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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended March 31, 2015

☐ **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 ☒ No ☐

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

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

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

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

Indicate the number of shares outstanding of each of the Registrant's classes of Common Stock as of April 27, 2015.

Class	**Number of Shares**
Common Stock $0.0001 par value	59,357,990

MOMENTA PHARMACEUTICALS, INC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Quarterly Report on Form 10-Q that are about future events or future results, or are otherwise not statements of 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 statements are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management. In some cases, these statements can be identified by words such as "anticipate," "believe," "continue," "could," "hope," "target," "project," "goal," "objective," "plan," "potential," "predict," "might," "estimate," "expect," "intend," "may," "seek", "should," "will," "would," "look forward" and other similar words or expressions, or the negative of these words or similar words or expressions. These statements include, but are not limited to, statements regarding our expectations regarding the development and utility of our products, product candidates and novel therapeutic programs, efforts to seek collaborators, including without limitation for M834, the timing of clinical trials and the availability of results, the significance and meaning of results of clinical trials, our ongoing litigation with Teva over Glatopa™ (glatiramer acetate injection) (formerly M356) and M356 (40 mg), collaboration revenues and research and development revenues, manufacturing, including our intent to rely on contract manufacturers, regulatory filings and approvals, market potential for Glatopa, and the sufficiency of our cash for future operations.

Any forward-looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Important factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. "Risk Factors" and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

MOMENTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)
(unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 97,608	$ 61,349
Marketable securities	101,096	130,180
Accounts receivable	5,872	7,427
Unbilled revenue	2,799	2,909
Prepaid expenses and other current assets	3,308	3,465
Total current assets	210,683	205,330
Property and equipment, net	23,872	25,422
Restricted cash	20,719	20,719
Intangible assets, net	4,324	4,589
Other long-term assets	156	156
Total assets	$ 259,754	$ 256,216
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,494	$ 7,433
Accrued expenses	7,311	10,348
Deferred revenue	9,770	5,490
Other current liabilities	538	518
Total current liabilities	23,113	23,789
Deferred revenue, net of current portion	19,541	25,508
Other long-term liabilities	400	551
Total liabilities	43,054	49,848
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $0.01 par value per share; 5,000 shares authorized at March 31, 2015 and December 31, 2014, 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 March 31, 2015 and December 31, 2014, 57,458 and 54,486 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	5	5
Additional paid-in capital	607,629	575,438
Accumulated other comprehensive income (loss)	2	(16)
Accumulated deficit	(390,936)	(369,059)
Total stockholders' equity	216,700	206,368
Total liabilities and stockholders' equity	$ 259,754	$ 256,216

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

MOMENTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Collaboration revenues:		
Product revenue	$ 2,722	$ 4,812
Research and development revenue	5,840	5,973
Total collaboration revenue	8,562	10,785
Operating expenses:		
Research and development*	22,749	26,692
General and administrative*	7,890	11,717
Total operating expenses	30,639	38,409
Operating loss	(22,077)	(27,624)
Other income:		
Interest income	112	200
Other income	88	62
Total other income	200	262
Net loss	$ (21,877)	$ (27,362)
Basic and diluted net loss per share	$ (0.40)	$ (0.53)
Weighted average shares used in computing basic and diluted net loss per share	54,492	51,356
Comprehensive loss:		
Net loss	$ (21,877)	$ (27,362)
Net unrealized holding gains (losses) on available-for-sale marketable securities	18	(16)
Comprehensive loss	$ (21,859)	$ (27,378)

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

Research and development	$ (2,215)	$ 1,545
General and administrative	$ (2,170)	$ 1,906

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

MOMENTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2015	2014
Cash Flows from Operating Activities:		
Net loss	$ (21,877)	$ (27,362)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash items:		
Depreciation and amortization	2,089	1,863
Share-based compensation expense (income)	(4,385)	3,451
Amortization of premium on investments	304	847
Amortization of intangibles	265	265
Changes in operating assets and liabilities:		
Accounts receivable	1,555	5,291
Unbilled revenue	110	(332)
Prepaid expenses and other current assets	157	(199)
Accounts payable	(1,939)	(1,453)
Accrued expenses	(3,037)	(1,423)
Deferred revenue	(1,687)	(1,041)
Other current liabilities	20	(19)
Other long-term liabilities	(151)	(97)
Net cash used in operating activities	(28,576)	(20,209)
Cash Flows from Investing Activities:		
Purchases of property and equipment	(539)	(2,503)
Purchases of marketable securities	(15,694)	(34,365)
Proceeds from maturities of marketable securities	44,492	70,980
Net cash provided by investing activities	28,259	34,112
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock under ATM facility	33,665	—
Proceeds from issuance of common stock under stock plans	2,911	1,841
Net cash provided by financing activities	36,576	1,841
Increase in cash and cash equivalents	36,259	15,744
Cash and cash equivalents, beginning of period	61,349	29,766
Cash and cash equivalents, end of period	$ 97,608	$ 45,510

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

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 focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for oncology and autoimmune disease. The Company presently derives all of its revenue from its collaborations.

Please see Note 10 "*Subsequent Events*" for information regarding marketing approval of Glatopa™ (glatiramer acetate injection) (formerly M356), the Company's generic equivalent of once-daily COPAXONE® 20 mg/mL, by the U.S. Food and Drug Administration on April 16, 2015. M356 now refers only to the generic version of three-times-weekly COPAXONE 40 mg/mL being developed by the Company.

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, 2014, 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 27, 2015. 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 months ended March 31, 2015 and 2014 (in thousands):

	Three Months Ended March 31,	
	2015	2014
Weighted-average anti-dilutive shares related to:		
Outstanding stock options	6,519	4,178
Restricted stock awards	685	922

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 months ended March 31, 2015 and 2014. 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, 668,160 performance-based restricted common stock awards which vest based upon U.S. Food and Drug Administration, or FDA, approval for Glatopa in the United States were excluded from diluted shares outstanding as the vesting condition for the amended awards, discussed further in Note 6 "*Share-Based Payments"* had not been met as of March 31, 2015.

Fair Value Measurements

The tables below present information about the Company's assets that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

Description	Balance as of March 31, 2015	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	$ 74,799	$ 74,799	$ —	$ —
Marketable securities:				
Corporate debt securities	46,889	—	46,889	—
Commercial paper obligations	6,649	—	6,649	—
Foreign government bonds	21,487	—	21,487	—
Asset-backed securities	26,071	—	26,071	—
Total	$ 175,895	$ 74,799	$ 101,096	$ —

Description	Balance as of December 31, 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	$ 55,283	$ 55,283	$ —	$ —
Corporate debt securities	980	—	980	—
Marketable securities:				
Corporate debt securities	70,668	—	70,668	—
Commercial paper obligations	15,250	—	15,250	—
Foreign government bonds	18,520	—	18,520	—
Asset-backed securities	25,742	—	25,742	—
Total	$ 186,443	$ 55,283	$ 131,160	$ —

There have been no impairments of the Company's assets measured and carried at fair value during the three months ended March 31, 2015 and 2014. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three months ended March 31, 2015. The fair value of Level 2 instruments classified as marketable securities were determined through third party pricing services. For a description of the Company's validation procedures related to prices provided by third party pricing services, refer to Note 2 "*Summary of Significant Accounting Policies: Fair Value Measurements*" to the Company's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2014. 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, U.S. treasury obligations, commercial paper, asset-backed securities and U.S. 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's cash equivalents are primarily composed of money market funds carried at fair value, which approximates cost at March 31, 2015 and December 31, 2014. The

Company classifies corporate debt securities, U.S. treasury obligations, commercial paper, asset-backed securities and U.S. government-sponsored enterprise securities as short-term and long-term marketable securities in its consolidated financial statements. See Note 2 "*Summary of Significant Accounting Policies: Cash, Cash Equivalents and Marketable Securities"* in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 for a discussion of the Company's accounting policies.

The following tables summarize the Company's cash, cash equivalents and marketable securities as of March 31, 2015 and December 31, 2014 (in thousands):

As of March 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 97,608	$ —	$ —	$ 97,608
Corporate debt securities due in one year or less	46,893	4	(8)	46,889
Commercial paper obligations due in one year or less	6,641	8	—	6,649
Foreign government bonds due in one year or less	21,487	1	(1)	21,487
Asset-backed securities due in one year or less	26,073	—	(2)	26,071
Total	$ 198,702	$ 13	$ (11)	$ 198,704
Reported as:				
Cash and cash equivalents	$ 97,608	$ —	$ —	$ 97,608
Marketable securities	101,094	13	(11)	101,096
Total	$ 198,702	$ 13	$ (11)	$ 198,704

As of December 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 60,369	$ —	$ —	$ 60,369
Corporate debt securities due in one year or less	71,669	3	(24)	71,648
Commercial paper obligations due in one year or less	15,237	13	—	15,250
Foreign government bonds due in one year or less	18,519	2	(1)	18,520
Asset-backed securities due in one year or less	25,751	—	(9)	25,742
Total	$ 191,545	$ 18	$ (34)	$ 191,529
Reported as:				
Cash and cash equivalents	$ 61,349	$ —	$ —	$ 61,349
Marketable securities	130,196	18	(34)	130,180
Total	$ 191,545	$ 18	$ (34)	$ 191,529

At March 31, 2015 and December 31, 2014, the Company held 31 and 44 marketable securities, respectively, that were in a continuous unrealized loss position for less than one year. At March 31, 2015, there were no securities in a continuous unrealized loss position for greater than one year. At December 31, 2014, there was one marketable security in a continuous unrealized loss position for greater than one year. The Company believes the unrealized losses were caused by fluctuations in interest rates.

The following table summarizes the aggregate fair value of these securities at March 31, 2015 and December 31, 2014 (in thousands):

	As of March 31, 2015		As of December 31, 2014	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities due in one year or less	$ 36,740	$ (8)	$ 63,221	$ (24)
Foreign government bonds due in one year or less	$ 10,714	$ (1)	$ 12,773	$ (1)
Asset-backed securities due in one year or less	$ 18,579	$ (2)	$ 25,742	$ (9)

Comprehensive Income (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 (loss) during the three months ended March 31, 2015 and 2014 (in thousands):

	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2015	$ (16)
Other comprehensive income before reclassifications	18
Amounts reclassified from accumulated other comprehensive income (loss)	—
Net current period other comprehensive income	18
Balance as of March 31, 2015	$ 2

	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2014	$ 25
Other comprehensive loss before reclassifications	(16)
Amounts reclassified from accumulated other comprehensive income (loss)	—
Net current period other comprehensive loss	(16)
Balance as of March 31, 2014	$ 9

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, or ASU 2014-09, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. The new standard will be effective for the Company on January 1, 2017. On April 29 2015, the Financial Accounting Standards Board (FASB) issued an exposure draft of a proposed Accounting Standards update that would delay by one year the effective date of its new revenue recognition standard and allow early adoption as of the original public entity effective date. Comments are due by 29 May 2015. The Company is currently evaluating the method of adoption and the potential impact that ASU 2014-09 may have on its financial position and results of operations.

3. Intangible Assets

Intangible assets consist solely of core developed technology acquired as part of a 2007 asset purchase agreement with Parivid LLC. See Part I, Item 1 "Business—Collaborations, Licenses and Asset Purchases—Parivid" in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 for relevant disclosures. The developed technology intangible assets are being amortized over the estimated useful life of the Enoxaparin Sodium Injection developed technology of approximately 10 years. As of March 31, 2015 and December 31, 2014, intangible assets, net of accumulated amortization, were as follows (in thousands):

		March 31, 2015		December 31, 2014	
	Weighted-Average Amortization Period (in years)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Total intangible assets for core and developed technology and non-compete agreement	10	$ 10,427	$ (6,103)	$ 10,427	$ (5,838)

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 March 31, 2015 and 2014.

The Company expects to incur amortization expense of appropriately $1.1 million per year for each of the next four years and $0.3 million in the fifth year.

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 and will remain restricted during the extension period, which ends in April 2018. 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 March 31, 2015 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 2,722	$ —	$ —	$ 2,722
Research and development revenue:				
Amortization of upfront payments	—	—	1,686	1,686
Research and development services and external costs	251	684	3,219	4,154
Total research and development revenue	$ 251	$ 684	$ 4,905	$ 5,840
Total collaboration revenues	$ 2,973	$ 684	$ 4,905	$ 8,562
Operating expenses:				
Research and development expense (1)	$ 31	$ 148	$ 608	$ 787
General and administrative expense (1)	$ 110	$ 77	$ 406	$ 593
Total operating expenses	$ 141	$ 225	$ 1,014	$ 1,380

	For the Three Months Ended March 31, 2014 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 4,812	$ —	$ —	$ 4,812
Research and development revenue:				
Amortization of upfront payments	—	239	803	1,042
Research and development services and external costs	323	190	4,418	4,931
Total research and development revenue	$ 323	$ 429	$ 5,221	$ 5,973
Total collaboration revenues	$ 5,135	$ 429	$ 5,221	$ 10,785
Operating expenses:				
Research and development expense (1)	$ 19	$ 296	$ 4,817	$ 5,132
General and administrative expense (1)	$ 9	$ 143	$ 30	$ 182
Total operating expenses	$ 28	$ 439	$ 4,847	$ 5,314

(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 2003, the Company 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, a generic version of Lovenox®, 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. The Company refers to Sandoz AG and Sandoz Inc. together as Sandoz.

Under the terms of the 2003 Sandoz Collaboration, the Company and Sandoz agreed to exclusively work with each other to develop and commercialize Enoxaparin Sodium Injection for any and all medical indications within the United States. In addition, the Company granted Sandoz an exclusive license under our intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States. The Company identified two significant deliverables in this arrangement consisting of: (i) the license and (ii) development and related services. The Company determined that the license did not meet the criteria for separation as it did not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company determined that a single unit of accounting exists with respect to the 2003 Sandoz Collaboration.

The Company is paid at cost for external costs incurred for commercial and related activities and is paid for full time equivalents, or FTEs, performing commercial and related services.

In July 2010, Sandoz began the commercial sale of Enoxaparin Sodium Injection. Under the 2003 Sandoz Collaboration, Sandoz is obligated to pay the Company a contractually defined profit share or a contractually defined royalty based 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 the Company 45% of the contractual profits from the sale of Enoxaparin Sodium Injection. In September 2011, FDA approved the ANDA for the enoxaparin product of Amphastar Pharmaceuticals, Inc., or Amphastar. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was obligated to pay the Company a royalty on its net sales of Enoxaparin Sodium Injection until the contractual profits from those net sales in a product year (July 1—June 30) reached a certain threshold. Upon achievement of the contractual profit threshold in December 2011, Sandoz was obligated to pay the Company a profit share for the remainder of the product year. In January 2012, following the grant by the Court of Appeals for the Federal Circuit, or CAFC, of a stay of the preliminary injunction previously issued by the United States District Court for the District of Massachusetts, Actavis Inc. (formerly Watson Pharmaceuticals, Inc.), or Actavis, announced that it and Amphastar launched their enoxaparin product. Consequently, in each product year, for net sales of enoxaparin up to a pre-defined sales threshold, Sandoz is obligated to pay the Company a royalty on net sales at a 10% rate, and for net sales above the sales threshold, at a 12% rate. See "Product revenue" in the tables above for product revenue 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.

The collaboration is governed by a joint steering committee and a joint project team, each consisting of an equal number of Sandoz and Company representatives. Most decisions must be made unanimously, with Sandoz collectively having one vote and the Company having one vote. Sandoz has the sole authority to determine the price at which it sells Enoxaparin Sodium Injection.

Certain development and legal expenses may reduce the amount of profit-share, royalty and milestone payments paid to the Company 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 the Company by Sandoz, but only up to 50% of these amounts due to the Company from Sandoz each quarter. 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 at the end of each product year which corresponds to the second quarter of the Company's fiscal year.

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

2006 Sandoz Collaboration

In 2006 and 2007, the Company 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, the Company and Sandoz AG agreed to exclusively collaborate on the development and commercialization of Glatopa and M356 (40 mg), among other products. Further, under the Second Sandoz Collaboration Agreement, the Company and Sandoz AG expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Under 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 was recognized as revenue on a straight-line basis over the estimated development period. 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 was fully earned and amortized to revenue as of September 30, 2014.

Under the Second Sandoz Collaboration Agreement, costs, including development costs and the costs of clinical studies, are borne by the Company and Sandoz AG in varying proportions depending on the type of expense and the related product. For Glatopa and M356 (40 mg), the Company is generally responsible for all of the development costs in the United States. For Glatopa and M356 (40 mg) outside of the United States and for Enoxaparin Sodium Injection in the European Union, the Company shares development costs in proportion to its profit sharing interest. All commercialization responsibilities are borne by Sandoz AG worldwide as they are incurred for all products. The Company and Sandoz AG will share profits in varying proportions, depending on the product. Upon commercialization, the Company will earn a 50% contractual profit share on worldwide net sales of Glatopa and M356 (40 mg). Profits on net sales of Glatopa and M356 (40 mg) 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. The Company is 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 the Company's profit sharing interest.

The Company earned a $10.0 million regulatory milestone payment upon Glatopa receiving sole FDA approval in April 2015. The Company is eligible to receive up to $153.0 million in additional milestone payments upon the achievement of certain regulatory, commercial and sales-based milestones for Glatopa in the United States and Enoxaparin Sodium Injection in the European Union. The Glatopa milestone payments include a $10.0 million milestone payment upon first commercial sale of Glatopa in the United States and up to $120.0 million in additional milestone payments upon the achievement of certain U.S. commercial and sales-based milestones for Glatopa. The Company is eligible to receive up to $23.0 million in sales-based and commercial milestones for Enoxaparin Sodium Injection in the European Union. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. 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. As of March 31, 2015, the Company had not earned and therefore had not recognized any milestone payments under this arrangement.

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. The Second Sandoz Collaboration Agreement may be terminated if either party breaches the Second Sandoz Collaboration Agreement or files for bankruptcy. In addition, either the Company or Sandoz AG may terminate the Second Sandoz Collaboration Agreement as it relates to the remaining products, on a product-by-product basis, if clinical trials are required.

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 biosimilars. The Company refers to this agreement as the Baxter Agreement. The Baxter Agreement became effective in February 2012.

Under the Baxter Agreement, the Company and Baxter agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilars, M923, a biosimilar of HUMIRA® (adalimumab), and M834, a biosimilar of ORENCIA® (abatacept). In addition, Baxter had the right to select four additional originator biologics to target for biosimilar development under the collaboration. In July 2012, Baxter selected an additional product: M511, a biosimilar of AVASTIN® (bevacizumab). In December 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. In February 2015, Baxter's right to select additional programs expired without being exercised. Also in February 2015, Baxter terminated in part the Baxter Agreement as it relates specifically to M834. The Company retains all worldwide development and commercialization rights for M834. The Baxter Agreement remains in effect and unchanged with respect to M923.

Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize M923 for all therapeutic indications. The Company has agreed to provide development and related services on a commercially reasonable basis through the filing of an IND or equivalent application in the European Union for M923. Development and related services 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 M923. 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 M923 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 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.

Baxter has a right of first negotiation with respect to collaborating with the Company on the development of any biosimilar product candidate that could compete with M923 based on the same mechanism of action. This right is effective until December 2017, subject to certain restrictions as outlined in the Baxter Agreement.

Under the terms of the Baxter Agreement, the Company received an initial cash payment of $33.0 million, a $7.0 million license payment for achieving pre-defined "minimum development criteria" for M834, and $12.0 million in technical and development milestone payments in connection with the UK Medicines and Healthcare Products Regulatory Agency's acceptance of Baxter's clinical trial application to initiate a pharmacokinetic clinical trial for M923. The Company is eligible to receive from Baxter, in aggregate, up to $50.0 million in regulatory milestone payments for M923, on a sliding scale, where, based on the product's regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval.

In addition, if M923 is 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 the 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 M923 on a country-by-country basis until there is no remaining payment obligation with respect to the 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;
- Baxter for its convenience; or
- the Company in the event Baxter does not exercise commercially reasonable efforts to commercialize M923 in the United States or other specified countries, provided that the Company also has certain rights to directly commercialize M923, 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 (M923 and M834) 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 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 M923 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 was allocated to the M834 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.

At the inception of the Baxter Agreement, the Company delivered development and product licenses for M923 and M834 and commenced revenue recognition of the arrangement consideration allocated to those products. In addition, the Company began revenue recognition for the arrangement consideration allocated to the joint steering committee unit of accounting. The Company records this revenue on a straight-line basis over the applicable performance period, which begins upon delivery of the development and product license and ends upon FDA approval of the product. The Company currently estimates that the performance period for M923 and for the joint steering committee is approximately six years.

As a result of Baxter's termination of its option to license M511 in December 2013, the expected consideration to be received under the arrangement was reduced by $7.0 million (the potential option payment for M511) as the number of deliverables decreased from seven deliverables to six deliverables. The Company determined that the change in expected consideration to be received under the arrangement represented 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. Of the $54.0 million, $11.0 million was allocated to the M923

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 was allocated to the M834 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.

In October 2014, the Company achieved pre-defined "minimum development criteria" for M834 and earned a $7.0 million license payment. The license payment was accounted for as part of the upfront fees and the expected consideration to be received under the arrangement increased from $54.0 million to $61.0 million. The Company reallocated the revised expected consideration of $61.0 million to the remaining deliverables under the agreement using the original best estimate of selling price. Of the $61.0 million, $12.4 million was allocated to the M923 product license together with the related research and development services, $12.4 million was allocated to each of the three additional product licenses with the related research and development services, $11.3 million was allocated to the M834 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 $137,000 was allocated to the joint steering committee unit of accounting.

Baxter's termination of M834 and the lapsing of Baxter's right to select additional products in February 2015 reduced the number of deliverables from six to two and decreased the total consideration from $61.0 million to $40.0 million. The Company determined that the change in total consideration received and total deliverables under the arrangement represented a change in estimate and, as a result, the Company reallocated the revised total consideration of $40.0 million to the remaining deliverables under the agreement using the original best estimate of selling price. The remaining deliverables are the combined unit of account for the M923 license and the related research and development services and the Company's participation on the joint steering committee. Of the $40.0 million, $39.6 million was allocated to the M923 product license together with the related research and development services and $0.4 million was allocated to the joint steering committee unit of accounting. The Company recognized the resulting change in revenue as a result of the decrease in deliverables and expected consideration on a prospective basis beginning in the first quarter of 2015. As of March 31, 2015, $29.3 million of revenue was deferred under this agreement, of which $9.8 million was included in current liabilities and $19.5 million was included in non-current liabilities in the consolidated balance sheet.

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 Company has concluded that the M923 technical development milestones and the IND 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 the non-refundable, technical development and IND milestones were recognized upon successful accomplishment of the milestones as research and development revenue.

The regulatory milestones, along with any associated royalty or profit sharing payments, will be considered contingent fees that will be recorded as earned in future periods.

6. Share-Based Payments

Incentive Award Plans

The 2013 Incentive Award Plan, or the 2013 Plan, as amended and restated, initially became effective on June 11, 2013, the date the Company received stockholder 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 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) 5,100,000 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). At March 31, 2015, 2,223,381 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.

On March 11, 2015, the board of directors approved an amendment and restatement of the 2013 Plan to, among other things, increase the shares of common stock available for grant under the 2013 Plan by 2,550,000 shares, subject to and effective upon approval of the amendment and restatement by our stockholders.

Share-Based Compensation

The Company recognizes the fair value of share-based compensation in its consolidated statements of comprehensive (loss) income. The Company records compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the employee stock purchase plan. 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.

The following table summarizes share-based compensation expense (income) recorded in the three months ended March 31, 2015 and 2014 (in millions):

	For the Three Months Ended March 31, 2015	For the Three Months Ended March 31, 2014
Outstanding employee and non-employee stock option grants	$ 2.4	$ 2.2
Outstanding restricted stock awards	(6.9)	1.2
Employee stock purchase plan	0.1	0.1
Total compensation cost (income)	$ (4.4)	$ 3.5

During the three months ended March 31, 2015, the Company granted 1,210,146 stock options, of which 1,165,146 granted in connection with annual merit awards and 45,000 were granted to new hires. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended March 31, 2015 and 2014 was $7.49 per option and $11.12 per option, respectively.

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

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Three Months Ended March 31, 2015	For the Three Months Ended March 31, 2014	For the Three Months Ended March 31, 2015	For the Three Months Ended March 31, 2014
Expected volatility	61%	67%	61%	66%
Expected dividends	—	—	—	—
Expected life (years)	6.2	6.2	0.5	0.5
Risk-free interest rate	1.8%	2.2%	0.1%	0.1%

At March 31, 2015, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $20.5 million, net of estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.8 years.

During the three months ended March 31, 2015, holders of options issued under the Company's stock plans exercised their right to acquire an aggregate of 225,400 shares of common stock. Additionally, during the three months ended March 31, 2015, the Company issued 58,398 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 three months ended March 31, 2015, the Company awarded 250,087 shares of time-based restricted common stock primarily to its officers in connection with its annual merit grants. The time-based restricted common stock vest as to 25% on the one year anniversary of the grant date and as to 6.25% quarterly over three years that follow 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. The performance-based restricted common stock vests upon FDA approval of Glatopa on or before the performance deadline date of March 28, 2015 according to the following vesting schedule: 50% of the shares vest upon FDA approval and 50% vest upon the one-year anniversary of FDA approval. The Company had historically determined that the performance condition was probable of being achieved by March 28, 2015 and, as a result, had recognized approximately $10.5 million of stock compensation costs related to the awards. On March 11, 2015, the Board of Directors approved an amendment to the awards extending the performance deadline date to September 1, 2015 and reducing the original number of shares subject to each award by 15% on the 29th of each month, beginning March 29, 2015. On March 29, 2015, 117,898 shares of performance-based restricted common stock were forfeited pursuant to the modified awards. The Company evaluated the modification and determined it was a Type III modification or "Improbable to Probable" pursuant to ASC 718 as the awards, on the date of modification, were no longer deemed to be probable of being earned by March 28, 2015. As a result, the Company reversed the cumulative compensation cost related to the original awards of $10.5 million in the first quarter of 2015. Also, in accordance with ASC 718, the Company re-measured the modified awards with a measurement date of March 11, 2015, and determined the aggregate compensation was $9.8 million. The FDA approved Glatopa on April 16, 2015. The Company will recognize the compensation cost of the new awards as follows: the first 50% of the awards will be expensed beginning on March 11, 2015 and ending on April 16, 2015, the date of FDA approval, and the remaining 50% of the awards expected to vest will be expensed beginning on March 11, 2015 and ending on April 16, 2016, the one year anniversary of FDA approval. Accordingly, approximately $3.0 million of stock compensation cost was recognized in the quarter ended March 31, 2015.

The Company recorded share-based compensation expense related to outstanding restricted stock awards, including the performance-based restricted common stock, of $(6.9) million and $1.2 million for the three months ended March 31, 2015 and 2014, respectively. As of March 31, 2015, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $14.2 million, which is expected to be recognized over the weighted average remaining requisite service period of 1.7 years.

A summary of the status of nonvested shares of restricted stock as of March 31, 2015 and the changes during the three months then ended are presented below (in thousands, except fair values):

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2015	1,174	$ 15.15
Granted	250	13.02
Vested	(85)	16.64
Forfeited	(127)	14.57
Nonvested at March 31, 2015	1,212	$ 14.67

Nonvested shares of restricted stock that have time-based or both performance-based and time-based vesting conditions as of March 31, 2015 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	544
Performance-based and time-based	668
Nonvested at March 31, 2015	1,212

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 (2012 - 2016), 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 both 2013 and 2014, 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, 2014, 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 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 Company paid Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under this facility.

The offering is being conducted by the Company pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission (Reg. No. 333-188227) and a related prospectus supplement. The Company intends to use the net proceeds from this facility to advance its development pipeline and for general corporate purposes, including working capital. As of March 31, 2015 the Company sold approximately 4.1 million shares of common stock under this facility, raising aggregate net proceeds of approximately $52.0 million. The Company sold approximately an additional 1.4 million shares of common stock under this facility subsequent to quarter-end through April 20, 2015 resulting in aggregate net proceeds of approximately $21.5 million.

In April 2015, the Company entered into a new At-the-Market Equity Offering Sales Agreement with 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. Sales of common stock under this facility will be made pursuant to an effective shelf registration statement previously filed with the Securities and Exchange Commission (Reg. No. 333-188227) and a related prospectus supplement. Please see Note 10 "*Subsequent Events*" for information regarding the new 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 commenced on 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 March 31, 2015 are as follows (in thousands):

	Operating Leases
April 1, 2015 through December 31, 2015	$ 8,406
2016	9,189
2017	4,924
2018	1,608
Total future minimum lease payments	$ 24,127

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.

Glatopa-and M356 (40 mg)-Related Litigation

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 Glatopa. 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 certifications 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, 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. 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 nine patents, including one non-Orange Book-listed patent which is set to expire in September 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. On January 20, 2015, the Supreme Court vacated the 2013 decision of the CAFC and remanded the case to the CAFC for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. The parties filed briefs with the CAFC on March 2, 2015. On April 16, 2015, upon FDA approval of Glatopa, the Company requested an expedited decision with a full opinion to follow later. The Company expects the CAFC could issue a decision at any time.

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 M356 (40 mg). 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, invalidity and unenforceability of both patents. On April 10, 2015, Teva and Yeda filed an additional suit against the Company and Sandoz in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for 40 mg/mL Copaxone, which issued in March 2015 and expires in 2030.

Enoxaparin Sodium Injection-related Litigation

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 District 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 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, 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 petition.

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 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 CAFC denied the motion in May 2014. The CAFC set a briefing schedule which ended in November 2014. The CAFC held a hearing on the Company's appeal on May 4, 2015 and the Company expects that the CAFC could issue a decision 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.

10. Subsequent Events

FDA Approval of Glatopa

On April 16, 2015, the FDA granted sole marketing approval of the ANDA for once-daily Glatopa™ (glatiramer acetate injection) 20 mg/mL, a generic equivalent of once-daily COPAXONE® 20 mg/mL. Glatopa, formerly referred to as M356, was developed under the Second Sandoz Collaboration Agreement. The Company earned a $10.0 million regulatory milestone payment upon Glatopa receiving sole FDA approval.

New ATM Sales Agreement

On April 21, 2015, the Company entered into a new At-the-Market Equity Offering Sales Agreement with 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 Company is required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of its common stock under this facility. From April 21 through April 30, 2015, the Company recorded net proceeds of $6.9 million from the sale of 0.4 million shares of common stock sold through the ATM.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014.

This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many important factors, such as those set forth under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Business Overview

Introduction

We are a biotechnology company focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for oncology and autoimmune disease. Our approach to drug discovery and development 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, evaluate the biological function of products and product candidates, and develop reliable and scalable manufacturing processes. The core objective of our platform is to resolve the complexity of molecular structures and related biologic systems. We believe our complex systems analysis platform gives us a competitive advantage in developing complex generics, biosimilars and novel therapeutics. In selecting our current development programs and in the evaluation of any potentially new programs, we look for those opportunities where we believe we can best leverage our platform to realize a competitive advantage to bring new medicines to patients and create value for our stockholders.

To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. Although we were profitable in fiscal years 2010 and 2011, since that time we have been incurring operating losses and we may potentially incur annual operating losses over the next several years as we advance our drug development portfolio. As of March 31, 2015, we had an accumulated deficit of $391 million. We will need to generate significant revenue to return to profitability. 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.

Complex Generics

Enoxaparin Sodium Injection —Generic Lovenox®

Excluding contractual adjustments under our collaboration agreement, our royalties on Enoxaparin Sodium Injection decreased from $4.8 million in the first three months of 2014 to $2.7 million in the first three months of 2015, on Sandoz net sales of $47.5 million and $25.9 million, respectively, for those periods. In addition to Sanofi's branded generic, which was launched in October 2011, and the generic product by Actavis and Amphastar, which was launched in January 2012, Teva announced that it launched a generic version of enoxaparin sodium injection in February 2015. These competitors and the potential entry of future generics may cause continued downward price pressure and decreased market share in the United States for our Enoxaparin Sodium Injection.

Glatopa™ — Generic Copaxone® (glatiramer acetate injection) 20 mg/mL (formerly M356)

On April 16, 2015, the FDA granted marketing approval of the Abbreviated New Drug Application for once-daily Glatopa TM (glatiramer acetate injection) 20 mg/mL (formerly referred to as M356), a generic equivalent of once-daily Copaxone® 20 mg/mL. Glatopa is the first "AP" rated, substitutable generic equivalent of once-daily Copaxone. Based upon receiving sole approval, we earned a $10.0 million regulatory milestone payment under our collaboration with Sandoz. We are eligible to receive another $10.0 million milestone payment upon first commercial sale of Glatopa. Sandoz is planning for a commercial launch of Glatopa in 2015.

The lawsuit filed against us by Teva and Yeda Research and Development Co., Ltd, or Yeda, in response to the filing of the ANDA with a Paragraph IV certification for Glatopa is on-going. The one patent subject to the suit that has not expired is set to expire in September 2015. A description of the proceedings is set forth under Part II, Item 1 *"Legal Proceedings*." Prior to the earlier of (i) the final resolution of the lawsuit (including all potential appeals) or (ii) September 2015, a launch of Glatopa would be at risk of a court finding that Glatopa infringes Teva's patent and, if Teva is ultimately successful, we and Sandoz could be liable for significant damages. Under our collaboration agreement, Sandoz has the right to decide whether and when to launch at risk and is evaluating the potential to launch prior to final resolution of the lawsuit (including all potential appeals). If Sandoz chooses to launch at risk, until the earlier of resolution of the patent litigation or September 2015, we expect to segregate and restrict cash flow we may receive from Sandoz related to our share of contractual profits on Sandoz's sales of Glatopa, during the at-risk period, for payment of potential damages. 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 Glatopa revenue, on a quarterly basis, until we have paid our share of the damages.

In addition to the current lawsuit, Teva may seek to take additional legal actions to challenge FDA approval of Glatopa and prevent or delay the launch of Glatopa. Such actions may include appealing FDA denials of its prior Citizen Petitions in U.S. federal district court and

seeking injunctive relief to reverse FDA approval of Glatopa. Such actions may also include seeking injunctive relief preventing launch in the existing patent litigation or the filing of additional patent infringement suits. For additional information about these and other possible actions, see the following important risks and uncertainties set forth under *Part II, Item 1A. "Risk Factors*": "*—If Teva is successful in the ongoing Copaxone patent litigation by enjoining the manufacture or sale of Glatopa by Sandoz or in otherwise asserting its alleged patent rights relating to the manufacturing and sale of Copaxone, Sandoz may not be able to launch Glatopa until September 2015, or we and Sandoz may have to pay significant damages if Sandoz launches before September 2015 and Glatopa is found to infringe Teva's patents;" "—If Teva sues the FDA seeking to reverse the FDA's denial of its citizen petitions seeking to prevent the marketing approval of Glatopa, and is successful, Sandoz could be prohibited from launching or continuing to sell Glatopa and our business would be materially adversely affected; " "—Teva may allege that we are infringing existing, additional issued or pending patents it holds. 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 the launch of Glatopa beyond September 2015, cause damages that reduce our contract profits, or interrupt future sales of Glatopa and may have a material adverse effect on our business;" and "—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."*

We believe there is a meaningful market opportunity for Glatopa. The price for Copaxone 20 mg/mL has increased over 165% since 2009 and there is no other generic for multiple sclerosis currently available. However, Teva received marketing approval of its three-times-weekly 40 mg/mL formulation of Copaxone in January 2014. In February 2015, Teva reported that over 60% of patients previously using its once-daily 20 mg/mL formulation have converted to its three-times-weekly formulation. Because Glatopa is only a substitutable generic version of the 20 mg/mL formulation of Copaxone, the market potential of Glatopa is negatively impacted by the conversion of patients from once-daily Copaxone to three-times-weekly Copaxone. Teva reported $4.2 billion in worldwide sales of Copaxone (20 mg/mL and 40 mg/mL) in 2014, $3.1 billion of which was from the United States.

Glatopa was formerly referred to as M356. M356 (40 mg) now refers to the Company's generic product candidate for three-times-weekly Copaxone 40 mg/mL.

M356 (40 mg) — Generic Three-times-weekly Copaxone® (glatiramer acetate injection), 40 mg/mL

In August 2014, an ANDA with a Paragraph IV certification for our generic version of three-times-weekly 40 mg/mL Copaxone was filed with the FDA. If we are successful in our challenge of the patents related to 40 mg/mL Copaxone, and assuming customary patent litigation timelines, we believe M356 (40 mg) could be approved, following expiration of any 30-month stay, if applicable, as early as the first quarter of 2017.

Biosimilars

M923 —Biosimilar HUMIRA® (adalimumab) Candidate

We and Baxter are pursuing a global regulatory strategy for M923. In December 2014, a clinical trial application, or CTA, to initiate a pharmacokinetic clinical trial for M923 was accepted by the UK Medicines and Healthcare Products Regulatory Agency. The trial, a randomized double-blind, single dose study in healthy volunteers to compare the pharmacokinetics, safety, tolerability and immunogenicity of M923 versus EU-sourced HUMIRA and US-sourced HUMIRA, commenced in the first quarter of 2015. Baxter plans to enroll approximately 300 volunteers across three sites and we expect data to be available in the fourth quarter of 2015. Baxter is planning to submit the first regulatory application for marketing approval for M923 as early as 2017.

M834 —Biosimilar ORENCIA® (abatacept) Candidate

M834 was previously being developed and commercialized in collaboration with Baxter. In February 2015, Baxter terminated in part our collaboration as it relates specifically to M834. Prior to termination, in October 2014, we achieved a pre-defined "minimum development criteria" milestone under the Baxter collaboration, resulting in us receiving a license payment of $7.0 million. Following Baxter's termination, we retain all worldwide development and commercialization rights for M834. We plan to continue to develop M834 with a goal of being able to enter clinical development in 2016 and continue to identify and explore potential collaboration opportunities for the program. We believe there is currently limited biosimilar competition for M834.

M511 —Biosimilar AVASTIN ® (bevacizumab) Candidate

M511 is a biosimilar candidate for AVASTIN® (bevacizumab). AVASTIN is a tumor-starving (anti-angiogenic) therapy. Avastin is designed to block a protein called vascular endothelial growth factor, or VEGF. Normal cells make VEGF, but some cancer cells make too much VEGF. Blocking VEGF may prevent the growth of new blood vessels, including normal blood vessels and blood vessels that feed tumors. AVASTIN is indicated for the treatment of patients with a certain type of brain tumor, and certain types of cancers of the kidney, lung, colon, cervix, and ovary. AVASTIN is marketed by Genentech.

M511 was previously under development in collaboration with Baxter. In December 2013, following an internal portfolio review, Baxter terminated its option to license M511 under the collaboration.

Other Biosimilar Candidates

We also have six other earlier stage biosimilar programs that we believe will allow us to broaden our biosimilar product portfolio and technology base. We seek to identify and collaborate with strategic partners who can bring best-in-class, global commercial capabilities and can help secure high quality, low cost manufacturing and distribution. We seek to leverage our capabilities and expertise to advance programs to a stage where we can derive optimal stockholder value from each of our collaborations.

In February 2015, Baxter's right to include three additional programs under our collaboration expired without being exercised. We continue to identify and explore potential opportunities to partner one or more of our biosimilar programs, other than M923, with a goal of entering into one or more agreements in the second half of 2015.

As of March 31, 2015, we had over 100 employees working on our biosimilars programs. We maintain a state-of-the-art development facility for bioprocess manufacturing development and scale-up.

Novel Therapeutics

Necuparanib

In October 2014, we successfully completed Part A and reported positive top-line data from our Phase 1/2 clinical trial in patients with advanced metastatic pancreatic cancer, which we initiated in 2012. We determined a maximum tolerated dose of 5 mg/kg. We believe the safety data and early signals of efficacy from Part A are very encouraging. We believe the 5 mg/kg dose has the potential to provide significantly higher levels of activity against multiple cancer targets than traditional anticoagulant heparins have achieved. At this dose level, no significant additional toxicity to what would be expected with the underlying Abraxane / gemcitabine combination was observed. Additionally, as the necuparanib dose was increased across cohorts, no dose proportional trends in adverse events were observed. We believe these results suggest the possibility of combining necuparanib with many other chemotherapy and targeted therapy standards of care in a variety of other tumor types. We plan to present more mature data from Part A in June 2015 at the American Society of Clinical Oncology annual meeting.

In October 2014, we initiated Part B, or Phase 2, of the Phase 1/2 trial. We expect data from Phase 2 to be available as early as the end of 2016 or the first half of 2017.

In June 2014, necuparanib received Orphan Drug Designation from the U.S. FDA for the treatment of pancreatic cancer. In December 2014, we received Fast-Track designation by the FDA for necuparanib as a first-line treatment in combination with Abraxane® and gemcitabine in patients with metastatic pancreatic cancer.

Other Novel Therapeutic Programs

We are continuing to advance our SIF3 and Anti-FcRn programs with a goal of entering both programs into clinical development in late 2016. We continue to identify and explore potential opportunities to partner the further development and commercialization of our hsIVIg program.

We believe these early stage programs could have the potential to produce product candidates capable of treating a large number of immunological disorders driven by antibodies, immune complexes, and Fc receptor biology. Such disorders include rheumatoid arthritis, autoimmune neurologic diseases such as Guillain-Barre syndrome, chronic inflammatory demyelinating neuropathy and myasthenia gravis, autoimmune blood disorders such as immune thrombocytopenic purpura, systemic autoimmune diseases such as dermatomyositis, lupus nephritis, and catastrophic antiphospholipid syndrome, antibody-mediated transplant rejection, and autoimmune blistering diseases, several of which have few treatment options.

At-the-Market Facilities

In order to invest in our development pipeline and for other general corporate purposes, in May 2014, we entered into an At-the-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, establishing an At-the-Market financing facility, or ATM, pursuant to which we authorized the sale of our common stock from time to time up to an aggregate of $75 million. In the three months ended March 31, 2015, we sold approximately 2.6 million shares of common stock under the ATM, raising net proceeds of approximately $33.7 million. Through March 31, 2015, we sold approximately 4.1 million shares of common stock under the ATM, raising net proceeds of approximately $52.0 million. From April 1, 2015 through April 20, 2015, we sold approximately 1.4 million additional shares of common stock under the ATM, raising net proceeds of approximately $21.5 million, and concluded sales under the May 2014 Sales Agreement. We paid Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock.

In April 2015, we entered into a new At-the-Market Equity Offering Sales Agreement with Stifel, establishing a new ATM, pursuant to which we may sell from time to time up to an aggregate of an additional $75 million of our common stock. We intend to use the net proceeds from this facility primarily for general corporate purposes, including working capital. We will pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under this facility. From April 21 through April 30, 2015, we recorded net proceeds of $6.9 million from the sale of 0.4 million shares of common stock sold under the new ATM.

Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

Collaboration Revenue

Collaboration revenue includes product revenue and research and development revenue earned under our collaborative arrangements. Product revenue consists of profit share and/or royalties 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.

For the three months ended March 31, 2015, we earned $2.7 million in royalties on Sandoz's reported net sales of Enoxaparin Sodium Injection of $25.9 million. For the three months ended March 31, 2014, we earned $4.8 million in royalties on Sandoz's reported net sales of Enoxaparin Sodium Injection of $47.5 million. The decrease in our product revenue of $2.1 million, or 44%, and the decrease in Sandoz's net sales of $21.6 million, or 45%, from the 2014 period to the 2015 period are both due to decreased unit sales due to lower market share, and lower prices in response to competitor pricing reductions on enoxaparin.

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 Sandoz's 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.

Research and Development Revenue

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 (all periods presented);
- under the 2006 Sandoz Collaboration for amortization of the equity premium (2014 period only);
- under the Baxter Agreement for reimbursement of research and development services and reimbursement of development costs for M923 (all periods presented); and
- under the Baxter Agreement for amortization of a portion of $40 million upfront and M834 license payment (all periods presented).

Research and development revenue was $5.8 million and $6.0 million for the three months ended March 31, 2015 and 2014, respectively. The decrease in research and development revenue of $0.2 million, or 3%, from the 2014 period to the 2015 period is primarily due to lower reimbursable development costs for M923.

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 2015 depending on our research and development activities.

Research and Development Expense

Research and development expenses consist of costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. We track the external research and development costs incurred for each of our product candidates. Our external research and development expenses consist primarily of:

- expenses incurred under agreements with consultants, third-party contract research organizations, or CROs, and investigative sites where all of our non-clinical studies and clinical trials are conducted;

- costs of acquiring originator comparator materials and manufacturing non-clinical study and clinical trial supplies and other materials from contract manufacturing organizations, or CMOs, and related costs associated with release and stability testing; and

- costs associated with process development activities.

Internal research and development costs are associated with activities performed by our research and development organization and consist primarily of:

- personnel-related expenses, which include salaries, benefits and share-based compensation; and

- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment and laboratory and other supplies.

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.

Research and development expense for the three months ended March 31, 2015 was $22.7 million, compared with $26.7 million for the three months ended March 31, 2014. The decrease of $4.0 million, or 15%, from the 2014 period to the 2015 period was primarily due to the reversal of prior period stock compensation expense associated with performance based stock awards. In 2011 and 2012, we granted broad-based performance stock awards that vested 50% upon approval of the Glatopa ANDA and 50% one year later. The awards were scheduled to expire March 28, 2015. In March 2015, we amended the awards to extend the performance period to September 2015, but with share amounts that decreased monthly. Upon the amendment, stock compensation previously recognized was reversed and stock compensation in the first quarter was recognized ratably based on the April 2015 Glatopa ANDA approval. In the first quarter of 2015 research and development expense included a stock compensation credit of $5.1 million and expense of $1.5 million relating to the performance grants.

The lengthy process of securing FDA approval for generics and 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 the amortization of our intangible asset, for each of our principal development programs for the three months ended March 31, 2015 and 2014. 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.

	Phase of Development as of March 31, 2015	Three Months Ended March 31, 2015		Project Inception to March 31, 2015
		2015	2014	
External Costs Incurred by Product Candidate:				
Glatopa and M356 (40 mg)—Generic Copaxone®	ANDAs filed (1)	$ 147	$ 296	$ 48,154
Necuparanib—Oncology Product Candidate	Phase 2	2,100	1,094	27,174
Biosimilars	Various (2)	3,896	5,815	59,418
Other novel therapeutic programs	Discovery	2,147	244	
Internal Costs		14,459	19,243	
Total Research and Development Expenses		$ 22,749	$ 26,692	

(1) Sandoz's ANDA for Glatopa was approved on April 16, 2015. The ANDA for M356 (40 mg) is currently under FDA review.

(2) Biosimilars includes M923, a biosimilar version of HUMIRA® (adalimumab), M834, a biosimilar version of ORENCIA® (abatacept), M511, a biosimilar version of AVASTIN® (bevacizumab), as well as other biosimilar candidates. A pharmacokinetic clinical trial for M923 commenced in the first quarter of 2015. M834 is in the non-clinical phase of development, and the other biosimilar candidates are in discovery and process development.

The decrease of $0.1 million in Glatopa and M356 (40 mg) external expenditures from the 2014 period to the 2015 period was due to lower process development activities, manufacturing and third-party costs. Our necuparanib external expenditures increased by $1.0 million from the 2014 period to the 2015 as Part B, or Phase 2, of the Phase 1/2 trial got underway. The decrease of $1.9 million in biosimilars external expenditures from the 2014 period to the 2015 period was due to lower third-party process development and contract research costs incurred for our M923 biosimilar. The increase of $1.9 million in other novel therapeutics program external expenditures from the 2014 period to the 2015 period was primarily due to increased expenditures to support development of product candidates.

The decrease of $4.8 million in research and development internal costs from the 2014 period to the 2015 period was primarily due to the reversal of prior period stock compensation expense associated with performance-based stock awards. In the first quarter of 2015 research and development expense included a stock compensation credit of $5.1 million and expense of $1.5 million relating to the performance grants.

General and Administrative Expense

General and administrative expenses consist primarily of salaries and other related costs for personnel in general and administrative functions, professional fees for legal and accounting services, royalty and license fees, insurance costs, and allocated rent, facility and lab supplies, and depreciation expense.

General and administrative expense for the three months ended March 31, 2015 was $7.9 million, compared with $11.7 million for the three months ended March 31, 2014. The decrease of $3.8 million, or 32%, from the 2014 period to the 2015 period was primarily due to the reversal of prior period stock compensation expenses associated with performance based stock awards. In the first quarter of 2015 general and administrative expense included a stock compensation credit of $5.4 million and expense of $1.5 million relating to the performance grants.

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

Interest Income

Interest income was $0.1 million and $0.2 million for the three months ended March 31, 2015 and 2014, respectively. The decrease of $0.1 million from the 2014 period to the 2015 period was primarily due to lower average investment balances.

Other Income

Other income was $0.1 million for each of the three months ended March 31, 2015 and 2014 and represents other income related to a job creation tax award that was granted to us in the fourth quarter of 2012.

Liquidity and Capital Resources

At March 31, 2015, we had $198.7 million in cash, cash equivalents and marketable securities and $5.9 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. We received an additional $28.4 million of cash in April through sales of common stock under our ATM facilities. Our funds at March 31, 2015 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 12 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 March 31, 2015.

We have funded our operations primarily through the sale of equity securities and payments received under our collaboration and license agreements, including product revenue from Sandoz's sales of Enoxaparin Sodium Injection. Since our inception through March 31, 2015, we have received $459 million through private and public issuances of equity securities. As of March 31, 2015, we had received a cumulative total of $605 million under our collaborations with Sandoz, including $461 million in Enoxaparin Sodium Injection product revenue, and $75 million under our collaboration with Baxter, including a $33 million upfront payment, $23 million in reimbursement of research and development services and costs and $19 million in license and milestone payments.

We expect to finance and manage our planned operating and expenditure requirements principally through our current cash, cash equivalents and marketable securities and capital raised through equity financings, including utilization of our At-the-Market financing facility. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2016.

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash used in operating activities	$ (28,576)	$ (20,209)
Net cash provided by investing activities	$ 28,259	$ 34,112
Net cash provided by financing activities	$ 36,576	$ 1,841
Net increase in cash and cash equivalents	$ 36,259	$ 15,744

Cash used in operating activities

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.

Cash used in operating activities was $28.6 million for the three months ended March 31, 2015 reflecting a net loss of $21.9 million. The net loss for the period includes $4.4 million of non-cash income, net, in stock compensation for the reversal of prior period stock compensation expense associated with performance-based stock awards. The net loss plus the net change in stock compensation was partially offset by non-cash charges of $2.4 million for depreciation and amortization of property, equipment and intangible assets and $0.3 million for amortization of purchased premiums on our marketable securities. In addition, the net change in our operating assets and liabilities used cash of $5.0 million and resulted from: decreases in accounts receivable and unbilled revenue totaling $1.7 million due to lower Enoxaparin Sodium Injection royalty revenue resulting from lower units sold and lower pricing due to a new market entrant; a decrease in accounts payable of $1.9 million due to timing of vendor payments; a decrease in accrued expenses of $3.0 million primarily due to the payout of employee bonuses for their performance in 2014; a decrease in deferred revenue of $1.7 million, due to higher quarterly amortization of revenue from the $33.0 million Baxter upfront payment and $7 million M834 license payment; and a decrease in other long-term liabilities of $0.2 million, of which $0.1 million represents the amortization of a job creation tax award and $0.1 million is the amortization of the tenant improvement allowance over the term of our facility lease.

Cash used in operating activities was $20.2 million for the three months ended March 31, 2014 reflecting a net loss of $27.4 million, which was partially offset by non-cash charges of $2.1 million for depreciation and amortization of property, equipment and intangible assets,

$3.5 million for share-based compensation and $0.8 million for amortization of purchased premiums on our marketable securities. In addition, the net change in our operating assets and liabilities provided cash of $0.7 million and resulted from a decrease in accounts receivable of $5.3 million due to the receipt of fourth quarter 2013 reimbursable M923 FTEs and expenses incurred in connection with the Baxter Agreement. The cash provided from the collection of accounts receivable of $5.3 million was offset by an increase in unbilled revenue of $0.3 million, due to increased reimbursable M923 FTEs and expenses partly offset by decreased reimbursable Glatopa and M356 (40 mg) FTEs and expenses; an increase in prepaid expenses and other current assets of $0.2 million, primarily due to advance license fee and clinical study payments to vendors; a decrease in accounts payable of $1.5 million due to timing of M923 expenses incurred in connection with the Baxter Agreement; a decrease in accrued expenses of $1.4 million as we paid bonuses to our employees for their performance in 2013; a decrease in deferred revenue of $1.0 million, primarily due to the quarterly amortization of revenue from the $33.0 million Baxter upfront payment; and a decrease in other long-term liabilities of $0.1 million primarily due to the amortization of a job creation tax award.

Cash provided by investing activities

Cash provided by investing activities of $28.3 million for the three months ended March 31, 2015 includes cash inflows of $44.5 million from maturities of marketable securities partially offset by cash outflows of $15.7 million for purchases of marketable securities and $0.5 million for capital equipment and leasehold improvements.

Cash provided by investing activities of $34.1 million for the three months ended March 31, 2014 includes cash inflows of $71.0 million from maturities of marketable securities partially offset by cash outflows of $34.4 million for purchases of marketable securities and $2.5 million for capital equipment and leasehold improvements.

Cash provided by financing activities

Cash provided by financing activities of $36.6 million for the three months ended March 31, 2015 includes $33.7 million of net proceeds from the sale of 2.6 million shares of our common stock under the ATM facility and $2.9 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Cash provided by financing activities of $1.8 million for the three months ended March 31, 2014 relate to 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 disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on February 27, 2015 have not materially changed since we filed that report.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us 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, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

There have been no significant changes to our accounting policies during the three months ended March 31, 2015, as compared to the significant accounting policies described in 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, 2014 filed with the SEC on February 27, 2015.

New Accounting Standards

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of United States money market, government-secured, and high-grade corporate securities, directly or through managed funds, with maturities of twenty-four months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the conservative nature of our investments, low prevailing market rates and relatively short effective maturities of debt instruments, interest rate risk is mitigated. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2015, 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 defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of March 31, 2015. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

There was no change in our internal control over financial reporting during the quarter ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Glatopa and M356 (40 mg)-Related 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 Glatopa. 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 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 certifications with respect to each listed patent. 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. 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 one non-Orange Book-listed patent which is set to expire in September 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. On January 20, 2015, the Supreme Court vacated the 2013 decision of the CAFC and remanded the case to the CAFC for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. The parties filed briefs with the CAFC on March 2, 2015. On April 16, 2015, upon FDA approval of Glatopa, we requested an expedited decision with a full opinion to follow later. We expect the CAFC could issue a decision at any time. During the pendency of this litigation or any appeal of a decision in this litigation, any launch of Glatopa would be a launch at risk of infringement and should a court rule in favor of Teva, a launch would be delayed until the expiration of the patent in September 2015.

Since 2008, Teva has filed eight Citizen Petitions with FDA requesting that FDA deny the approval of any ANDA filed for generic Copaxone. Of the eight, Teva withdrew one and the FDA denied seven Citizen Petitions, most recently in April 2015 in connection with approving Glatopa. In May 2014, Teva filed suit against the FDA in the United States District Court for the District of Columbia, 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. Teva had not filed suit relating to the denial of its Citizen Petition at the time of FDA marketing approval of Glatopa. Teva may file suit seeking to reverse the FDA approval of Glatopa or otherwise continue to engage in activities that seek to challenge the approval, or delay the launch of Glatopa.

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 M356 (40 mg). 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. A trial in the district court is scheduled for September 2016. On April 10, 2015, Teva and Yeda filed an additional suit against the Company and Sandoz in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for 40 mg/mL Copaxone, which issued in March 2015 and expires in 2030.

Enoxaparin Sodium Injection-Related Proceedings

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 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.

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 CAFC denied the motion in May 2014. The CAFC set a briefing schedule which ended in November 2014. The CAFC held a hearing on our appeal on May 4, 2015, and we expect a decision 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.

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 March 31, 2015, our accumulated deficit was $391 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 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 the ongoing Copaxone patent litigation by enjoining the manufacture or sale of Glatopa by Sandoz or in otherwise asserting its alleged patent rights relating to the manufacturing and sale of Copaxone, Sandoz may not be able to launch Glatopa until September 2015, or we and Sandoz may have to pay significant damages if Sandoz launches before September 2015 and Glatopa is ultimately found to infringe Teva's patents.

In July 2012, the United States Federal District Court in the Southern District of New York (the "District Court") 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*" in this Quarterly Report on Form 10-Q. 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. Teva appealed the CAFC decision to the Supreme Court of the United States, which in January 2015, vacated the CAFC's 2013 decision and remanded the case to the CAFC to reconsider and rule on the validity of the patent.

Should Teva succeed in the CAFC on remand, the launch of Glatopa may not occur until September 2015, which would impair our ability to commercialize Glatopa and harm our business and financial condition. Furthermore, even if the decision of the CAFC is favorable to us, Teva may appeal the decision. If Sandoz launches Glatopa prior to a final decision in the patent case (including potential appeals), and Teva is ultimately successful, we and Sandoz may be liable for significant damages and our business and financial condition would be materially harmed. The possibility of incurring liability for such damages may reduce the scope of, or may delay, any launch of Glatopa prior to resolution of the patent litigation. In addition, until the conclusion of the lawsuit, we may not utilize Glatopa cash flows to support program investments, which would limit our ability to invest in ongoing R&D programs or require us to raise capital through equity or debt offerings.

Teva may allege that we are infringing existing, additional issued or pending patents it holds. 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 the launch of Glatopa beyond September 2015, cause damages that reduce our contract profits or interrupt future sales of Glatopa and may have a material adverse effect on our business .

Teva may assert existing, additional issued or pending patents with respect to Glatopa, and it may claim that we are infringing those patents, including in connection with the on-going Copaxone patent litigation or otherwise. 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 Glatopa which could delay the launch of Glatopa potentially for a significant period beyond September 2015 and prohibiting the use of any manufactured product for commercial sale. Furthermore, we may be ordered to pay damages, potentially including treble damages, if Sandoz launches Glatopa prior to a decision resolving these patent claims 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 Glatopa, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

If Teva sues the FDA seeking to reverse the FDA's denial of its citizen petitions seeking to prevent the marketing approval of Glatopa, and is successful, Sandoz could be prohibited from launching or continuing to sell Glatopa and our business would be materially adversely affected.

Since 2008, Teva has filed eight Citizen Petitions with FDA requesting that FDA deny the approval of any ANDA filed for generic Copaxone. Of the eight, Teva withdrew one and the FDA denied seven, most recently in April 2015 in connection with approving Glatopa. In May 2014, Teva filed suit against the FDA in the United States District Court for the District of Columbia, 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. Teva had not filed suit challenging the April 2015 denial of its Citizen Petition at the time of FDA marketing approval of Glatopa. Should Teva file suit seeking to reverse the FDA approval of Glatopa and succeeds, Sandoz could be prohibited from launching or continuing to sell Glatopa until the marketing approval is reinstated by the FDA. Should this occur, our business would be materially adversely affected, we would be limited in our ability to invest in ongoing research and development, and we would have a greater need to raise capital through equity or debt offerings.

If other generic versions of the brand name drugs, or other biosimilars of the reference originator biologics, for which we have products or product candidates, including Glatopa, M356 (40 mg) and M923, 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 current or potential future generic or biosimilar product offerings, including Glatopa, M356 (40 mg) and M923, 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 would likely decline significantly. In addition, the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that reference product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). A determination that another company's product is interchangeable with HUMIRA or another of the reference brand products for which we have a product candidate prior to approval of M923 or other applicable product candidate may therefore delay the potential determination that our product is interchangeable with the reference product, which may materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

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 the FDA. In February 2015, Teva reported that over 60% of patients previously using its once-daily formulation have converted to its three-times-weekly formulation. As a result, the market potential for Glatopa has decreased, and may decrease further as additional patients are converted from once-daily Copaxone to three-times-weekly Copaxone. 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 that may offer patients a more convenient form of administration, increased efficacy or improved safety profile. 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 therapeutic 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.

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 delay, limit or cease our product development efforts or other operations.

As of March 31, 2015, we had cash, cash equivalents and marketable securities totaling $198.7 million. For the three months ended March 31, 2015, we had a net loss of $21.9 million and cash used in operating activities of $28.6 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 and commercialization 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 will depend on many factors, including but not limited to:

- the level of sales of Enoxaparin Sodium Injection;
- our willingness to utilize any Glatopa 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 Copaxone-related patent infringement litigation matters against us;
- the timing and scope of the launch and commercialization of our product candidates, including Glatopa;
- whether Teva sues for injunctive relief reversing the FDA's marketing approval of Glatopa, and the outcome of any such litigation;
- 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 additional strategic collaborations for our non-partnered programs, as well as the terms and timing of any milestone, royalty or profit share payments thereunder;
- 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 and manage our planned operating and capital expenditure requirements principally through our current cash, cash equivalents and marketable securities and capital raised through equity financings, including utilization of our At-the-Market financing facility. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2016. We may seek additional funding in the future through third-party collaborations and licensing arrangements, public or private 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.

We may need to enter into collaborations, joint ventures or other alliances with other companies that can provide capabilities and funds for the development and commercialization of our product candidates. If we are unsuccessful in forming or maintaining these arrangements on favorable terms, our business could be adversely affected.

Because we have limited or no internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we may need to enter into strategic alliances with other companies. For example, we have entered into collaboration agreements to develop and commercialize our complex generics programs and certain of our biosimilar programs. In the future, we may also find it necessary to form similar strategic alliances with major pharmaceutical companies to jointly develop and/or commercialize other product candidates across our product areas. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. These alliances may involve the other company purchasing a significant number of shares of our common stock. Future alliances may involve similar or greater sales of equity, debt financing or other funding arrangements. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

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

Our near-term ability to generate Enoxaparin 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.

If our patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful, we may be liable for damages. In addition, third parties may be able to commercialize generic Lovenox products 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 regulatory exclusivity or patent extension amendments to unrelated federal legislation.

The FDA's practice is to rule within 150 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 150-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. To date, Teva Neuroscience, Inc. has filed eight Citizen Petitions regarding Glatopa, of which seven have been denied and dismissed and one was withdrawn by Teva. However, Teva may 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 Teva were to succeed in court in reversing the

denial of its Citizen Petitions by the FDA, the approval of Glatopa could be overturned and Sandoz could be delayed in launching Glatopa or be unable to continue future sales of Glatopa, which would materially harm our business.

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, which 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;
- 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 Glatopa 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
- the availability and amount of government and third-party payor reimbursement.

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

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

We are dependent on the members of our management team for our business success. Our employment arrangements with our executive officers are terminable by either party on short notice or no notice. We do not carry 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. If we lose key members of our management team, or are unable to attract and retain qualified personnel, our business could be negatively affected.

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. We cannot be sure that the product liability insurance coverage we maintain 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.

Our business and operations would suffer in the event of system failures or security breaches.

Our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure or security breach by employees or others may pose a risk that sensitive data, including clinical trial data, intellectual property, trade secrets or personal information belonging to us, our patients or our collaborators may be exposed to unauthorized persons or to the public. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture and commercialize our products and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our products and product candidates could be delayed, and the trading price of our common stock could be adversely affected.

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 incur costs and allocate resources to identify and develop additional product candidates or acquire or make investments in companies or technologies without realizing any benefit, which could have an adverse effect on our business, results of operations and financial condition or cash flows.

Along with continuing to progress our current product candidates, the long-term success of our business also depends on our ability to successfully identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs and product candidates that ultimately prove to be unsuccessful.

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

- we may find that the acquired company or assets does not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;
- difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;
- difficulty incorporating the acquired technologies;
- difficulties or failures with the performance of the acquired technologies or drug products;
- we may face product liability risks associated with the sale of the acquired company's products;
- disruption or diversion of management's attention by transition or integration issues and the complexity of managing diverse locations;
- difficulty maintaining uniform standards, internal controls, procedures and policies;
- the acquisition may result in litigation from terminated employees or third parties; and
- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

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

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

If we fail to maintain appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business.

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment requires the commitment of significant financial and managerial resources.

Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

Risks Relating to Development and Regulatory Approval

The future success of our business is significantly dependent on the success of our M356 (40mg) product candidate. If we are not able to obtain regulatory approval for commercial sale of M356 (40mg) product candidate, 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 (40 mg). Our application for M356 (40 mg) has been under review with the FDA since February 2014. To receive approval, we will be required to demonstrate to the satisfaction of the FDA, among other things, that M356 (40 mg):

- contains the same active ingredients as Copaxone 40mg;
- is of the same dosage form, strength and route of administration as Copaxone 40 mg, and has the same labeling as the approved labeling for Copaxone 40mg, 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 (40 mg) to Copaxone 40mg 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 (40 mg) or that M356 (40 mg) and Copaxone 40mg 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 (40 mg) will receive FDA approval as therapeutically equivalent to Copaxone 40mg.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Copaxone 40mg, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of M356 (40 mg) 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 (40 mg) could adversely affect our operating results by restricting or significantly delaying our introduction of M356 (40 mg).

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. For example, the FDA only recently issued final guidance on certain matters concerning approval of biosimilars, including quality considerations and scientific considerations and to date, only one biosimilar product has been approved, and, to our knowledge, only a few biosimilar applications have been accepted for review by the FDA, under the 351(k) pathway. The new pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing brand product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the brand product and (2) interchangeable 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. Our strategy to reduce and target clinical requirements by relying on analytical and functional non-clinical data may not be successful or may take longer than strategies that rely more heavily on clinical trial data.

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 in 2015 or future years. Depending on the timing and the extent of these funding, meeting and review disruptions, our 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, it could materially reduce sales in those states which would substantially harm our business.

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 that 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 and in initial human clinical studies of a development candidate may not predict the results that will be obtained in subsequent 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 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 and private payors determine whether to apply generic drug reimbursement approaches to reimbursement or to develop alternative approaches under Medicare, Medicaid and private insurance coverage. For example, under Medicare Part B, the assignment of reimbursement codes to a reference drug product and its generic equivalent creates a strong incentive for generic conversion. CMS has decided to assign separate reimbursement codes for non-interchangeable biosimilars but has not made a decision regarding interchangeable biologic products. Reimbursement uncertainty could adversely impact market acceptance of biosimilar products.

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

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

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

Furthermore, health care reform legislation that was enacted in 2010 and is now being implemented 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 BPCI 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.

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.

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 applications for M356 (40 mg) 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. For example, two of our European patents are being challenged in opposition proceedings before the European Patent Office. 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.

There is presently uncertainty regarding the scope of the safe harbor from patent infringement under federal patent law, 35 USC section 271(e)(1), for activities related to developing and submitting information under a federal law. This uncertainty is especially high for our patents protecting our testing methods. The scope and application of the safe harbor is the subject of our on-going patent litigation with Amphastar. Additional information about this litigation is set forth under Part II, Item 1 "*Legal Proceedings*" in this Quarterly Report on Form 10-Q. The uncertainty regarding the scope of the safe harbor 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 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 may be 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.

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 program, 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, if we were able to do so, could cause significant delays that could prevent us from completing the development and commercialization of such product. Any alternative collaboration could also be on less favorable terms to us. 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.

Under our collaboration agreements, we are dependent upon Sandoz to successfully continue to commercialize Enoxaparin Sodium Injection and we will be dependent on Sandoz to successfully commercialize Glatopa and, if it is approved, M356 (40 mg). We do not control Sandoz's commercialization activities or the resources it allocates to our products. Our interests and Sandoz's interests may differ or conflict from time-to-time or we may disagree with Sandoz's level of effort or resource allocation. Sandoz may internally prioritize our products differently than we do or it may fail to allocate sufficient resources to effectively or optimally commercialize our products. If these events were to occur, our business would be adversely affected.

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 the Agreement, the development and commercialization of our lead biosimilar, M923, 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 Baxter for its convenience;
- by us in the event Baxter does not exercise commercially reasonable efforts to commercialize M923 in the United States or other specified countries, provided, that we also have certain rights to directly commercialize M923, 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 M923 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, if we were able to do so, could cause significant delays that could prevent us from commercializing our biosimilar candidates. For example, in February 2015, Baxter terminated in part the Baxter Agreement as it relates specifically to M834. As a result, continued development of M834 may be delayed until we can enter into another collaboration to develop that program. Any alternative collaboration could also be on less favorable terms to us. In addition, we may need to seek additional financing to support the research, development and commercialization of any terminated products or alternatively we may decide to discontinue any 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 M923 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 M923.

Under the Baxter Agreement, we are dependent upon Baxter to successfully conduct clinical trials for, and if approved, commercialize M923. We do not control Baxter's administration of the clinical trials, commercialization activities or the resources it allocates to M923. Our interests and Baxter's interests may differ or conflict from time to time, or we may disagree with Baxter's level of effort or resource allocation. Baxter may internally prioritize M923 differently than we do or it may not allocate sufficient resources to effectively or optimally administer clinical trials for, or commercialize, M923. If these events were to occur, our business would be adversely affected.

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, including, for example, a change in control or internal corporate restructuring, of any of our collaboration partners or third party manufacturers could result in delayed timelines on our products. In addition, we may have to re-establish working relationships and familiarize new counterparts with our products and business. Any such change may result in the collaboration partner or third party manufacturer internally re-prioritizing our programs or decreasing resources allocated to support our programs. Similar changes with respect to any of our other collaborators 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:

- 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:

- any delay in launch of Glatopa;
- additional regulatory or legal actions by Teva to overturn Glatopa approval or prevent or delay launch of Glatopa;
- 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 Glatopa or M356 (40 mg) programs, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M356 (40 mg) 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;
- 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	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.1	At-the-Market Equity Offering Sales Agreement, dated as of April 21, 2015, by and between Momenta Pharmaceuticals, Inc. and Stifel, Nicolaus & Company, Incorporated.	8-K	10.1	4/21/15	000-50797
*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.

The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014, (ii) the Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014, (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014, 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: May 5, 2015

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

Date: May 5, 2015

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

Exhibit 31.1

CERTIFICATION

I, Craig A. Wheeler certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 5, 2015

/s/ Craig A. Wheeler
Craig A. Wheeler
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Richard P. Shea certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 5, 2015

/s/ Richard P. Shea
Richard P. Shea
Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Richard P. Shea, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 5, 2015

/s/ Craig A. Wheeler
Craig A. Wheeler
President and Chief Executive Officer

Dated: May 5, 2015

/s/ Richard P. Shea
Richard P. Shea
Senior Vice President and Chief Financial Officer