $18.1 million, net of estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.5 years.

During the nine months ended September 30, 2014, holders of options issued under the Company s stock plans exercised their right to acquire an aggregate of 155,944 shares of common stock. Additionally, during the nine months ended September 30, 2014, the Company issued 98,910 shares of common stock to employees under the ESPP.

Restricted Stock Awards

The Company has also made awards of time-based and performance-based restricted common stock to employees and officers. During the nine months ended September 30, 2014, the Company awarded 227,394 shares of time-based restricted common stock to its officers in connection with its annual merit grant. The time-based restricted common stock fully vests over the four years following the grant date. The time-based awards are generally forfeited if the employment relationship terminates with the Company prior to vesting. Between 2011 and early 2013, the Company awarded 949,620 shares of performance-based restricted common stock to employees and officers. 50% of the shares vest upon FDA approval in the United States for M356, the Company s second major generic program, provided that approval occurs on or before March 28, 2015. The remaining 50% of the awards vest on the one-year anniversary of approval, as long as approval occurs on or before March 28, 2015 and the employment relationship exists on the anniversary date. Each quarter the Company evaluates its estimate of the implicit service period over which the fair value of the awards will be recognized and expensed. The Company determined that it was probable that the performance condition would be achieved and therefore is expensing the fair value of the shares over the implicit service period. In September 2014, the Company revised its estimate of the implicit service period and the impact of this change in estimate on the Company s net loss and net loss per share for the three months ended September 30, 2014 was immaterial.

The Company recorded share-based compensation expense related to nonvested, outstanding restricted stock awards, including the performance-based shares, because the Company determined that it was probable the performance condition would be achieved, of $0.8 million and $1.0 million for the three months ended September 30, 2014 and 2013, respectively. The Company recorded share-based compensation expense related to nonvested, outstanding restricted stock awards, including the performance-based shares, because the Company determined that it was probable the performance condition would be achieved, of $3.0 million for each of the nine months ended September 30, 2014 and 2013. As of September 30, 2014, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $6.8 million, which is expected to be recognized over the weighted average remaining requisite service period of 1.6 years.

A summary of the status of nonvested shares of restricted stock as of September 30, 2014 and the changes during the nine months then ended are presented below (in thousands, except fair values):

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2014	1,134	$ 14.41
Granted	227	17.96
Vested	(113)	13.57
Forfeited	(23)	14.78
Nonvested at September 30, 2014	1,225	$ 15.14

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of September 30, 2014 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	411
Performance-based	814
Nonvested at September 30, 2014	1,225

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7. Tax Incentive Agreement

In March 2012, the Company entered into a Tax Incentive Agreement with the Massachusetts Life Sciences Center, or MLSC, under the MLSC s Life Sciences Tax Incentive Program, or the Program, to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences in the Commonwealth of Massachusetts. The Program was established in 2008 in order to incentivize life sciences companies to create new sustained jobs in Massachusetts. Under the Tax Incentive Agreement, companies receive an award from the MLSC upon attaining job creation commitment. Jobs must be maintained for at least five years, during which time a portion of the grant proceeds can be recovered by the Massachusetts Department of Revenue if the Company does not maintain its job creation commitments. As the Company attained its job creation commitment in 2012 and maintained it in 2013, it recognized one-fifth of the $1.1 million job creation tax award, or $0.2 million, as other income in each of the years ended December 31, 2013 and 2012. The unearned portion of the award is included in other liabilities in the consolidated balance sheet. The Company will continue to recognize an equal portion of the award as other income over the five year period it must maintain its job creation commitments.

8. At-The-Market Offering

In May 2014, the Company entered into an At-The-Market Equity Offering Sales Agreement, or the Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which the Company is authorized to issue and sell shares of its common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal.

The offering is being conducted by the Company pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission. The proceeds from this facility will be used to advance our development pipeline and for general corporate purposes, including working capital. As of September 30, 2014, no shares were issued pursuant to the Sales Agreement.

9. Commitments and Contingencies

Operating Leases

The Company leases office space and equipment under various operating lease agreements.

In September 2004, the Company entered into an agreement with Vertex Pharmaceuticals, or Vertex, to lease 53,323 square feet of office and laboratory space located on the fourth and fifth floors at 675 West Kendall Street, Cambridge, Massachusetts, for an initial term of 80 months, or the West Kendall Sublease. In November 2005, the Company amended the West Kendall Sublease to lease an additional 25,131 square feet through April 2011. In April 2010, the Company exercised its right to extend the West Kendall Sublease for one additional term of 48 months, ending April 2015, or on such other earlier date as provided in accordance with the West Kendall Sublease. During the extension term, which commenced on May 1, 2011, annual rental payments increased by approximately $1.2 million over the previous annual rental rate. On July 15, 2014, the Company and Vertex entered into an agreement to extend the term of the West Kendall Sublease through April 2018, or such other

earlier date as provided in accordance with the West Kendall Sublease. During the extension term, which will commence May 1, 2015, annual rental payments will be approximately $4.8 million.

In December 2011, the Company entered into an agreement to lease 68,575 square feet of office and laboratory space located on the first and second floors at 320 Bent Street, Cambridge, Massachusetts, for a term of approximately 18 months, or the First Bent Street Sublease. The Company gained access to the subleased space in December 2011 and, consequently, the Company commenced expensing the applicable rent on a straight-line basis beginning in December 2011. Annual rental payments due under the First Bent Street Sublease were approximately $2.3 million.

On February 5, 2013, the Company and BMR-Rogers Street LLC, or BMR, entered into a lease agreement, or the Second Bent Street Lease, to lease 104,678 square feet of office and laboratory space located in the basement and first and second floors at 320 Bent Street, Cambridge, Massachusetts, beginning on September 1, 2013 and ending on August 31, 2016. Annual rental payments due under the Second Bent Street Lease are approximately $6.1 million during the first lease year, $6.2 million during the second lease year and $6.3 million during the third lease year. BMR agreed to pay the Company a tenant improvement allowance of $0.7 million for reimbursement of laboratory and office improvements made by the Company (and subsequently reimbursed by BMR). The Company has recorded short and long-term liabilities for the construction allowance in its consolidated balance sheet, which is being amortized on a straight-line basis through a reduction to rental expense over the term of the lease.

The Company has two consecutive options to extend the term of the Second Bent Street Lease for one year each at the then-current fair market value. In addition, the Company has two additional consecutive options to extend the term of the Second Bent Street Lease for five years each for the office and laboratory space located in the basement portion of the leased space at the then-current fair market value.

Total operating lease commitments as of September 30, 2014 are as follows (in thousands):

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		Operating Leases
October 1, 2014 through December 31, 2014	$	2,774
2015		11,177
2016		9,189
2017		4,924
2018		1,608
Total future minimum lease payments	$	29,672

Legal Contingencies

The Company is involved in various litigation matters that arise from time to time in the ordinary course of business. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect the Company, its results of operations, financial condition and cash flows. The Company s general practice is to expense legal fees as services are rendered in connection with legal matters, and to accrue for liabilities when losses are probable and reasonably estimable. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of any accrual on its consolidated balance sheets.

On August 28, 2008, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against the Company and Sandoz in the United States Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 20 mg/mL formulation of M356. The suit alleged infringement related to four of the seven Orange Book-listed patents for Copaxone and sought declaratory and injunctive relief that would prohibit the launch of the Company s product until the last to expire of these patents. The Orange Book is a publication of the FDA that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and includes patents that are purported by the drug application owner to protect each drug. If there is a patent listed for the branded drug in the Orange Book at the time of submission of an ANDA, or at any time before an ANDA is approved, a generic manufacturer s ANDA must include one of four types of patent certification with respect to each listed patent. See Part I, Item 1. Business Regulatory and Legal Matters in the Company s Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on February 28, 2014. The Company and Sandoz asserted various defenses and filed counterclaims for declaratory judgments to have all seven of the Orange Book-listed patents, as well as two additional patents, in the same patent family adjudicated in that lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book-listed patents for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against the Company and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. The Orange Book-listed patents and one non-Orange Book-listed patent expires on May 24, 2014 and one non-Orange Book-listed patent expires on September 1, 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz ANDA or Mylan ANDA prior to the expiration of the Orange Book-listed patents. In July 2012, the Company appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the patents, including the one patent set to expire in 2015. The other patents expired on May 24, 2014. The CAFC remanded the case to the District Court to modify the injunction in light of the CAFC decision. In September 2013, Teva filed a petition for rehearing of the CAFC decision, and on October 18, 2013 the CAFC denied the petition. Teva filed a petition for review by the Supreme Court of the United States in January 2014 and in March 2014 the Supreme Court granted certiorari in the case in order to review the appropriate standard for deference to district court findings related to claim construction. Briefing was completed in September 2014, and oral argument was held in October 2014. The Supreme Court could render a decision by the end of the year or during the first half of 2015. While the Company believes the Supreme Court should affirm the CAFC decision, it could rule otherwise and, among other things, remand the case to a lower court for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. During the pendency of this litigation any launch of the generic Copaxone product would be a launch at risk of infringement.

On September 10, 2014, Teva and Yeda filed suit against the Company and Sandoz in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 40 mg/mL formulation of M356. The suit alleges infringement related to two Orange Book-listed patents for 40 mg/mL Copaxone, each expiring in 2030, and seeks declaratory and injunctive relief prohibiting the launch of the Company s product until the last to expire of these patents. The Company and Sandoz have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidatity and unenforceability of both patents.

On September 21, 2011, the Company and Sandoz sued Amphastar, Actavis and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of the Company s patents. Also in September, 2011, the Company filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Actavis and International Medical Systems, Ltd. from selling their enoxaparin product in the United States. In October 2011, the court granted the Company s motion for a preliminary injunction and entered an order enjoining Amphastar, Actavis and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin product in the United States until the conclusion of a trial on the merits and required the Company and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar, Actavis and International Medical Systems, Ltd. appealed the decision and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court. In September 2012, the Company filed a petition with the CAFC for a rehearing by the full court *en banc*, which was denied. In February 2013, the Company filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court and in June 2013 the Supreme Court denied the request.

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In January 2013, Amphastar and Actavis filed a motion for summary judgment in the District Court following the decision from the CAFC and in July 2013, the District Court granted the motion for summary judgment. The Company has filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling. The Company opposed this motion and the Court denied the motion in May 2014. The CAFC has set a briefing schedule which ends in November 2014. A hearing could be expected in late 2014 or the first half of 2015, and a decision could be expected in 2015. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company is not successful in any appeal, and Amphastar and Actavis are able to prove they suffered damages as a result of the preliminary injunction, the Company could be liable for damages for up to $35 million of the security bond. Amphastar has filed motions to increase the amount of the security bond, which the Company and Sandoz have opposed.

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

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

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 Securities Exchange Act of 1934, as amended. 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, nonclinical and clinical trial results, the outcome of litigation and the sufficiency of our cash for future operations. Forward-looking statements can be identified by terminology such as anticipate, believe, could, could increase the likelihood, hope, target, project, goals, potential, predict, might, estimate, expect, intend, is planned, may, should, will, will enable, would be expected, look forward, may provide, would or similar terms, variations of such terms or the negative of those terms.

We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below under Risk Factors in Item 1A of Part II of this Quarterly Report on Form 10-Q. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Business Overview

The Company

We are a biotechnology company operating in three product areas: Complex Generics, Biosimilars and Novel Drugs. Our approach is built around a complex systems analysis platform that we use to obtain a detailed understanding of complex chemical and biologic systems, design product candidates based on this knowledge, analyze sets of biological data to evaluate the biological function of our products, and develop manufacturing processes that enable our products to be reliably produced. Our first commercial product, developed in collaboration with Sandoz, Enoxaparin Sodium Injection, a generic version of Lovenox®, was approved in July of 2010, validating our development approach as well as the commercial value of our platform. In the period from commercial launch through September 2011, we capitalized on the advantage of having the only generic version of Lovenox in the marketplace and recognized over $340 million in revenue from this product.

The core objective of our complex systems analysis platform is to resolve the complexity of molecular structures and related biologic systems. For the complex systems we seek to understand, we first map the key measurements needed to provide comprehensive data on the system. We then develop a set of analytic tools and methods that include a combination of standard analytics, modified analytic approaches and custom developed analytics and methods. The modified and custom analytics may be protected by trade secrets or patents. The analytic set we use for a

development program is designed to provide comprehensive data on the complex molecular mixture and target biology, including providing multiple related and complementary, or orthogonal, measures of the system. We also may use computer software to mine and synthesize the data to yield insights that advance our development programs across all three product areas. As we expand our infrastructure, intellectual property and knowledge of complex biologies, we accrue advantages as well. For example, the process development and manufacturing expertise developed from our complex generic and biosimilars efforts can be directly used to advance our novel drug candidates. The investments in biocharacterization made for our biosimilars program provide a core of models and biologic data sets that can form the basis of inquiries in our novel drug research. And the analytic tools and methods and biologic models we develop help build a substantial toolset that can be used across our programs.

As of September 30, 2014, we had an accumulated deficit of approximately $353 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. We have been incurring operating losses and we expect to incur annual operating losses over the next several years as we advance our drug development portfolio. We expect that our return to profitability, if at all, will most likely come from the commercialization of the products in our drug development portfolio. Additionally, we plan to continue to evaluate possible acquisitions or licensing of rights to related technologies, products or assets that fit within our growth strategy. Accordingly, we will need to generate significant revenue to return to profitability.

Our Product Areas

Complex Generics

In our Complex Generics product area, we develop generic versions of complex drugs that were originally approved by the United States Food and Drug Administration, or FDA, as New Drug Applications, or NDAs. Therefore, we have been able to access the existing 505(j) generic

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regulatory pathway and have submitted Abbreviated New Drug Applications, or ANDAs, for these products. Enoxaparin Sodium Injection, our first product to receive FDA marketing approval under an ANDA, is a generic version of Lovenox (enoxaparin sodium injection) and has been developed and commercialized in collaboration with Sandoz Inc. and Sandoz AG, collectively Sandoz, affiliates of Novartis AG. Lovenox is a complex drug consisting of a mixture of polysaccharide chains and is a widely-prescribed low molecular weight heparin, or LMWH, used for the prevention and treatment of deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS.

Our second complex generic product candidate, M356, is designed to be a once-daily 20 mg/mL generic version of Copaxone® (glatiramer acetate injection), a complex drug consisting of a synthetic mixture of polypeptide chains. Copaxone is indicated for treatment of patients with relapsing-remitting multiple sclerosis, or RRMS, a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. We are also collaborating with Sandoz to develop and commercialize a three-times-a-week 40 mg/mL generic Copaxone, and the Sandoz ANDAs for both formulations are currently under FDA review.

Most drugs approved as NDAs are simple small molecules that are easy to duplicate. However, products such as Lovenox and Copaxone are complex molecular mixtures that are difficult to analyze and therefore difficult to reproduce as generics. We use our complex systems analysis platform to define the detailed structures present in these complex drugs. Once the precise structures are identified, or characterized, this structural characterization of the brand product is used to guide the development of a precise manufacturing process to produce a generic version. Finally, to demonstrate that the biological function of our generic replicates that of the brand, we utilize our complex systems analysis platform to evaluate and compare multiple orthogonal sets of biologic data from in-vitro, in-vivo and ex-vivo models.

Biosimilars

Our second product area is biosimilars, which is targeted toward developing biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. In March 2010, an abbreviated regulatory process was codified in Section 351(k) of the Patient Protection and Affordable Care Act of 2010. This new pathway opened the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. By 2015, sales of biosimilars are expected to reach between $1.9 billion to $2.6 billion. For biosimilars, we seek to better understand the complex systems within cells that are involved in the assembly of proteins. This knowledge enables us to select the appropriate cell line and to manipulate the cell s outputs using novel control strategies during the manufacturing with the goal of producing a biologic with structural similarity to the brand. Nevertheless, because of the complexity and variability of biologic manufacturing systems, it is important to evaluate whether any small differences between the biosimilar and the brand would be related to potential clinical differences. To minimize this residual uncertainty, we evaluate orthogonal sets of both structural and biologic data (biocharacterization) from in-vitro, in-vivo and ex-vivo models to compare the function of the brand product and our product. We believe that our complex systems analysis approaches, including these characterization methods, can significantly reduce residual uncertainty and may enable a relative reduction or even elimination of certain clinical trial requirements.

In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines state that FDA will use a step-wise review that considers the totality-of-the-evidence in determining extent of the clinical development program. This approach puts a substantial emphasis on structural and functional characterization data in evaluating biosimilar products for approval. We believe that our strategy for the development of biosimilars aligns well with the framework that the FDA has outlined in the draft guidance documents.

In December 2011, we and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively, Baxter, entered into a global collaboration and license agreement, or the Baxter Agreement. The Baxter Agreement became effective in February 2012. Baxter is

an established healthcare company with global product development, manufacturing and commercial capabilities.

Under the Baxter Agreement, we and Baxter agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilar product candidates, which are:

- Our most advanced biosimilar M923 is a biosimilar for HUMIRA® (adalimumab), a product indicated for certain autoimmune and inflammatory diseases. In October 2014, Baxter submitted a clinical trial application to support the initiation of a Phase 1 clinical trial in the European Union. Acceptance of the clinical trial application triggers two development milestones under the Baxter Agreement for an aggregate payment of $12.0 million.

- M834, a biosimilar also indicated for certain autoimmune and inflammatory diseases. In October 2014, we achieved a pre-defined minimum development criteria milestone under the Baxter Agreement and earned (and collected from Baxter) a $7.0 million license payment.

In addition to collaborating with Baxter to develop and commercialize biosimilars, we are also investing in a set of early stage biosimilar programs in order to allow us to broaden our future biosimilar product portfolio and technology base.

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Novel Drugs

We believe that applying our complex systems analysis platform to the discovery and development of novel medicines can enhance our probability of success in a number of ways. As with our complex generics and biosimilars, our platform gives us a detailed understanding of the complex structures of our novel product candidates, their associated manufacturing processes and controls, and the targeted biologic systems.

Our most advanced novel candidate, necuparanib (formerly M402), is being evaluated in a Phase 1/2 clinical study as a potential anti-cancer agent. In preclinical models, necuparanib binds to multiple growth factors, adhesion molecules and chemokines to inhibit tumor angiogenesis, progression, and metastasis. In October 2014, we completed Part A of the study, determined the dose to take forward into Part B, and released initial safety and efficacy data from Part A.

We are also applying our complex systems analysis platform to identify potential improvements we can design into presently marketed complex mixture drugs. By evaluating their interaction with biologic systems, we can obtain an enhanced understanding of their function to identify biological activities we can exploit. This is the approach behind our novel drug research efforts to exploit the sialylation of intravenous immunoglobulin, or IVIg, and to identify drug candidates that target autoantibodies and immune complexes that drive many autoimmune diseases.

Our Collaborations

In 2003, we entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc. to jointly develop, manufacture and commercialize Enoxaparin Sodium Injection in the United States. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration to Sandoz AG, an affiliate of Novartis Pharma AG.

In 2006 and 2007, we entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, with Novartis Pharma AG, and a collaboration and license agreement, as amended, or the Second Sandoz Collaboration Agreement, with Sandoz AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Second Sandoz Collaboration Agreement, we and Sandoz AG expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Further, under the Second Sandoz Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products. 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. As of September 30, 2014, Novartis AG owns approximately 9% of our outstanding common stock.

In July 2010, Sandoz began the commercial sale of Enoxaparin Sodium Injection. The profit-share or royalties Sandoz is obligated to pay us under the 2003 Sandoz Collaboration differ depending on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there are one or more third-party competitors which are not Sanofi-Aventis marketing a Lovenox-Equivalent Product. From July 2010 through September 2011, no third-party competitor was marketing a Lovenox-Equivalent Product;

therefore, during that period, Sandoz paid us 45% of the contractual profits from the sale of Enoxaparin Sodium Injection. In September 2011, FDA approved the ANDA for the enoxaparin product of Amphastar Pharmaceuticals, Inc. or Amphastar. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed by Sanofi-Aventis. In January 2012, following the Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued against them by the United States District Court, Watson Pharmaceuticals, Inc. (now Actavis, Inc., or Actavis) and Amphastar launched their third-party competitor enoxaparin product. Consequently, in each product year, for net sales of Enoxaparin Sodium Injection up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales payable at a 10% rate, and for net sales above the sales threshold, payable at a 12% rate.

Certain development and legal expenses may reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz. Any product liability costs and certain other expenses arising from patent litigation may also reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz, but only up to 50% of these amounts due to us from Sandoz each quarter. Our contractual share of these development and legal expenses is subject to an annual adjustment at the end of each product year, and ends with the product year ending June 2015. The annual adjustment of $2.2 million for the product year ending June 30, 2014 was decreased by $2.1 million to reflect an adjustment to royalties earned in the product year ended June 30, 2012. The annual adjustment was $3.8 million for the product year ended June 30, 2013. Annual adjustments are recorded as a reduction in product revenue.

In December 2011, we and Baxter entered into the Baxter Agreement under which we agreed to collaborate, on a world-wide basis, on the development and commercialization of biosimilars. The Baxter Agreement became effective in February 2012. To accelerate efforts in the biosimilars space and address this growing global market, we significantly increased the headcount and related operating expenses dedicated to our biosimilars program in 2012 and 2013. We expect that any increase in operating expenses in future years will be partially offset in those years by revenues from option fees and milestone payments under the Baxter Agreement, subject to achievement of technical and regulatory criteria. Under the Baxter Agreement, we and Baxter are collaborating on the development and commercialization of M923, a biosimilar for HUMIRA®, and M834, a biosimilar indicated for certain autoimmune and inflammatory diseases. Baxter has the right, until February 2015, to select up to three additional biosimilars to be included in the collaboration.

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Financial Operations Overview

Revenue

Our revenue has been primarily derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. In 2012, we began recognizing revenue under the Baxter Agreement as we deliver product licenses and research and development services under that collaboration. In the near term, our current and future revenues are dependent upon the continued successful commercialization of Enoxaparin Sodium Injection, license fees and milestone payments earned under the Baxter Agreement and potential profit share payments and milestones from our 2006 Sandoz Collaboration. In the longer term, our revenue growth will depend upon the successful clinical development, regulatory approval and launch of new commercial products and the pursuit of external business development opportunities. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of revenue we earn under our collaborative or strategic relationships.

Research and Development

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, nonclinical and 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.

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 royalty and license fees, facility and insurance costs not otherwise included in research and development expenses and professional fees for legal and accounting services and other general expenses.

Our Portfolio

Complex Generics

Enoxaparin Sodium Injection Generic Lovenox®

Enoxaparin Sodium Injection, our first product to receive marketing approval under an ANDA, is a generic version of Lovenox. Lovenox is a complex drug consisting of a mixture of polysaccharide chains and is a widely-prescribed low molecular weight heparin, or LMWH, used for the prevention and treatment of deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. Lovenox is distributed worldwide by Sanofi-Aventis U.S. LLC, or Sanofi-Aventis, and is also known outside the United States as Clexane® and Klexane®. Under our 2003 Sandoz Collaboration, we work with Sandoz exclusively to develop, manufacture and commercialize Enoxaparin Sodium Injection in the United States. Sandoz is responsible for funding substantially all of the United States-related Enoxaparin Sodium Injection development, regulatory, legal and commercialization costs, other than legal expenses incurred by each party in connection with the patent suits filed against Teva Pharmaceutical Industries Ltd., or Teva, in December 2010 and Amphastar Pharmaceuticals, Inc., or Amphastar, Actavis, Inc., or Actavis, and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in September 2011. In these cases, we and Sandoz each bear our own legal expenses.

Sandoz submitted ANDAs in its name to the FDA for Enoxaparin Sodium Injection in syringe and vial forms, seeking approval to market Enoxaparin Sodium Injection in the United States. The ANDA for the syringe form of Enoxaparin Sodium Injection was approved in July 2010, making it the first ANDA for a generic Lovenox to be approved by FDA. The ANDA for the vial form of Enoxaparin Sodium Injection was approved in December 2011.

In September 2011, we and Sandoz sued Amphastar, Actavis and International Medical Systems, Ltd. in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Actavis and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the District Court granted our motion for a preliminary injunction and entered an order enjoining Amphastar, Actavis and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin product in the United States until the conclusion of a trial on the merits and requiring us and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar, Actavis and International Medical Systems, Ltd. appealed the decision to the Court of Appeals for the Federal Circuit, or

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CAFC, and in January 2012, the CAFC stayed the preliminary injunction. Amphastar has filed motions to increase the amount of the security bond, which we and Sandoz have opposed. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court, holding that Amphastar s use of our patented method for processing Enoxaparin Sodium Injection was protected by the safe harbor from patent infringement under federal patent law, 35 U.S.C. Section 271(e)(1).

In January 2013, Amphastar and Actavis filed a motion for summary judgment in the District Court following the decision from the CAFC and in July 2013, the District Court granted the motion for summary judgment. We have filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling. We opposed this motion and the Court denied the motion in May 2014. The CAFC has set a briefing schedule which ends in November 2014. A hearing could be expected in late 2014 or the first half of 2015, and a decision could be expected in 2015.

In December 2010, we sued Teva in the United States District Court for the District of Massachusetts for infringement of two of our patents related to Enoxaparin Sodium Injection. In January 2013, Teva filed a motion for summary judgment in the District Court following the decision from the CAFC in the aforementioned case and in July 2013, the District Court granted the motion for summary judgment. We have filed a notice of appeal of the decision to the CAFC, and in June 2014 filed our opening brief. We anticipate that this case will be heard in parallel with the suit against Amphastar and Actavis.

M356 Generic Copaxone® (glatiramer acetate injection)

Our second complex generic product candidate, M356, is designed to be a generic version of Copaxone (glatiramer acetate injection), a complex drug consisting of a synthetic mixture of polypeptide chains. Copaxone is indicated for treatment of patients with relapsing-remitting multiple sclerosis, or RRMS, a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva. Copaxone is available in both a once-daily 20 mg/mL formulation, which was approved by the FDA in 1996, and a three-times-a-week 40 mg/mL formulation, which was approved in January 2014. Under the Second Sandoz Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products. Given its structure as a complex mixture of polypeptide chains of various lengths and sequences, there are significant technical challenges involved in thoroughly characterizing Copaxone and in manufacturing an equivalent version. We believe our technology can be applied to characterize glatiramer acetate and to develop a generic product that has the same active ingredient as Copaxone. We are continuing to expand our portfolio of pending patent applications related to glatiramer acetate injection.

Under the Second Sandoz Collaboration Agreement, costs, including development costs and the costs of clinical studies, will be borne by the parties in varying proportions depending on the type of expense and the related product. For M356, we are generally responsible for all of the development costs in the United States. For M356 outside of the United States and for Enoxaparin Sodium Injection in the European Union, we share development costs in proportion to our profit sharing interest. All commercialization responsibilities will be borne by Sandoz AG worldwide as they are incurred for all products. Upon commercialization, we will earn a 50% contractual profit share on worldwide net sales of M356. Profits on net sales of M356 will be calculated by deducting from net sales the costs of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. We are reimbursed at cost for any full-time equivalent employee expenses as well as any external costs incurred in the development of products to the extent development costs are born by Sandoz AG. Sandoz AG is responsible for funding all of the legal expenses incurred under the Second Sandoz Collaboration Agreement; however a portion of certain legal expenses, including any patent infringement damages, will be offset against the profit-sharing amounts in proportion to our profit sharing interest. The parties will share profits in varying proportions, depending on the product.

In December 2007, Sandoz submitted to the FDA an ANDA seeking approval to market a once-daily 20 mg/mL M356 in the United States containing a Paragraph IV certification. This is a certification by the ANDA applicant that the patent relating to the drug product that is the subject of the ANDA is invalid, unenforceable or will not be infringed. In July 2008, the FDA notified Sandoz that it had accepted the ANDA for review as of December 27, 2007. The Sandoz ANDA for the 20 mg/mL formulation of M356 is currently under FDA review.

In collaboration with Sandoz, we also developed a three-timesaweek 40 mg/mL formulation of generic Copaxone. Sandoz submitted an ANDA to the FDA in February 2014 seeking approval to market the 40 mg/mL formulation containing a Paragraph IV certification. On August 28, 2014, the FDA notified Sandoz that it had accepted the ANDA for review with a filing date of February 14, 2014 and that Sandoz s ANDA would be eligible for the grant of a 180-day generic exclusivity period upon approval with other applicants who filed on the same date. The Sandoz ANDA for the 40 mg/mL formulation of M356 is currently under FDA review.

Since 2008, Teva has filed seven Citizen Petitions with FDA requesting that FDA deny the approval of any ANDA filed for generic Copaxone. The FDA has denied five of the Citizen Petitions filed by Teva, Teva withdrew one and one is pending. Teva filed suit against the FDA in the United States District Court for the District of Columbia in May 2014, seeking a court order granting the relief sought in the Citizen Petitions. We and Sandoz intervened in the suit, and following a hearing on a motion for the preliminary injunction, the Court dismissed the case for lack of jurisdiction prior to approval of the ANDA. We anticipate Teva will continue to engage in activities that seek to challenge the approval of our M356 ANDAs.

Subsequent to FDA s acceptance of the 20 mg/mL M356 ANDA for review, in August 2008, Teva and related entities and Yeda Research and Development Co., Ltd., filed suit against us and Sandoz in the United States Federal District Court in the Southern District of New York. The suit alleged infringement related to four of the seven Orange Book-listed patents for Copaxone. The Orange Book is a publication of the FDA that

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identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and includes patents that are purported by the drug application owner to protect each drug. If there is a patent listed for the branded drug in the Orange Book at the time of submission of an ANDA, or at any time before an ANDA is approved, a generic manufacturer s ANDA must include one of four types of patent certification with respect to each listed patent. See Part I, Item 1. Business Regulatory and Legal Matters in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on February 28, 2014. We and Sandoz asserted various defenses and filed counterclaims for declaratory judgments to have all seven of the Orange Book-listed patents, as well as two additional patents, in the same patent family adjudicated in that lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book-listed patents for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against us and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. The Orange Book-listed patents and one non-Orange Book-listed patent expire on May 24, 2014 and one non-Orange Book-listed patent expires on September 1, 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. Section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz ANDA or Mylan ANDA prior to the expiration of the Orange Book-listed patents. In July 2012, we appealed the decision to the CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the patents, including the one patent set to expire in 2015. The other patents expired on May 24, 2014. The CAFC remanded the case to the District Court to modify the injunction in light of the CAFC decision. In September 2013, Teva filed a petition for rehearing of the CAFC decision, and in October 2013 the CAFC denied the petition. Teva filed a petition for review by the Supreme Court of the United States in January 2014 and in March 2014 the Supreme Court granted certiorari in the case in order to review the appropriate standard for deference to district court findings in claim construction. Briefing was completed in September 2014, and oral argument was held in October 2014. The Supreme Court could render a decision by the end of the year or during the first half of 2015. While we believe the Supreme Court should affirm the CAFC decision, it could rule otherwise and, among other things, remand the case to a lower court for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. During the pendency of this litigation any launch of the generic Copaxone product would be a launch at risk of infringement. On April 18, 2014, the Supreme Court denied Teva s request for a stay of the CAFC ruling. Teva had sought to prohibit the introduction of an FDA-approved generic Copaxone until the Supreme Court resolution of the case.

On September 10, 2014, Teva and related entities and Yeda Research and Development Co., Ltd., filed suit against us and Sandoz in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 40 mg/mL formulation of M356. The suit alleges infringement related to two Orange Book-listed patents for 40 mg/mL Copaxone and seeks declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents.

Biosimilars

We are also applying our complex systems analysis platform to the development of biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. In March 2010, an abbreviated regulatory process was codified in Section 351(k) of the Patient Protection and Affordable Care Act of 2010. This new pathway opened the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. By 2015, sales of biosimilars are expected to reach between $1.9 billion to $2.6 billion. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines state that FDA will use a step-wise review that considers the totality-of-the-evidence in determining extent of the clinical development program. This approach puts a substantial emphasis on structural and functional characterization data in evaluating biosimilar products for approval. We believe that our strategy for the development of biosimilars aligns well with the framework that the FDA has outlined in the draft guidance documents.

Given the inadequacies of standard technology available at the time of original review and approval, many of these therapeutic proteins have not been thoroughly characterized. Most of these products are complex glycoprotein mixtures, consisting of proteins that contain branched sugars, various cross linkages, and backbone modifications that vary from molecule to molecule. These variations can impart specific biological

properties to the therapeutic protein. We believe our approach to thoroughly understand these variations and engineer a highly similar biologic has the potential to drive regulatory advantages such as a reduction in the level of clinical data required for approval, the ability to achieve extrapolation of indications, and/or the achievement of a designation of interchangeability, which would allow our products to be directly substituted for brand products at the pharmacy.

In December 2011, we and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively, Baxter, entered into a global collaboration and license agreement, or the Baxter Agreement, to develop and commercialize biosimilars. The Baxter Agreement became effective in February 2012. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities. Under the Baxter Agreement, we and Baxter agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilar product candidates, M923, a biosimilar for HUMIRA®, and M834, a biosimilar indicated for certain autoimmune and inflammatory diseases. In October 2014, Baxter submitted a clinical trial application for M923 to support the initiation of a Phase 1 clinical trial in the European Union. Acceptance of the clinical trial application triggers two M923 development milestones under the Baxter Agreement for an aggregate payment of $12.0 million. Also in October 2014, we achieved a pre-defined minimum development criteria milestone for M834 and earned (and collected from Baxter) a $7.0 million milestone payment.

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In addition to collaborating with Baxter on M923 and M834, we are evaluating additional products for biosimilar development. Baxter has the right, until February 2015, to select up to three additional biosimilars to be included in the collaboration.

We are also investing in a set of earlier stage biosimilar programs that will allow us to broaden our biosimilar product portfolio and technology base.

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

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

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

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

The new law is complex and is in the initial stages of being interpreted and implemented by the FDA. As a result, we expect that its ultimate impact, implementation and meaning will be subject to uncertainty for years to come.

Novel Drugs

Overview

Our novel drugs program uses the established characterization and process engineering capabilities from our complex generics and biosimilars programs with a focus on polysaccharides and therapeutic proteins.

Necuparanib

Necuparanib is a novel oncology drug candidate engineered to have a broad range of effects on tumor cells. The use of heparins to treat venous thrombosis in cancer patients has generated numerous reports of antitumor activity; however, the dose of these products has been limited by their anticoagulant activity. Necuparanib, which is derived from unfractionated heparin, has been engineered to have significantly reduced anticoagulant activity while preserving the relevant antitumor properties of heparin. In June 2014, necuparanib received Orphan Drug Designation from the U.S. FDA for the treatment of pancreatic cancer. The FDA s Orphan Drug Designation program provides orphan status to drugs and biologics intended to treat, diagnose or prevent rare diseases/disorders, defined as affecting fewer than 200,000 people in the U.S. This designation provides certain incentives, including federal grants, tax credits, and waiver of Prescription Drug User Fee Act, or PDUFA, filing fees. A product with orphan drug status also has the potential to receive a seven-year orphan drug exclusivity once approved.

Researchers have conducted a series of nonclinical experiments using mouse and rat tumor models of pancreatic, breast, colorectal, ovarian, and prostate cancer as well as melanoma to test the hypothesis that necuparanib can modulate tumor progression and metastasis. Necuparanib exhibits potent binding to multiple heparin-binding growth factors, adhesion molecules, and chemokines (such as VEGF, FGF-2, SDF-1, P-selectin, etc.) and neutralizes these by blocking the interaction with their receptors or by dissolving their gradients in the tumor microenvironment. As a result, necuparanib has been shown in these models to inhibit tumor cell progression, metastasis, and angiogenesis. Additionally, the nonclinical data showed that necuparanib in combination with gemcitabine prolonged survival and substantially lowered the incidence of metastasis, suggesting that necuparanib has the potential to complement conventional chemotherapy. We believe that necuparanib s mechanism of action, by binding to multiple heparin binding factors involved in tumor growth and metastasis, creates the potential for necuparanib to contribute to efficacy in a broad range of cancers.

In 2012, we initiated a Phase 1/2 clinical study in patients with advanced metastatic pancreatic cancer. The trial consists of two parts and will evaluate the safety, potential efficacy, pharmacokinetics and pharmacodynamics of necuparanib in combination with nab-paclitaxel and

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gemcitabine. Part A is an open-label, multiple ascending dose escalation study. We have successfully completed the Part A dose escalation component of the Phase 1/2 trial and selected the dose to take forward into Part B of the study. Part B will be a randomized, controlled, proof of concept study to evaluate the antitumor activity of necuparanib in combination with nab-paclitaxel and gemcitabine, compared with nab-paclitaxel and gemcitabine alone. In October 2014, we released initial clinical data from Part A and we expect to report additional clinical data from Part A including safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy in the first half of 2015. Part B of the study was also initiated in October 2014.

Discovery Research Program

The majority of human diseases result from the interaction of a complex web of biologic systems. We believe our core analytical tools and approach may enable new insights into the complex biology underlying diseases. This enhanced understanding should help us establish the relative role of different biological targets and related cell signaling pathways in contributing to the disease process. Our goal is to leverage this knowledge to identify novel targets, novel combinations of therapies, and possibly exploit the multi-targeting nature of complex mixture molecules to develop novel products which may positively modulate multiple pathways in a disease.

We are now focusing our efforts towards developing novel recombinant product candidates for the treatment of autoimmune diseases. Certain autoimmune diseases are currently treated with IVIg. IVIg contains pooled, human immunoglobulin G, or IgG, antibodies purified from the plasma of over one thousand blood donors. IVIg is approved in several inflammatory disease indications including idiopathic thrombocytopenic purpura, Kawasaki disease, and chronic inflammatory demyelinating polyneuropathy. Currently, IVIg is manufactured from large pools of human plasma, resulting in a high cost supply chain and limited supply due to usage in treating primary immunodeficiency for diseases such as AIDS. While not a focus of our research, usage in AIDS further limits available supply of IVIg for the treatment of autoimmune diseases. Increasing demand for IVIg products already exceeds available supply worldwide thus limiting broader clinical applications.

We have advanced our understanding of the the complex biology underlying the anti-inflammatory effects of IVIg and the biologic impact of sialylation, a method to add sialic acid to proteins, on the activity of IVIg as well as the behavior of recombinant molecules engineered from the Fc region of IgG. Through our testing in various models of inflammation and our biological characterization of patients treated with IVIg, we have gained a deeper understanding of the basic biologic pathways by which these molecules mediate their therapeutic effects. We are advancing three novel autoimmune candidates toward clinical development over the next 18-24 months including:

- Hyper-sialylated IVIg, or hsIVIg, a hyper-sialylated version of IVIg with many in-vivo models showing increased anti-inflammatory activity at a much lower dose, which may enable a simpler administration with the potential for superior efficacy.

- Selective immunomodulator of Fc receptors, or SIF3, a novel recombinant protein containing three IgG Fc regions joined carefully to maximize activity. Preclinical data has demonstrated that this construct enhances the molecules avidity and affinity for the Fc receptors. Using these data, we plan to advance this program with the goal of developing an IVIg-like efficacy profile at lower doses, potentially reducing the risks associated with plasma-derived products.

- Anti-FcRn antibody, a fully-human monoclonal antibody that blocks the neonatal Fc receptor, or FcRn. This receptor recycles IgG antibodies, enabling a long half-life. Blocking of this receptor with our antibody effectively inhibits the binding of IgGs and leads to their rapid

clearance. We believe these data demonstrate high potential for acute and chronic / intermittent therapies in a broad range of autoantibody driven disease.

Results of Operations

Three Months Ended September 30, 2014 and 2013

Collaboration Revenue

Collaboration revenue includes product revenue and research and development revenue earned under our collaborative arrangements. Product revenue consists of profit share, royalties and commercial milestones earned from Sandoz on sales of Enoxaparin Sodium Injection following its commercial launch in July 2010. A portion of Enoxaparin Sodium Injection 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. The contractual share of these development and other expenses is subject to an annual claw-back adjustment at the end of each product year, and ends with the product year ending June 2015. During the three months ended September 30, 2014, we earned $4.7 million in royalties on Sandoz s reported net sales of Enoxaparin Sodium Injection of $48 million. During the three months ended September 30, 2013, we earned $4.8 million in royalties on Sandoz s reported net sales of Enoxaparin Sodium Injection of $58 million. The decrease in our product revenue of $0.1 million, or 2%, and the decrease in Sandoz s net sales of $10 million, or 17%, from the 2013 period to the 2014 period are both due to lower prices in response to competitor pricing reductions on enoxaparin.

Research and development revenue generally consists of amounts earned by us:

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- under the 2003 Sandoz Collaboration and 2006 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs;
- under the 2006 Sandoz Collaboration for amortization of the equity premium;
- under the Baxter Agreement for reimbursement of research and development services and reimbursement of development costs; and
- under the Baxter Agreement for amortization of the $33 million upfront payment.

Research and development revenue was $4.6 million and $6.0 million for the three months ended September 30, 2014 and 2013, respectively. The decrease in research and development revenue of $1.4 million, or 23%, from the 2013 period to the 2014 period is due to a decrease in reimbursable M923 research and development services and expenses incurred in connection with the Baxter Agreement.

We expect collaborative research and development revenue earned by us related to expense reimbursement from Baxter and Sandoz will fluctuate from quarter to quarter in 2014 depending on our research and development activities. We expect to continue to amortize the $33.0 million upfront payment from Baxter as we deliver research and development services under the Baxter Agreement, with anticipated amortization for the fourth quarter of 2014 of approximately $0.8 million related to the two licensed biosimilars.

There are a number of factors that make it difficult for us to predict the magnitude of future Enoxaparin Sodium Injection product revenue, including the impact of generic competition on the Sandoz market share; the pricing of products that compete with Enoxaparin Sodium Injection and other actions taken by our competitors; the inventory levels of Enoxaparin Sodium Injection maintained by wholesalers, distributors and other customers; the frequency of re-orders by existing customers and the change in estimates for product reserves. Accordingly, our Enoxaparin Sodium Injection product revenue in previous quarters may not be indicative of future Enoxaparin Sodium Injection product revenue. The change in Sandoz contractual payment terms, along with additional generic competition, has caused, and we expect will continue to cause, our future product revenue from Enoxaparin Sodium Injection to be significantly reduced compared to revenues earned during the product s exclusivity period.

Research and Development Expense

Research and development expense for the three months ended September 30, 2014 was $27.5 million, compared with $27.4 million for the three months ended September 30, 2013. The increase of $0.1 million, or less than 1/2%, from the 2013 period to the 2014 period resulted from increases of: $2.0 million in costs incurred to advance our research program; $1.2 million in necuparanib clinical costs incurred to complete the Part A dose escalation component of the Phase 1/2 trial; and $0.9 million in facility related costs due to additional subleased laboratory and office space. These increases were offset by a $4.0 million decrease in consulting, third-party process development and contract research costs incurred for our biosimilars in development.

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

the timing and outcome of any approvals, we are currently unable to estimate when, if ever, our product candidates will generate revenues and cash flows.

The following table sets forth the primary components of our research and development external expenditures, including amortization of an intangible asset, for each of our principal development programs for the three months ended September 30, 2014 and 2013. The figures in the table include project expenditures incurred by us and reimbursed by our collaborators, but exclude project expenditures incurred by our collaborators. Although we track and accumulate personnel effort by percentage of time spent on our programs, a significant portion of our internal research and development costs, including salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies are not directly charged to programs. Therefore, our methods for accounting for internal research and development costs preclude us from reporting these costs on a project-by-project basis. Certain prior period amounts have been reclassified to conform to the current period presentation.

	Research and Development Expense (in thousands)		
Development Programs (Status)	**Three Months Ended September 30, 2014**	**Three Months Ended September 30, 2013**	**Project Inception to September 30, 2014**
M356 (ANDA Filed)	$ 444	$ 362	$ 48,060
Necuparanib (Phase 1/2)	2,079	851	22,867
Biosimilars (Development)	4,049	8,402	50,129
Discovery programs	2,706	701	
Research and development internal costs	18,230	17,119	
Total research and development expense	$ 27,508	$ 27,435	

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M356 external spend remained consistent from the 2013 period to the 2014 period due to timing of third-party contract manufacturing and research activities. The increase of $1.2 million in necuparanib external expenditures from the 2013 period to the 2014 period was due to additional work necessary for the completion of the Part A dose escalation component of the Phase 1/2 trial. The decrease of $4.4 million in biosimilars external expenditures from the 2013 period to the 2014 period was due to lower third-party process development and contract research costs incurred for our biosimilars in development. The increase of $2.0 million in discovery program external expenditures from the 2013 period to the 2014 period was due to costs incurred to advance our novel drugs research program.

Research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $1.1 million from the 2013 period to the 2014 period was driven by increases in facility related costs due to additional subleased laboratory and office space and additional research and development related costs to support our development programs.

General and Administrative

General and administrative expense for the three months ended September 30, 2014 was $11.1 million, compared to $9.0 million for the three months ended September 30, 2013. General and administrative expense increased by $2.1 million, or 23 %, from the 2013 period to the 2014 period due to increases of: $0.9 million in professional fees, driven mainly by corporate and IP legal fees; $0.7 million in rent and facility-related costs due to additional subleased laboratory and office space; and $0.5 million in salary, salary-related and stock compensation associated with our annual merit salary increase and grants of stock options and stock awards.

Interest Income

Interest income on available-for-sale marketable securities was $0.1 million and $0.2 million for the three months ended September 30, 2014 and 2013, respectively. The decrease of $0.1 million from the 2013 period to the 2014 period was due to lower average cash and marketable securities investment balances.

Other Income

Other income was $0.1 million for each of the three months ended September 30, 2014 and 2013 and represents income recognition related to a job creation tax awarded to us in the fourth quarter of 2012.

Nine Months Ended September 30, 2014 and 2013

Collaboration Revenue

During the nine months ended September 30, 2014, we earned $15.2 million in product revenue, which includes $15.3 million in royalties on Sandoz s reported net sales of Enoxaparin Sodium Injection of $150 million, offset by $2.2 million of our contractual share of development and other expenses for the product year ending June 30, 2014, and increased by $2.1 million to reflect an adjustment to royalties earned in the product year ended June 30, 2012.

During the nine months ended September 30, 2013, we earned $11.8 million in product revenue, which includes $15.6 million in royalties on Sandoz s reported net sales of Enoxaparin Sodium Injection of $162 million less our contractual share of development and other expenses for the product year ending June 30, 2013 of $3.8 million.

Research and development revenue generally consists of amounts earned by us:

- under the 2003 Sandoz Collaboration and 2006 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs;
- under the 2006 Sandoz Collaboration for amortization of the equity premium;
- under the Baxter Agreement for reimbursement of research and development services and reimbursement of development costs; and
- under the Baxter Agreement for amortization of the $33 million upfront payment.

Research and development revenue was $15.9 million and $10.9 million for the nine months ended September 30, 2014 and 2013, respectively. The increase in research and development revenue of $5.0 million, or 46%, from the 2013 period to the 2014 period is due to higher reimbursable M923 research and development services and expenses incurred in connection with the Baxter Agreement.

There are a number of factors that make it difficult for us to predict the magnitude of future Enoxaparin Sodium Injection product revenue, including the impact of generic competition on the Sandoz market share; the pricing of products that compete with Enoxaparin Sodium Injection and other actions taken by our competitors; the inventory levels of Enoxaparin Sodium Injection maintained by wholesalers, distributors and other customers; the frequency of re-orders by existing customers and the change in estimates for product reserves. Accordingly, our Enoxaparin Sodium Injection product revenue in previous quarters may not be indicative of future Enoxaparin Sodium Injection product revenue. The change

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in Sandoz contractual payment terms, along with additional generic competition, has caused, and we expect will continue to cause, our future product revenue from Enoxaparin Sodium Injection to be significantly reduced compared to revenues earned during the product s exclusivity period.

Research and Development Expense

Research and development expense for the nine months ended September 30, 2014 was $80.3 million, compared with $71.8 million for the nine months ended September 30, 2013. The increase of $8.5 million, or 12%, from the 2013 period to the 2014 period resulted from increases of: $3.1 million in facility related costs due to additional subleased laboratory and office space; $2.3 million in salary, salary-related and stock compensation associated with our annual merit salary increase and grants of stock options and stock awards; $2.0 million in costs incurred to advance our research program; $1.9 million in necuparanib clinical costs incurred to complete the Part A dose escalation component of the Phase 1/2 trial; and $0.7 million in laboratory supplies to support our programs. These increases were offset by a $1.5 million decrease in consulting, third-party process development and contract research costs incurred for our biosimilars in development.

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

The following table sets forth the primary components of our research and development external expenditures, including amortization of an intangible asset, for each of our principal development programs for the nine months ended September 30, 2014 and 2013. The figures in the table include project expenditures incurred by us and reimbursed by our collaborators, but exclude project expenditures incurred by our collaborators. Although we track and accumulate personnel effort by percentage of time spent on our programs, a significant portion of our internal research and development costs, including salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies are not directly charged to programs. Therefore, our methods for accounting for internal research and development costs preclude us from reporting these costs on a project-by-project basis. Certain prior period amounts have been reclassified to conform to the current period presentation.

	Research and Development Expense (in thousands)		
Development Programs (Status)	**Nine Months Ended September 30, 2014**	**Nine Months Ended September 30, 2013**	**Project Inception to September 30, 2014**
M356 (ANDA Filed)	$ 973	$ 1,238	$ 48,060
Necuparanib (Phase 1/2)	4,532	2,654	22,867
Biosimilars (Development)	14,189	15,659	50,129
Discovery programs	4,203	1,474	
Research and development internal costs	56,392	50,746	
Total research and development expense	$ 80,289	$ 71,771	

The decrease of $0.3 million in M356 external expenditures from the 2013 period to the 2014 period was primarily due to reduced third-party contract manufacturing and research costs. The increase of $1.9 million in necuparanib external expenditures from the 2013 period to the 2014 period was due to additional work necessary for the completion of the Part A dose escalation component of the Phase 1/2 trial. The decrease of $1.5 million in biosimilars external expenditures from the 2013 period to the 2014 period was due to lower third-party process development and contract research costs incurred for our biosimilars in development. The increase of $2.7 million in discovery program external expenditures from the 2013 period to the 2014 period was primarily due to increased expenditures to support our novel drugs research program.

Research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $5.6 million from the 2013 period to the 2014 period was driven by increases in facility related costs due to additional subleased laboratory and office space and additional research and development related costs to support our development programs.

General and Administrative

General and administrative expense for the nine months ended September 30, 2014 was $34.0 million, compared to $30.2 million for the nine months ended September 30, 2013. General and administrative expense increased by $3.8 million, or 13%, from the 2013 period to the 2014 period due to increases of: $1.9 million in allocated rent and facility-related costs due to additional subleased laboratory and office space; $1.5 million in salary, salary-related and stock compensation associated with our annual merit salary increase and grants of stock options and stock awards; and $0.4 million in professional fees, driven mainly by increased IT infrastructure and tax-related accounting fees.

Interest Income

Interest income on available-for-sale marketable securities was $0.5 million and $0.7 million for the nine months ended September 30, 2014 and 2013, respectively. The decrease of $0.2 million from the 2013 period to the 2014 period was due to lower average cash and marketable securities investment balances.

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Other Income

Other income was $0.2 million for each of the nine months ended September 30, 2014 and 2013 and represents income recognition related to a job creation tax awarded to us in the fourth quarter of 2012.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of equity securities and payments from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, including profit share/royalty payments related to sales of Enoxaparin Sodium Injection. Since our inception through September 30, 2014, we have received $406 million through private and public issuance of equity securities. As of September 30, 2014, we had received a cumulative total of $592 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, a $33.0 million upfront payment and $19 million in reimbursement of research and development services and external costs under the Baxter Agreement.

From July 2010 through September 2011, our Enoxaparin Sodium Injection product was the sole generic Lovenox, and Sandoz paid us a 45% profit share of contractual net sales. During this time, we recorded $340 million in Enoxaparin Sodium Injection product revenues, making us profitable in those two fiscal years. Under the terms of our agreement with Sandoz, the October 2011 launch of an authorized generic Lovenox triggered a change in the basis of our product revenue from profit share to a hybrid profit share / royalty on Sandoz s net sales of Enoxaparin Sodium Injection. In January 2012, the launch of a third-party competitor s generic Lovenox product changed the basis of our product revenue from hybrid profit share / royalty to straight royalty on Sandoz s net sales of Enoxaparin Sodium Injection. This competition and the resulting contractual changes significantly reduced product revenues and for 2013, we recorded a net loss. We have been incurring operating losses and we expect to incur annual operating losses over the next several years as we advance our drug development portfolio. We expect that our return to profitability, if at all, will most likely come from the commercialization of the products in our drug development portfolio.

Our generic Copaxone application is pending FDA approval and is subject to patent litigation. The multiple sclerosis market is evolving rapidly with the introduction of Teva s three-times-a-week formulation of Copaxone, which received FDA marketing approval in January 2014, and the success of oral therapies. This competition may reduce potential sales of our generic Copaxone product. Due to the uncertain outcome of pending patent litigation, Sandoz is currently evaluating the potential to launch prior to the Supreme Court s decision following FDA approval of our generic Copaxone. Even if Sandoz chooses to launch our generic Copaxone product upon approval by FDA, until the patent litigation is resolved we expect to segregate any M356 product revenue for payment of potential damages. At a minimum, if we and Sandoz become liable for damages due to an at-risk launch we are required to pay our contractual portion of the damage amount to Sandoz by deductions of up to 50% of our post-decision M356 revenue, on a quarterly basis, until we have paid our share of the damages.

In order to preserve our ability to invest in our development pipeline and for other general corporate purposes during this time of financial uncertainty, in May 2014 we established an At-the-Market, or ATM, financing facility, pursuant to which we are authorized to sell up to $75 million of our common stock. We expect to finance our planned operating requirements principally through our current cash, cash equivalents and marketable securities, cash from operations and utilization of the ATM vehicle to raise capital. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2015. 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 other important factors, and actual results could vary materially from our expectations. 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, 2014, we had $176.5 million in cash, cash equivalents and marketable securities and $7.6 million in accounts receivable. In addition, we also held $20.7 million in restricted cash, of which $17.5 million serves as collateral for a security bond posted in the litigation against Actavis, Amphastar and International Medical Systems, Ltd. Our funds at September 30, 2014 were primarily invested in senior debt of government-sponsored enterprises, commercial paper, asset-backed securities, corporate debt securities and United States money market funds, directly or through managed funds, with remaining maturities of 24 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. We do not believe that our cash equivalents and marketable securities were subject to significant market risk at September 30, 2014.

During the nine months ended September 30, 2014 and 2013, our operating activities used cash of $64.1 million and $60.0 million, respectively. The cash provided by or used for operating activities generally approximates our net loss adjusted for non-cash items and changes in operating assets and liabilities.

For the nine months ended September 30, 2014, our net loss adjusted for non-cash items was $63.8 million. For the nine months ended September 30, 2014, non-cash items include share-based compensation of $10.5 million, depreciation and amortization of our property, equipment and intangible assets of $6.4 million and amortization of purchased premiums on our marketable securities of $1.9 million. The net change in our operating assets and liabilities used cash of $0.3 million and resulted from: decreases in accounts receivable of $5.4 million and unbilled revenue of $0.4 million due to lower reimbursable M923 FTEs and expenses incurred in connection with the Baxter Agreement; an increase in prepaid expenses and other current assets of $0.3 million, primarily due to advance payments to vendors for software license fees and equipment maintenance agreements offset by lower interest receivable on lower average cash and marketable securities investment balances; a decrease in accounts payable of $3.2 million due to the payment of third-party contract expenses incurred for our biosimilars and M356 programs; an increase in accrued expenses of $0.5 million primarily due to timing of M834-related third-party contract expenses; a decrease in deferred revenue of $2.8 million, primarily due to the amortization of revenue related to the $33.0 million upfront payment made to us by Baxter

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in 2012 under our collaboration; and a decrease in other long-term liabilities of $0.3 million primarily due to the annual amortization of a job creation tax award.

For the nine months ended September 30, 2013, our net loss adjusted for non-cash items was $60.8 million. For the nine months ended September 30, 2013, non-cash items include share-based compensation of $9.4 million, depreciation and amortization of our property, equipment and intangible assets of $5.3 million and amortization of purchased premiums on our marketable securities of $2.6 million. In addition, the net change in our operating assets and liabilities provided cash of $0.8 million and resulted from: a decrease in accounts receivable of $4.4 million due to lower Enoxaparin Sodium Injection prices in response to aggressive competitor pricing reductions and a decrease in Enoxaparin Sodium Injection units sold; an increase in unbilled revenue of $4.5 million, primarily due to an increase in reimbursable M923 expenses incurred in connection with the Baxter Agreement; an increase in restricted cash of $0.7 million due to the designation of this cash as collateral for a letter of credit related to the lease of office and laboratory space at 320 Bent Street; an increase in accounts payable of $2.6 million and an increase in accrued expenses of $2.1 million primarily due to timing of activities incurred in connection with the Baxter Agreement; and a decrease in deferred revenue of $3.0 million, primarily due to the amortization of revenue related to the $33.0 million upfront payment made to us by Baxter in 2012 under our collaboration.

During the nine months ended September 30, 2014, our investing activities provided cash of $86.6 million. In the nine months ended September 30, 2014, we received $161.3 million from maturities of marketable securities and we used $68.8 million of cash to purchase marketable securities. Additionally, during the nine months ended September 30, 2014, we used $5.9 million of cash to purchase laboratory equipment and leasehold improvements.

During the nine months ended September 30, 2013, our investing activities provided cash of $39.7 million. In the nine months ended September 30, 2013, we received $220.6 million from maturities of marketable securities and $3.8 million from sales of marketable securities. Additionally, during the first nine months of 2013, we used $178.1 million of cash to purchase marketable securities and $6.6 million for the purchase of laboratory equipment and leasehold improvements.

Net cash provided by financing activities was $2.6 million and $4.5 million for the nine months ended September 30, 2014 and 2013, respectively, in the form of net proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations including royalties payable to third parties and operating lease obligations.

The following table summarizes our contractual obligations and commercial commitments after giving effect to our extension of the sublease term for office and laboratory space on West Kendall Street in Cambridge, Massachusetts in July 2014 (in thousands):

Contractual Obligations	Total	October 1, 2014 to December 31, 2014	2015 through 2016	2017 through 2018	After 2018
License maintenance obligations	$ 930	$	$ 465	$ 465	$ *
License royalty obligations	300	60	120	120	*
Operating lease obligations	29,672	2,774	20,366	6,532	
Total contractual obligations	$ 30,902	$ 2,834	$ 20,951	$ 7,117	$

*After 2018, the annual obligations, which extend through the life of the patents, 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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of revenues and expenses during the reporting periods. Additionally, we are required to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the balance sheet dates. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and share-based payments. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Please read Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2013 for a discussion of our critical accounting policies and estimates.

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Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of United States money market, government-secured, and high-grade corporate securities, directly or through managed funds, with maturities of twenty-four months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the conservative nature of our investments, low prevailing market rates and relatively short effective maturities of debt instruments, we believe that interest rate risk is mitigated. If market interest rates were to increase immediately and uniformly by 10% from levels at September 30, 2014, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the 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, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) occurred during the three months ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On August 28, 2008, Teva and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against us and Sandoz in the United States Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 20 mg/mL formulation of M356. The suit alleged infringement related to four of the seven Orange Book-listed patents for Copaxone and seeks declaratory and injunctive relief that would prohibit the launch of our product until the last to expire of these patents. The Orange Book is a publication of the FDA that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and includes patents that are purported by the drug application owner to protect each drug. If there is a patent listed for the branded drug in the Orange Book at the time of submission of an ANDA, or at any time before an ANDA is approved, a generic manufacturer s ANDA must include one of four types of patent certification with respect to each listed patent. See Part I, Item 1. Business Regulatory and Legal Matters in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on February 28, 2014. We and Sandoz asserted various defenses 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 that lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book-listed patents for Copaxone, and in October 2010, the Court consolidated the Mylan case with the case against us and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. The Orange Book-listed patents and one non-Orange Book-listed patent expire on May 24, 2014 and one non-Orange Book-listed patent expires on September 1, 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz ANDA or Mylan ANDA prior to the expiration of the Orange Book-listed patents. In July 2012, we appealed the decision to the CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the nine patents, including the one patent set to expire in 2015. The other patents expired on May 24, 2014. The CAFC remanded the case to the District Court to modify the injunction in light of the CAFC decision. In September 2013, Teva filed a petition for rehearing of the CAFC decision, and in October 2013 the CAFC denied the petition. Teva filed a petition for review by the Supreme Court of the United States in January 2014 and in March 2014 the Supreme Court granted certiorari in the case in order to review the appropriate standard for deference to district court findings in claim construction. Briefing was completed in September 2014, and oral argument was held in October 2014. The Supreme Court could render a decision by the end of the year or during the first half of 2015. While we believe the Supreme Court should affirm the CAFC decision, it could rule otherwise and, among other things, remand the case a lower court for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. During the pendency of this litigation any launch of the generic Copaxone product would be a launch at risk of infringement. On April 18, 2014, the Supreme Court denied Teva s request for a stay of the CAFC ruling. Teva had sought to prohibit the introduction of an FDA-approved generic Copaxone until the Supreme Court resolution of the case.

Since 2008, Teva has filed seven Citizen Petitions with FDA requesting that FDA deny the approval of any ANDA filed for generic Copaxone. The FDA has denied five of the Citizen Petitions filed by Teva, Teva withdrew one and one is pending. Teva filed suit against the FDA in the United States District Court for the District of Columbia in May 2014, seeking a court order granting the relief sought in the Citizen Petitions. We and Sandoz intervened in the suit, and following a hearing on a motion for the preliminary injunction, the Court dismissed the case for lack of jurisdiction prior to approval of the ANDA. We anticipate Teva will continue to engage in activities that seek to challenge the approval of our M356 ANDA.

On September 10, 2014, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against us and Sandoz in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 40 mg/mL formulation of M356. The suit alleges infringement related to two Orange Book-listed patents for 40 mg/mL Copaxone, each expiring in 2030, and seeks declaratory and injunctive relief prohibiting the launch of our

product until the last to expire of these patents. We and Sandoz have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of both patents.

On September 21, 2011, we and Sandoz sued Amphastar, Actavis, and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September, 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Actavis and International Medical Systems, Ltd. from selling their enoxaparin product in the United States. In October 2011, the District Court granted our motion for a preliminary injunction and entered an order enjoining Amphastar, Actavis and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and required us and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar, Actavis and International Medical Systems, Ltd. appealed the decision to the CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court. In September 2012, we filed a petition with the CAFC for rehearing by the full court *en banc*, which was denied. In February 2013, we filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court and in June 2013 the Supreme Court denied the petition.

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In January 2013, Amphastar and Actavis filed a motion for summary judgment in the District Court following the decision from the CAFC and in July 2013, the District Court granted the motion for summary judgment. We have filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling. We opposed this motion and the Court denied the motion in May 2014. The CAFC has set a briefing schedule which ends in November. A hearing could be expected in late 2014 or the first half of 2015, and a decision could be expected in 2015.

In the event that we are not successful in any appeal, and Amphastar and Actavis are able to prove they suffered damages as a result of the preliminary injunction, we could be liable for damages for up to $35 million of the security bond. Amphastar has filed motions to increase the amount of the security bond, which we and Sandoz have opposed. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz will prevail in this patent enforcement suit.

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Item 1A. Risk Factors

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

Risks Relating to Our Business

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

We have incurred significant losses since our inception in May 2001. At September 30, 2014, our accumulated deficit was $353 million. We may incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our other drug candidates, and effectively manufacture, market and sell any drugs we successfully develop. Accordingly, we may not generate significant revenue in the longer term and, even if we do generate significant revenue, we may never achieve long-term profitability.

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

If Teva is successful in its appeal to the Supreme Court of the United States in the ongoing Copaxone patent litigation, we may not be able to launch M356, if approved by the FDA, until September 2015, or we may suffer significant damages if we do launch M356.

In July 2012, the United States Federal District Court in the Southern District of New York issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. See Part II, Item 1, Legal Proceedings above in this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014. The Orange Book-listed patents and one non-Orange Book-listed patent expired on May 24, 2014, however one non-Orange Book-listed patent does not expire until September 1, 2015. In July 2012, we appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the nine patents, including the one patent set to expire in September 2015. In March 2014, the Supreme Court of the United States agreed to hear Teva s appeal in this case. Briefing was completed in September 2014, and oral argument was held in October 2014. A decision is expected in the first half of 2015. The Supreme Court could affirm the CAFC finding of invalidity, reverse the CAFC finding of invalidity or decide the legal question presented and remand the case to the CAFC to reconsider and rule on the validity of the patent.

If the CAFC decision that the claims in the patent scheduled to expire in September 2015 are invalid is reversed on appeal or remanded, the launch of M356, if approved, may not occur until the earlier of a finding of invalidity at the CAFC on remand or September 2015, which would impair our ability to commercialize M356 and harm our business and financial condition. Furthermore, if M356 is approved by the FDA prior to a decision in the patent case, and we and Sandoz launch prior to such decision, and Teva is ultimately successful in its appeal, we and Sandoz may be liable for significant damages and our business and financial condition would be materially harmed. In addition, we may not be able to utilize M356 cash flows to support program investments until the conclusion of the lawsuit, which would limit our ability to invest in ongoing R&D programs or require us to raise capital through equity or debt offerings.

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

Generic versions of our products contribute most significantly to revenues at the time of their launch, especially with limited competition. As such, the timing of competition can have a significant impact on our financial results. We expect that certain of our product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. For example, in September 2009, Mylan announced that the FDA had accepted for filing its ANDA for generic Copaxone and in 2011 Synthon announced that it submitted an ANDA to the FDA for a 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 share. As this happens, and 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 or biosimilar 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.

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If an improved version of a reference brand product, such as Copaxone, is developed that has a new product profile and labeling, the improved version of the product could significantly reduce the market share of the original reference brand product, and may cause a significant decline in sales or potential sales of our generic and biosimilar products.

Brand companies may develop improved versions of a reference brand product as part of a life cycle extension strategy, and may obtain approval of the improved version under a supplemental new drug application, for a drug, or biologics license application for a biologic. Should the brand company succeed in obtaining an approval of an improved product, it may capture a significant share of the collective reference brand product market and significantly reduce the market for the original reference brand product and thereby the potential size of the market for our generic or biosimilar products. For example, in January 2014, Teva s three-times-a-week formulation of Copaxone received marketing approval by FDA. Teva s new formulation will compete with our M356 product. In addition, the improved product may be protected by additional patent rights as well as have the benefit, in the case of drugs, of an additional three years of FDA marketing approval exclusivity, which would prohibit a generic version of the improved product for some period of time. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

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

Competition in the biotechnology industry is intense. Brand name products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference brand product to our generic product and generic or biosimilar product candidates, such as Copaxone, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete.

Current injectable treatments commonly used to treat multiple sclerosis, including Copaxone, are competing with novel drug products, including oral therapies. These oral therapies may offer patients a more convenient form of administration than Copaxone and may provide increased efficacy.

If the market for the reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

Teva may allege that we are infringing existing, additional issued or pending patents they hold. If this occurs we may expend substantial resources in resulting litigation, the outcome of which would be uncertain. Any unfavorable outcome in such litigation could delay our launch of M356, if approved, and may have a material adverse effect on our business.

Teva may assert existing, additional issued or pending patents, and it may claim that we are infringing those patents, including in connection with the pending review by the Supreme Court of the United States of the 2013 appellate ruling that patent claims previously asserted against us and Sandoz were invalid. We expect to continue to incur significant expenses to respond to and litigate these claims. In addition, if we are unsuccessful in litigation, or pending the outcome of litigation or while litigation is pending, a court could issue a temporary injunction or a permanent injunction preventing us from marketing and selling M356. Furthermore, we may be ordered to pay damages, potentially including

treble damages, if we launch M356 prior to a decision of the patent case and are subsequently found to have willfully infringed Teva s patent rights. Litigation concerning intellectual property and proprietary technologies is widespread and can be protracted and expensive, and can distract management and other key personnel from running our business.

If we were unsuccessful in any additional patent suits brought by Teva, we may be unable to effectively market M356, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Our current product revenue is dependent on the continued successful manufacture and commercialization of Enoxaparin Sodium Injection.

Our near-term ability to generate product revenue depends, in large part, on Sandoz s continued ability to manufacture and commercialize Enoxaparin Sodium Injection, maintain pricing levels and market share and compete with Lovenox brand competition as well as authorized and other generic competition.

Sandoz is facing increasing competition and pricing pressure from brand, authorized generic and other currently-approved generic competitors, which has and will continue to impact Sandoz net sales of Enoxaparin Sodium Injection, which will therefore impact our product revenue. Furthermore, other competitors may in the future receive approval to market generic enoxaparin products which would further impact our product revenue.

Due to these circumstances, the resulting market price for our Enoxaparin Sodium Injection product has decreased and may decrease further, and we have lost market share and may continue to lose market share for Enoxaparin Sodium Injection. All of this may further impact our revenue from Enoxaparin Sodium Injection and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

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

If we are not successful in the patent litigation against Amphastar and Actavis and do not succeed in obtaining injunctive relief or damages, the reduction in our revenue stream will be permanent and our ability to fund future discovery and development programs may suffer. Furthermore, in the event that we are not successful in our appeal of the District Court decision to grant summary judgment against us, and Amphastar and Actavis are able to prove they suffered damages as a result of the preliminary injunction having been in effect, we could be liable for up to $35 million of the security bond for such damages. This amount may be increased if Amphastar and Actavis are successful in their motion to increase the amount of the security bond.

In addition, if we are not successful in the patent case against Teva and do not succeed in obtaining injunctive relief or a declaratory judgment, we may lose additional market share for Enoxaparin Sodium Injection. Consequently, our revenue would be reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

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

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

- settling patent lawsuits with generic or biosimilar companies, resulting in such patents remaining an obstacle for generic or biosimilar 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 or biosimilar applications;

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

- restricting access to reference brand products for equivalence and biosimilarity testing that interfere with timely generic and biosimilar development plans, respectively;

- conducting medical education with physicians, payors and regulators that claim that generic or biosimilar products are too complex for generic or biosimilar approval and influence potential market share;

- seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;

- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;

- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic 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 or biosimilars; and

- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

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

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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.

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

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

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

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

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

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

Many of our competitors have:

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

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

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

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

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

- the safety and effectiveness of our products;

- with regard to our generic or biosimilar product candidates, the differential availability of clinical data and experience and willingness of physicians, payors and formularies to rely on biosimilarity data;

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- 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
- the strength of our patent position.

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

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

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

Even if we receive approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which could adversely affect our ability to generate sufficient revenue from product sales to maintain or grow our business.

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

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

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the competitive pricing of our products;
- physician confidence in the safety and efficacy of complex generic products or biosimilars;
- the absence of, or limited clinical data available from sameness, biosimilarity or interchangeability testing of our complex generic or biosimilar products;
- the success and extent of our physician education and marketing programs;
- the clinical, medical affairs, sales, distribution and marketing efforts of competitors; and

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

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

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

As of September 30, 2014, we had cash, cash equivalents and marketable securities totaling $176.5 million. For the nine months ended September 30, 2014, we had a net loss of $82.6 million and cash used in operating activities of $64.1 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, nonclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements may vary depending on the following:

- the level of sales of Enoxaparin Sodium Injection;

- our ability to utilize M356 cash flows, in whole or in part, generated before resolution of the Copaxone patent case;

- whether a final decision, after appeal, is issued in favor of Teva in its patent infringement litigation matters against us;

- the timing of the approval, launch and commercialization of our product candidates, including M356;

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

- the advancement of our biosimilar product candidates and receipt of license and milestone payments under our Baxter Agreement;

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

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

- the ability to enter into strategic collaborations;

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

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

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

We expect to finance our planned operating requirements principally through our current cash, cash equivalents and marketable securities and capital raised through equity financings, including utilization of our At-the-Market facility. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2015. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings or from other sources. Any additional capital raised through the sale of equity may dilute existing investors percentage ownership of our common stock. Capital raised through debt financing would require us to make periodic interest payments and may impose potentially restrictive covenants on the conduct of our business. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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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 key person 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. Another component of retention is the intrinsic value of equity awards, including stock options. Many stock options granted to our executives and employees are now under pressure given our recent stock performance.

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 pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.

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

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

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

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

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

- difficulty incorporating the acquired technologies;

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

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

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- 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 candidate, M356, as a therapeutic equivalent to Copaxone, our future results of operations will be adversely affected.

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

- contains the same active ingredients as Copaxone;

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

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

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

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

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

Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of biosimilars has been enacted, the standards for determining similarity or interchangeability for biosimilars are only just being implemented by the FDA. Therefore, substantial uncertainty remains about the potential value our proprietary technology platform can offer to biosimilars 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 biosimilars. The new pathway contemplates

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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 biologic products, which in addition to being biosimilar can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. Only interchangeable biosimilar products would be considered interchangeable at the retail pharmacy level without the intervention of a physician. The new legislation authorizes but does not require the FDA to establish standards or criteria for determining biosimilarity and interchangeability, and also authorizes the FDA to use its discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis. Our competitive advantage in this area will depend on our success in demonstrating to the FDA that our analytics, biocharacterization and protein engineering platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the agency begins to implement the new law. In addition, the FDA will likely require significant new resources and expertise to review biosimilar applications, and the timeliness of the review and approval of our future applications could be adversely affected if there were a decline or even limited growth in FDA funding.

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

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

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

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

Furthermore, the new regulatory pathway creates the risk that the brand company, during its 12-year marketing exclusivity period, will develop and replace its product with a non-substitutable or modified product that may also qualify for an additional 12-year marketing exclusivity period, reducing the opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. Finally, the new legislation also creates the risk that, as brand and biosimilar 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 biosimilars approval.

In addition, there is reconsideration and legislative debate that could lead to the repeal or amendment of the new healthcare legislation. If the legislation is significantly amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected. Similarly, the legislative debate at the federal level regarding the federal government budget in 2013 restricted federal agency funding for the biosimilar pathway, including biosimilar user fee funding for fiscal year 2014, and has resulted in delays in the conduct of meetings with biosimilar applicants and the review of biosimilar meeting and application information. The scheduling and conduct of biosimilar meeting and applications review was also suspended during the U.S. Government shutdown in October 2013, and could be subject to future suspensions as a result of future deadlocks in passage of federal appropriations bills. Depending on the timing and the extent of these funding, meeting and review disruptions, the Company s development of biosimilar products could be delayed.

Even if we are able to obtain regulatory approval for our generic and interchangeable biologic product candidates as therapeutically equivalent or interchangeable, 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 or interchangeable biologic products are not substitutable at the pharmacy level for their reference listed drugs, this could materially reduce sales of our products and our business would suffer.

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and provide it with an A rating in the FDA s Orange Book, this designation is not binding on state pharmacy boards or agencies for generic drugs. As a result, in states that do not deem our generic drug 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.

While a designation of interchangeability is a finding by the FDA that a biosimilar can be substituted at the pharmacy without physician intervention or prescription, brand pharmaceutical companies are lobbying state legislatures to enact physician prescription requirements, or in the absence of a prescription, physician and patient notification requirements, special labeling requirements and alternative naming requirements which if enacted could create barriers to substitution and adoption rates of interchangeable biologics as well as biosimilars. Should this occur with respect to one of our biosimilars or interchangeable biologic product candidates, and it is not determined to be unlawful or preempted by federal law, it could materially reduce sales in those states which would substantially harm our business.

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If our nonclinical studies and clinical trials for our development candidates, including necuparanib, 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 product candidates, we are required to demonstrate through nonclinical studies and clinical trials that our drug development candidates are safe and effective. Nonclinical 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 nonclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, nonclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize necuparanib 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 nonclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional nonclinical 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;

- 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; and

- we may decide to modify or expand the clinical trials we are undertaking if new agents are introduced which influence current standard of care and medical practice, warranting a revision to our clinical development plan.

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

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

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

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

Even after approval, any drugs or biological products we develop will be subject to ongoing regulatory review, including the review of clinical results which are reported after our products are made commercially available. Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, the manufacturer and manufacturing facilities we use to produce any of our product

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

In addition, the FDA s policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

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

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

- neither experimental nor investigational.

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

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

We also anticipate that application of the existing and evolving reimbursement regimes to biosimilar products will be somewhat uncertain as CMS determines whether to apply generic drug reimbursement approaches or to develop new mechanisms for assigning reimbursement codes to biosimilar products. Reimbursement uncertainty could adversely impact market acceptance of biosimilar products.

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

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

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

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

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

Additionally, the new law establishes an abbreviated regulatory pathway for the approval of biosimilars and provides that brand biologic products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new approval pathway for biosimilars and adjusting reimbursement for biosimilars, the new law could promote the development and commercialization of biosimilars. However, given the uncertainty of how the law will be interpreted and implemented, the impact of the law on our strategy for biosimilars 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 biosimilars 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 biosimilars based on cost savings, it could also have the effect of reducing biosimilars market share.

The financial impact of this United States health care reform legislation over the next few years will depend on a number of factors, including but not limited to the issuance of implementation regulations and guidance and changes in sales volumes for products eligible for the new system of rebates, discounts and fees. Assuming our products are approved for commercial sale, the new legislation could also have a positive impact on

us by increasing the aggregate number of persons with health care coverage in the United States and expanding the market for our products, but such increases, if any, are unlikely to be realized until approximately 2014 at the earliest.

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

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

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

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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. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Insurance may not provide adequate coverage against potential liabilities and we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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

The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in the review and approval of ANDAs and amendments or supplements due to insufficient staffing and resources. Resource constraints have also resulted in significant delays in conducting ANDA-related pre-approval inspections. Enactment of user fee legislation in 2012 is only beginning to fund additional resources and the impact of the new legislation which implements goals and metrics for application review has been reported by the FDA to have had limited impact to this backlog and the delays as it recruits and trains new FDA staff. Until such time as resources are actually increased and in place at the FDA, our applications and supplements may be subject to significant delays during their review cycles.

Risks Relating to Patents and Licenses

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

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

Assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to

commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

Although we are aggressively pursuing patent applications on our innovative approaches to characterization and manufacture of complex generics, biosimilars and new drugs, there is presently uncertainty regarding the scope of the safe harbor from a patent infringement enforcement under federal patent law, 35 USC section 271(e)(1). This uncertainty may impair our ability to enforce certain of our patent rights and reduce the likelihood of enforcing certain of our patent rights to protect our innovations and our products. Accordingly, we do not know the degree of future enforceability for some of our proprietary rights.

The breadth of patent claims allowed in any patents issued to us or to others may be unclear. 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

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our patents are invalidated or otherwise limited, other companies will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

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

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

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

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

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

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

If we remain 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 continue to resort to litigation to enforce a patent issued to us or to determine the scope and validity of a third-party patent or other proprietary rights such as trade secrets in jurisdictions where we intend to market our products, including the United States, the European

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

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

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Risks Relating to Our Dependence on Third Parties

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

2003 Sandoz Collaboration

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

Accordingly, if Sandoz terminates the 2003 Sandoz Collaboration, we may decide to discontinue the Enoxaparin Sodium Injection project, or our revenue may be reduced, any one of which could have a material adverse effect on our business.

2006 Sandoz Collaboration

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

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

The Baxter Agreement may be terminated:

- by either party for breach by the other party (in whole or on a product by product or country-by-country basis);
- by either party for bankruptcy of the other party;
- by us in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;
- by Baxter for its convenience (in whole or on a product by product basis);
- by us in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided, that we also have certain rights to directly commercialize such product, as opposed to terminating the Baxter Agreement, in event of such a breach by Baxter; or
- by either party in the event there is a condition constituting force majeure for more than a certain consecutive number of days.

If the Baxter Agreement were terminated by Baxter for convenience or if Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products in the specified time frame or if we terminate the Baxter Agreement for breach by Baxter, while we would have the right to research, develop, manufacture or commercialize the terminated products or license a third party to do so, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from commercializing our

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biosimilar candidates. In addition, we may need to seek additional financing to support the research, development and commercialization of the terminated products or alternatively we may decide to discontinue the terminated products, which could have a material adverse effect on our business. If Baxter terminates the Baxter Agreement due to our uncured breach, Baxter would retain the exclusive right to commercialize the terminated products on a world-wide basis, subject to certain payment obligations to us as outlined in the Agreement. In addition, depending upon the timing of the termination, we would no longer have any influence over or input into the clinical development strategy or/and the commercialization strategy or/and the legal strategy of the products in the territory.

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

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

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

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

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

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

A significant change in the business operations of, or a change in senior executive management within, our collaboration partners or third party manufacturers could have a negative impact on our business operations.

Since many of our product candidates are developed under collaborations with third parties, we do not have sole decision making authority with respect to commercialization or development of those product candidates. We have built relationships and work collaboratively with our third party collaborators and manufacturers to ensure the success of our development and commercialization efforts. A significant change in the senior management team, or business operations, of any of our collaboration partners or third party manufacturers could result in delayed timelines on our products. In addition, we may have to train new teams to become familiar with our products and business. Any of these changes may negatively impact our business operations.

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:

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- a classified board of directors;

- a prohibition on actions by our stockholders by written consent; and

- limitations on the removal of directors.

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

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

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

- failure to obtain FDA approval for the M356 20 mg/mL ANDA or other announcements that indicated a delay in the approval of the M356 20 mg/mL ANDA;

- delays in achievement of, or failure to achieve, program milestones that are associated with the valuation of our company or significant milestone revenue;

- failure of Enoxaparin Sodium Injection to sustain profitable sales or market share that meet expectations of securities analysts;

- 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 20 mg/mL ANDA approval;

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

- a decision in favor of or against Teva or Amphastar and Actavis in our patent litigation suits, or a settlement related to any case;

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

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

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

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

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

- enactment of legislation that repeals the law enacting the biosimilar regulatory approval pathway or amends the law in a manner that is adverse to our biosimilar development strategy;

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

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

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- 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 product development and commercialization collaborations;

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

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

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

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

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

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

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

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Item 6. **Exhibits**

Exhibit Number	Description
*31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
**32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
***101.INS	XBRL Instance Document.
***101.SCH	XBRL Taxonomy Extension Schema Document.
***101.CAL	XBRL Taxonomy Calculation Linkbase Document.
***101.LAB	XBRL Taxonomy Label Linkbase Document.
***101.PRE	XBRL Taxonomy Presentation Linkbase Document.
***101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
***101.REF	XBRL Taxonomy Reference Linkbase Document.

* Filed herewith.

** Furnished herewith.

*** Submitted elecontronically herewith.

The following materials from Registrant s Quarterly Report on Form 10-Q for the period ended September 30, 2014, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at September 30, 2014 and December 31, 2013, (ii) the Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013, (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013, and (iv) Notes to Unaudited, Condensed Consolidated Financial Statements.

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SIGNATURES

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

Momenta Pharmaceuticals, Inc.

Date: November 7, 2014

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

Date: November 7, 2014

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