MOMENTA PHARMACEUTICALS INC
Form 10-Q
May 06, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended March 31, 2016

or

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

For the Transition Period from to

Commission File Number 000-50797

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(617) 491-9700

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

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

As of April 12, 2016, there were 69,496,190 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

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MOMENTA PHARMACEUTICALS, INC.

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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, contemplate, target, likely, goal, objective, plan, potential, predict, might, estimate, expect, intend, may, seek , should, will, would, can, pursue 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 collaboration partners, including without limitation for our biosimilar programs; the timing of clinical trials and the availability of results; the significance and meaning of results of clinical trials, including without limitation, results from our necuparanib clinical trial; the timing of launch of products and product candidates; GLATOPA® (glatiramer acetate injection) product revenues and market potential; the timing and outcome of litigation and legal proceedings; collaboration revenues and research and development revenues; manufacturing, including our intent to rely on contract manufacturers; regulatory filings, reviews and approvals; the sufficiency of our cash for future operations; our expectations regarding our potential future profitability; our intended uses of proceeds from financing activities; Enoxaparin Sodium Injection product revenues and market potential; our expectations regarding product candidate development costs; our expectations regarding receipt of contingent milestone payments from Mylan Ireland Limited in 2016; accounting policies; our estimates regarding the fair value of our investment portfolio; and our market risk exposure with respect to derivative, foreign currency and other financial instruments.

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.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

MOMENTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

(unaudited)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 89,431	$ 61,461
Marketable securities	256,359	288,583
Collaboration receivable	21,742	21,185
Prepaid expenses and other current assets	4,405	3,479
Total current assets	371,937	374,708
Marketable securities	17,038	
Property and equipment, net	21,547	21,896
Restricted cash	20,660	20,660
Intangible assets, net	3,263	3,528
Other long-term assets	978	248
Total assets	$ 435,423	$ 421,040
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,388	$ 4,053
Accrued expenses	16,231	24,499
Deferred revenue	17,144	9,770
Other current liabilities	110	460
Total current liabilities	36,873	38,782
Deferred revenue, net of current portion	46,475	12,213
Other long-term liabilities	592	69
Total liabilities	83,940	51,064
Commitments and contingencies (Note 8)		
Stockholders Equity:		
Preferred stock, $0.01 par value per share; 5,000 shares authorized, 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, 69,495 shares issued and 69,376 shares outstanding at March 31, 2016 and 69,077 shares issued and 68,958 outstanding at December 31, 2015	7	7
Additional paid-in capital	829,771	824,385

Accumulated other comprehensive income		137		4
Accumulated deficit		(476,384)		(452,372)
Treasury stock, at cost, 119 shares		(2,048)		(2,048)
Total stockholders equity		351,483		369,976
Total liabilities and stockholders equity	$	435,423	$	421,040

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

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MOMENTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Collaboration revenues:		
Product revenue	$ 14,800	$ 2,722
Research and development revenue	5,050	5,840
Total collaboration revenue	19,850	8,562
Operating expenses:		
Research and development*	28,757	22,749
General and administrative*	15,647	7,890
Total operating expenses	44,404	30,639
Operating loss	(24,554)	(22,077)
Other income:		
Interest income	480	112
Other income	62	88
Total other income	542	200
Net loss	$ (24,012)	$ (21,877)
Basic and diluted net loss per share	$ (0.35)	$ (0.40)
Weighted average shares used in computing basic and diluted net loss per share	68,285	54,492
Comprehensive loss:		
Net loss	$ (24,012)	$ (21,877)
Net unrealized holding gains on available-for-sale marketable securities	133	18
Comprehensive loss	$ (23,879)	$ (21,859)

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

Research and development	$ 2,065	$ (2,215)
General and administrative	$ 2,763	$ (2,170)

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

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MOMENTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2016	2015
Cash Flows from Operating Activities:		
Net loss	$ (24,012)	$ (21,877)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Non-cash items:		
Depreciation and amortization	1,889	2,089
Share-based compensation expense (income)	4,828	(4,385)
Amortization of premium on investments	290	304
Amortization of intangibles	265	265
Changes in operating assets and liabilities:		
Collaboration receivable	(557)	1,665
Prepaid expenses and other current assets	(926)	157
Other long-term assets	(730)	
Accounts payable	(665)	(1,939)
Accrued expenses	(8,268)	(3,037)
Deferred revenue	41,636	(1,687)
Other current liabilities	(350)	20
Other long-term liabilities	523	(151)
Net cash provided by (used in) operating activities	13,923	(28,576)
Cash Flows from Investing Activities:		
Purchases of property and equipment	(1,540)	(539)
Purchases of marketable securities	(119,368)	(15,694)
Proceeds from maturities of marketable securities	134,397	44,492
Net cash provided by investing activities	13,489	28,259
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock under ATM facilities		33,665
Proceeds from issuance of common stock under stock plans	558	2,911
Net cash provided by financing activities	558	36,576
Increase in cash and cash equivalents	27,970	36,259
Cash and cash equivalents, beginning of period	61,461	61,349
Cash and cash equivalents, end of period	$ 89,431	$ 97,608

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

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MOMENTA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED, CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company

Business

Momenta Pharmaceuticals, Inc., or 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.

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, 2015, 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 26, 2016. 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 condensed 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.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists; services have been performed or products have been delivered; the fee is fixed or determinable; and collection is reasonably assured.

The Company has entered into collaboration and license agreements with pharmaceutical companies for the development and commercialization of certain of its product candidates. The Company s performance obligations under the terms of these agreements may include (i) transfer of intellectual property rights (licenses), (ii) providing research and development services, and (iii) participation on joint steering committees with the collaborators. Non-refundable payments to the Company under these agreements may include up-front license fees, payments for research and development activities, payments based upon the achievement of defined collaboration objectives and profit share or royalties on product sales.

At March 31, 2016, the Company had collaboration and license agreements with Sandoz AG (formerly Sandoz N.V. and Biochemie West Indies, N.V.), an affiliate of Novartis Pharma AG, and Sandoz Inc. (formerly Geneva Pharmaceuticals, Inc.), collectively referred to as Sandoz, Sandoz AG, Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated, collectively referred to as Baxalta, and Mylan Ireland Limited, a wholly-owned, indirect subsidiary of Mylan N.V., or Mylan.

The Company evaluates multiple element agreements under the Financial Accounting Standards Board s, or FASB, Accounting Standards Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. When evaluating multiple element

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arrangements under ASU 2009-13, the Company identifies the deliverables included within the agreement and determines whether the deliverables under the arrangement represent separate units of accounting. Deliverables under the arrangement are a separate unit of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item and delivery or performance of the undelivered items are considered probable and substantially within the Company s control. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The Company considers whether the collaborator can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, and whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered items.

Arrangement consideration generally includes up-front license fees and non-substantive options to purchase additional products or services. The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The Company determines the estimated selling price for deliverables using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE nor TPE is available. Determining the BESP for a deliverable requires significant judgment. The Company uses BESP to estimate the selling price for licenses to the Company s proprietary technology, since the Company often does not have VSOE or TPE of selling price for these deliverables. In those circumstances where the Company utilizes BESP to determine the estimated selling price of a license to the Company s proprietary technology, the Company considers entity specific factors, including those factors contemplated in negotiating the agreements as well as the license fees negotiated in similar license arrangements. Management may be required to exercise considerable judgment in estimating the selling prices of identified units of accounting under its agreements. In validating the Company s BESP, the Company evaluates whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple deliverables.

Up-Front License Fees

Up-front payments received in connection with licenses of the Company s technology rights are deferred if facts and circumstances dictate that the license does not have stand-alone value. When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, it is combined with other deliverables and the revenue of the combined unit of accounting is recorded based on the method appropriate for the last delivered item. The Company recognizes revenue from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the period over which the research and development services are expected to occur. Accordingly, the Company is required to make estimates regarding the development timelines for product candidates being developed pursuant to any applicable agreement. The determination of the length of the period over which to recognize the revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Quarterly, the Company reassesses its period of substantial involvement over which the Company amortizes its up-front license fees and makes adjustments as appropriate. The Company s estimates regarding the period of performance under its collaborative research and development and licensing agreements have changed in the past and may change in the future. Any change in the Company s estimates could result in changes to the Company s results for the period over which the revenues from an up-front license fee are recognized.

Milestones

At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive, in accordance with ASU No. 2010-17, Revenue Recognition Milestone Method. A milestone is defined as an event that can only be achieved based on the Company s performance, and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement.

Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones under accounting guidance. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the Company s performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company s performance to achieve the milestone, (b) the consideration relates solely to past performance (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement and (d) the milestone fee is refundable or adjusts based on future performance or non-performance. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Payments that are contingent upon the achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met. At March 31, 2016, the Company had no milestones under its collaborative arrangements that were deemed substantive.

The regulatory milestones under the collaboration with Baxalta are considered to be contingent fees that will be recorded if earned in future periods.

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Sales-based and commercial milestones are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Profit Share and Royalties on Sandoz Sales of Enoxaparin Sodium Injection® and GLATOPA®

Profit share and royalty revenue is reported as product revenue and is recognized based upon net sales or contractual profit of licensed products in licensed territories in the period the sales occur as provided by the collaboration agreement. The amount of net sales or contractual profit is determined based on amounts provided by the collaborator and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. The Company is highly dependent on its collaborators for timely and accurate information regarding any net revenues realized from sales of Enoxaparin Sodium Injection and GLATOPA in order to accurately report its results of operations.

Research and Development Revenue under Collaborations with Sandoz and Baxalta

Under its collaborations with Sandoz and Baxalta, the Company is reimbursed at a contractual full-time equivalent, or FTE, rate for any FTE employee expenses as well as any external costs incurred for commercial and related activities. The Company recognizes research and development revenue from FTE services and external costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenues are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such commercial and related services.

Collaboration Receivable

Collaboration receivable represents:

- Amounts due to the Company for profit share on Sandoz sales of Enoxaparin Sodium Injection and GLATOPA;

- Amounts due to the Company for reimbursement of research and development services and external costs under the collaborations with Sandoz and Baxalta; and

- The net amount due from Mylan for its 50% share of collaboration expenses under the cost-sharing arrangement.

The Company has not recorded any allowance for uncollectible accounts or bad debt write-offs and it monitors its receivables to facilitate timely payment.

Deferred Revenue

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

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, 2016 and 2015 (in thousands):

	Three Months Ended March 31,	
	2016	**2015**
Weighted-average anti-dilutive shares related to:		
Outstanding stock options	6,659	6,519
Restricted stock awards	335	685

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, 2016 and 2015. 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, 308,095 performance-based restricted common stock awards vested on April 18, 2016, the one year anniversary of the U.S. Food and Drug Administration, or FDA, approval for GLATOPA in the United States,

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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, 2016.

Fair Value Measurements

The tables below present information about the Company s assets that are regularly measured and carried at fair value as of March 31, 2016 and December 31, 2015, 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, 2016	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 and overnight repurchase agreements	$ 86,685	$ 62,685	$ 24,000	$
Marketable securities:				
U.S. government-sponsored enterprise securities	4,999		4,999	
Corporate debt securities	74,479		74,479	
Commercial paper obligations	111,578		111,578	
Asset-backed securities	82,341		82,341	
Total	$ 360,082	$ 62,685	$ 297,397	$

Description	Balance as of December 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 and overnight repurchase agreements	$ 54,077	$ 30,077	$ 24,000	$
Marketable securities:				
U.S. government-sponsored enterprise securities	24,290		24,290	
Corporate debt securities	73,651		73,651	
Commercial paper obligations	125,805		125,805	
Asset-backed securities	64,837		64,837	
Total	$ 342,660	$ 30,077	$ 312,583	$

There have been no impairments of the Company s assets measured and carried at fair value during the three months ended March 31, 2016 and 2015. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three months ended March 31, 2016. 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, 2015. The carrying amounts reflected in the Company s accompanying 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.

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Cash, Cash Equivalents and Marketable Securities

The Company s cash equivalents are primarily composed of money market funds carried at fair value, which approximates cost at March 31, 2016 and December 31, 2015. The Company classifies corporate debt securities, 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, 2015 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, 2016 and December 31, 2015 (in thousands):

As of March 31, 2016	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash, money market funds and overnight repurchase agreements	$ 89,431	$	$	$ 89,431
U.S. government-sponsored enterprise securities due in one year or less	4,998	1		4,999
Corporate debt securities due in one year or less	74,473	8	(2)	74,479
Commercial paper obligations due in one year or less	111,449	129		111,578
Asset-backed securities due in one year or less	65,302	15	(14)	65,303
Asset-backed securities due in two years or less	17,038	4	(4)	17,038
Total	$ 362,691	$ 157	$ (20)	$ 362,828
Reported as:				
Cash and cash equivalents	$ 89,431	$	$	$ 89,431
Marketable securities	273,260	157	(20)	273,397
Total	$ 362,691	$ 157	$ (20)	$ 362,828

As of December 31, 2015	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash, money market funds and overnight repurchase agreements	$ 61,461	$	$	$ 61,461
U.S. government-sponsored enterprise securities due in one year or less	24,285	5		24,290
Corporate debt securities due in one year or less	73,735	1	(84)	73,652
Commercial paper obligations due in one year or less	125,693	120	(8)	125,805

Asset-backed securities due in one year or less	64,866		(30)	64,836
Total	$ 350,040	$ 126	$ (122)	$ 350,044
Reported as:				
Cash and cash equivalents	$ 61,461	$	$	$ 61,461
Marketable securities	288,579	126	(122)	288,583
Total	$ 350,040	$ 126	$ (122)	$ 350,044

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At March 31, 2016 and December 31, 2015, the Company held 11 and 66 marketable securities, respectively, that were in a continuous unrealized loss position for less than one year. At March 31, 2016 and December 31, 2015, there were no securities 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 as of March 31, 2016 and December 31, 2015 (in thousands):

	As of March 31, 2016		As of December 31, 2015	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities due in one year or less	$ 20,024	$ (2)	$ 70,657	$ (84)
Commercial paper obligations due in one year or less	$	$	$ 33,734	$ (8)
Asset-backed securities due in one year or less	$ 22,944	$ (14)	$ 61,337	$ (30)
Asset-backed securities due in two years or less	$ 8,015	$ (4)	$	$

Treasury Stock

Treasury stock represents common stock currently owned by the Company as a result of shares withheld from the vesting of performance-based restricted common stock to satisfy minimum tax withholding requirements.

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.

New Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company is currently evaluating the method of adoption and the potential

impact that Topic 606 may have on its financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements Going Concern (Subtopic 205-40). The ASU requires all entities to evaluate for the existence of conditions or events that raise substantial doubt about the entity s ability to continue as a going concern within one year after the issuance date of its financial statements. The accounting standard is effective for interim and annual

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periods after December 15, 2016, and will not have a material impact on the consolidated financial statements, but may impact the Company s footnote disclosures regarding liquidity.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. The adoption of this standard in the first quarter of 2016 did not have a material impact on the Company s financial position or results of operations as its net deferred tax assets have been fully offset by a valuation allowance.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net). This new standard relates to when another party, along with the entity, is involved in providing a good or a service to a customer. In those circumstances, Topic 606 requires the entity to determine whether the nature of its promise is to provide that good or service to the customer (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). This determination is based upon whether the entity controls the good or the service before it is transferred to the customer. The Company will adopt this new standard concurrently with adoption of ASU No. 2014-09.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Under the new standard all excess tax benefits and tax deficiencies should be recognized as income tax expense or benefit in the income statement. The tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity also should recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. The new standard also provides for companies to make an entity-wide accounting policy election on how to account for award forfeitures. Entities can either estimate the number of awards that are expected to vest (current GAAP) or account for forfeitures when they occur. The accounting standard is effective for interim and annual periods after December 15, 2016. Early adoption is permitted for any entity in any interim or annual period. The Company is currently evaluating the impact of adopting this new accounting standard 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, 2015 for relevant disclosures. The developed technology intangible assets are being amortized over the estimated useful life of the Enoxaparin Sodium Injection and GLATOPA developed technologies of approximately 10 years. As of March 31, 2016 and December 31, 2015, intangible assets, net of accumulated amortization, were as follows (in thousands):

	March 31, 2016			December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Total intangible assets for core and developed technology and non-compete agreement	$ 10,427	$ (7,164)	$ 3,263	$ 10,427	$ (6,899)	$ 3,528

The weighted-average amortization period for the Company s intangible assets is 10 years. 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, 2016 and 2015.

The Company expects to incur amortization expense of approximately $1.1 million per year for each of the next three years and $0.1 million in the fourth year.

4. Restricted Cash

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Amphastar, International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. and Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), or Actavis, as discussed within Note 8, *Commitments and Contingencies* . Amphastar, International Medical Systems, Ltd. and Amphastar Pharmaceuticals, Inc. are collectively referred to as Amphastar. 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 $2.4 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 April 2018 and therefore is classified as non-current in the Company s consolidated balance sheet. The Company will earn interest on the balance.

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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

At March 31, 2016, the Company had collaboration and license agreements with Sandoz, Sandoz AG, Baxalta and Mylan.

The Company records product revenue based on Sandoz sales of Enoxaparin Sodium Injection and GLATOPA.

Research and development revenue generally consists of amounts earned by us under our collaborations for technical development, regulatory and commercial milestones; reimbursement of research and development services and reimbursement of development costs under our collaborative arrangements with Sandoz and Baxalta; and recognition of the arrangement consideration under the collaborations with Baxalta and Mylan.

The collaboration with Mylan is a cost-sharing arrangement pursuant to which reimbursement for Mylan s 50% share of collaboration expenses is recorded as a reduction to research and development expense and general and administrative expense depending on the nature of the activities.

The following tables provide amounts by year and by line item included in the Company s accompanying condensed consolidated statements of operations and comprehensive loss attributable to transactions arising from its significant collaborative arrangements and all other arrangements, as defined in the Financial Accounting Standards Board s Accounting Standards Codification Topic 808, *Collaborative Arrangements*. The dollar amounts in the tables below are in thousands.

	For the Three Months Ended March 31, 2016				
	2003 Sandoz Collaboration Agreement	**2006 Sandoz Collaboration Agreement**	**Baxalta Collaboration Agreement**	**Mylan Collaboration Agreement (1)**	**Total Collaborations**
Collaboration revenues:					
Product revenue	$	$ 14,800	$	$	$ 14,800
Research and development revenue:					
Recognition of upfront payments and license payments			2,442	922	3,364
Research and development services and external costs under Sandoz and Baxalta collaborations	77	645	964		1,686
Total research and development revenue	$ 77	$ 645	$ 3,406	$ 922	$ 5,050
Total collaboration revenues	$ 77	$ 15,445	$ 3,406	$ 922	$ 19,850
Operating expenses:					
	$	$ 293	$ 314	$ 3,680	$ 4,287

Research and development expense(2)(3)					
General and administrative expense(2)(3)	$ 1,064	$ 95	$ 282	$ 112	$ 1,553
Total operating expenses	$ 1,064	$ 388	$ 596	$ 3,792	$ 5,840

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	For the Three Months Ended March 31, 2015			
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Baxalta Collaboration Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 2,722	$	$	$ 2,722
Research and development revenue:				
Milestone payments				
Recognition of upfront payments and license 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(2)	$ 31	$ 148	$ 608	$ 787
General and administrative expense(2)	$ 110	$ 77	$ 406	$ 593
Total operating expenses	$ 141	$ 225	$ 1,014	$ 1,380

(1) The Mylan Collaboration Agreement, as defined below, became effective on February 9, 2016.

(2) 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 the majority of such costs are not directly charged to programs.

(3) As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, the Company offset approximately $3.7 million against research and development costs and $0.1 million against general and administrative costs during the three months ended March 31, 2016.

2003 Sandoz Collaboration Agreement

In 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration Agreement, with Sandoz to jointly develop, manufacture and commercialize Enoxaparin Sodium Injection, a generic version of LOVENOX®, in the United States. Under the terms of the 2003 Sandoz Collaboration Agreement, 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 its intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States.

Sandoz began selling Enoxaparin Sodium Injection in July 2010. For the three months ended March 2015, the Company received a 10% royalty on net sales. In June 2015, the Company and Sandoz amended the 2003 Sandoz Collaboration Agreement, effective April 1, 2015, to provide that Sandoz would pay the Company 50% of contractually-defined profits on sales. Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended March 31, 2016, and therefore the Company did not record product revenue for Enoxaparin Sodium

Injection in the period. See Product revenue in the table above for product revenue earned by the Company in the three months ended March 31, 2015 on Sandoz sales of Enoxaparin Sodium Injection.

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 Company s contractual share of such development and legal expenses is subject to an annual claw-back adjustment at the end of each of the first five product years, with the product year beginning on July 1 and ending on June 30. The annual adjustment can only reduce the Company s profits, royalties and milestones by up to 50% in a given calendar quarter and any excess amount due will be carried forward into future quarters and reduce any profits in those future periods until it is paid in full. Annual adjustments, including amounts carried forward into future periods, are recorded as a reduction in product revenue.

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2006 Sandoz Collaboration Agreement

In 2006 and 2007, the Company entered into a series of agreements, including a collaboration and license agreement, as amended, or the 2006 Sandoz Collaboration Agreement, with Sandoz AG; and a stock purchase agreement and an investor rights agreement, with Novartis. Under the 2006 Sandoz Collaboration Agreement, the Company and Sandoz AG agreed to exclusively collaborate on the development and commercialization of GLATOPA and M356, among other products. Costs, including development costs and the costs of clinical studies, will be borne by the parties in varying proportions depending on the type of expense. For GLATOPA and M356, the Company is generally responsible for all of the development costs in the United States. For GLATOPA and M356 outside of the United States, the Company shares development costs in proportion to its profit sharing interest. The Company is reimbursed at a contractual FTE rate for any FTE employee expenses as well as any external costs incurred in the development of products to the extent development costs are born by Sandoz. All commercialization costs are borne by Sandoz.

Sandoz commenced sales of GLATOPA in the United States on June 18, 2015. Under the 2006 Sandoz Collaboration Agreement, the Company earns 50% of contractually-defined profits on Sandoz worldwide net sales of GLATOPA. The Company is entitled to earn 50% of contractually-defined profits on Sandoz worldwide net sales of M356, if and when M356 is commercialized. Profits on net sales of GLATOPA and M356 are 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. Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement; however a portion of certain legal expenses, including any patent infringement damages, can be offset against the profit-sharing amounts in proportion to the Company s 50% profit sharing interest.

For the three months ended March 31, 2016, the Company recorded $14.8 million in product revenues from Sandoz sales of GLATOPA. The Company is eligible to receive in the aggregate up to $120.0 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA and M356 in the United States. 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.

The term of the 2006 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 2006 Sandoz Collaboration Agreement. The 2006 Sandoz Collaboration Agreement may be terminated if either party breaches the 2006 Sandoz Collaboration Agreement or files for bankruptcy. In addition, either the Company or Sandoz AG may terminate the 2006 Sandoz Collaboration Agreement with respect to M356, if clinical trials are required for regulatory approval of M356.

Baxalta Collaboration Agreement

The Company and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively referred to as Baxter, entered into a global collaboration and license agreement effective February 2012, or the Baxter Collaboration Agreement, to develop and commercialize biosimilars, including M923. In connection with Baxter s internal corporate restructuring in July 2015, Baxter assigned all of its rights and obligations under the Baxter Collaboration Agreement to Baxalta. In light of the assignment, all references to Baxter and the Baxter Collaboration Agreement have been replaced with references to Baxalta and the Baxalta Collaboration Agreement, respectively.

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

Under the Baxalta Collaboration 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 Investigational New Drug application, or IND, or equivalent application in the European Union for M923. Development and related services include high-resolution analytics, characterization, and product and process development. Baxalta 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 Baxalta, 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 is reimbursed at a contractual FTE rate for any FTE employee expenses and external development costs for reimbursable activities related to M923.

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Baxalta 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 Baxalta Collaboration 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 Baxalta s clinical trial application to initiate a pharmacokinetic clinical trial for M923. The Company is eligible to receive from Baxalta, 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, Baxalta 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 Baxalta Collaboration Agreement.

The Baxalta Collaboration Agreement may be terminated by:

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

- Baxalta for its convenience; or

- the Company in the event Baxalta 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 Baxalta Collaboration Agreement, in event of such a breach by Baxalta.

In accordance with FASB s ASU No. 2009-13: Multiple-Deliverable Revenue Arrangements (Topic 615), the Company identified the deliverables at the inception of the Baxalta Collaboration Agreement. The deliverables were determined to include (i) six development and product licenses, for each of M923, M834 and the four additional collaboration products, (ii) research and development services related to each of M923, M834 and the four additional collaboration products and (iii) the Company s participation in a joint steering committee. The Company determined that each of the license deliverables does not have stand-alone value apart from the related research and development services deliverables because (1) there are no other vendors selling similar, competing products on a stand-alone basis, (2) Baxalta does not have the contractual right to resell the license, and (3) Baxalta 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 with respect to this arrangement separate units of accounting exist for each of the six licenses together with the related research and development services, as well as the one unit of accounting for the joint steering

committee. The estimated selling price for these units of accounting was determined based on similar license arrangements and the nature of the research and development services to be performed for Baxalta and market rates for similar services. At the inception of the Baxalta Collaboration Agreement, arrangement consideration of $61.0 million, which included the $33.0 million upfront payment and aggregate option payments for the four additional collaboration products 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 collaboration 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 Baxalta Collaboration 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. Baxalta s termination of its option to license M511 in December 2013 as well as its termination of M834 and the lapsing of its right to select additional products in February 2015 reduced the number of deliverables from seven 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. 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

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years. As of March 31, 2016, $19.5 million of revenue was deferred under this agreement, of which $9.8 million was included in current liabilities and $9.7 million was included in non-current liabilities in the consolidated balance sheet.

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.

Mylan Collaboration Agreement

On January 8, 2016, the Company and Mylan entered into a collaboration agreement, or the Mylan Collaboration Agreement, which became effective on February 9, 2016, pursuant to which the Company and Mylan agreed to collaborate exclusively, on a world-wide basis, to develop, manufacture and commercialize six of the Company s biosimilar candidates, including M834.

Under the terms of the Mylan Collaboration Agreement, Mylan agreed to pay the Company a non-refundable upfront payment of $45 million. In addition, the Company and Mylan share equally costs (including development, manufacturing, commercialization and certain legal expenses) and profits (losses) with respect to such product candidates, with Mylan funding its share of collaboration expenses incurred by the Company, in part, through up to six contingent milestone payments, totaling up to $200 million across the six product candidates.

For each product candidate other than M834, at a specified stage of early development, the Company and Mylan will each decide, based on the product candidate s development progress and commercial considerations, whether to continue the development, manufacture and commercialization of such product candidate under the collaboration or to terminate the collaboration with respect to such product candidate.

Under the Mylan Collaboration Agreement, the Company granted Mylan an exclusive license under the Company s intellectual property rights to develop, manufacture and commercialize the product candidates for all therapeutic indications, and Mylan granted the Company a co-exclusive license under Mylan s intellectual property rights for the Company to perform its development and manufacturing activities under the product work plans agreed by the parties, and to perform certain commercialization activities to be agreed by the joint steering committee for such product candidates if the Company exercises its co-commercialization option described below. The Company and Mylan established a joint steering committee consisting of an equal number of members from the Company and Mylan to oversee and manage the development, manufacture and commercialization of product candidates under the collaboration. Unless otherwise determined by the joint steering committee, it is anticipated that, in collaboration with the other party, (a) the Company will be primarily responsible for nonclinical development activities and initial clinical development activities for product candidates; additional (pivotal or Phase 3 equivalent) clinical development activities for M834; and regulatory activities for product candidates in the United States through regulatory approval; and (b) Mylan will be primarily responsible for additional (pivotal or Phase 3 equivalent) clinical development activities for product candidates other than M834; regulatory activities for the product candidates outside the United States; and regulatory activities for products in the United States after regulatory approval, when all marketing authorizations for the products in the United States will be transferred to Mylan. Mylan will commercialize any approved products, with the Company having an option to co-commercialize, in a supporting commercial role, any approved products in the United States. The joint steering committee is responsible for allocating responsibilities for other activities under the collaboration.

The term of the collaboration will continue throughout the development and commercialization of the product candidates, on a product-by-product and country-by-country basis, until development and commercialization by or on behalf of the Company and Mylan

pursuant to the Mylan Collaboration Agreement has ceased for a continuous period of two years for a given product candidate in a given country, unless earlier terminated by either party pursuant to the terms of the Mylan Collaboration Agreement.

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party will have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries. In the case of a termination for convenience, the other party will have the right to continue. If a termination occurs, the licenses granted to the non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that has the right to continue the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

In accordance with FASB s ASU No. 2009-13: Multiple-Deliverable Revenue Arrangements (Topic 615), the Company identified the deliverables at the inception of the Mylan Collaboration Agreement. The deliverables were determined to include (i) six development and product licenses, for each of M834 and the five additional collaboration products, (ii) research and development services related to each of M834 and the five additional collaboration products and (iii) the Company s participation in the joint steering committee. The Company has determined that each of the license deliverables does not have stand-alone value apart from the related research and development services deliverables because (1) there are no other vendors selling similar, competing products on a stand-alone basis, (2) Mylan does not have the contractual right to resell the license, and (3) Mylan 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 with respect to this arrangement separate units of accounting exist for each of the six licenses together with the related research and development services, or the combined units of accounting, as well as a

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separate unit of accounting for participation in the joint steering committee. VSOE and TPE were not available for the combined units of accounting. As such, the Company determined BESP for the combined units of accounting based on an analysis of its existing license arrangements and other available data and the nature and extent of the research and development services to be performed. BESP for the joint steering committee unit of accounting was based on market rates for similar services. At the inception of the Mylan Collaboration Agreement, total arrangement consideration of $45 million was allocated to each of the units of accounting based on the relative selling price method. Of the $45 million, $8.2 million was allocated to the M834 combined unit of accounting, between $5.7 million and $9.0 million to the five additional combined units of accounting, considering the products stage of development at the time the licenses were delivered. $51,000 was allocated to the joint steering committee unit of accounting. Changes in the key assumptions used to determine BESP for the units of accounting would not have a significant effect on the allocation of arrangement consideration.

At the inception of the Mylan Collaboration Agreement, the Company delivered development and product licenses for all six collaboration products and commenced revenue recognition of the arrangement consideration allocated the respective units of accounting. In addition, the Company began revenue recognition for the arrangement consideration allocated to the joint steering committee unit of accounting. The Company is recording revenue on a straight-line basis over the applicable performance period during which the research and development services are expected to be delivered, 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 the M834 unit of accounting is approximately four years, an average of approximately seven years for the additional five combined units of accounting and approximately eight years for the joint steering committee unit of accounting. As of March 31, 2016, of the $45 million in total arrangement consideration, $0.9 million was recognized as research and development revenue and $7.4 million was included in current liabilities and $36.7 million was included in non-current liabilities in the consolidated balance sheet.

As discussed above, the Mylan Collaboration Agreement became effective on February 9, 2016. Beginning on February 9, 2016, the Company shares collaboration expenses with Mylan and, as such, the net amount due from Mylan for its 50% share of collaboration expenses is recorded as a collaboration receivable in the consolidated balance sheet and a reduction in research and development and/or general and administrative expenses in the consolidated statement of operations and comprehensive loss, in accordance with the Company s policy, which is consistent with the nature of the cost reimbursement. Collaboration costs incurred by the Company are recorded as research and development expense and/or general and administrative expense, depending on the nature of the activities, as incurred.

As discussed above, Mylan will fund a portion of its 50% share of collaboration expenses through up to $200 million in contingent milestone payments across the six product candidates. The contingent payments will reduce the collaboration receivable balance and any unused portion of the contingent payment will be available to offset Mylan s 50% share of collaboration costs in future periods. If in a given year a contingent payment is not expected to be made by Mylan in a collaboration year and there is no balance available from a prior contingent payment balance as of the beginning of the collaboration year, the parties will reconcile total collaboration expenses on a semi-annual basis and Mylan will make a payment to the Company. For the quarter ended March 31, 2016, the Company reduced research and development expenses by $3.7 million and general and administrative expenses by $0.1 million, representing Mylan s 50% share of collaboration expenses.

6. Share-Based Payments

Share-Based Compensation

The following table summarizes share-based compensation expense (income) recorded in the three months ended March 31, 2016 and 2015 (in thousands):

Share-based compensation expense (income)	For the Three Months Ended March 31, 2016	For the Three Months Ended March 31, 2015
Outstanding employee and non-employee stock option grants	$ 2,758	$ 2,370
Outstanding restricted stock awards	1,958	(6,850)
Employee stock purchase plan	112	95
Total compensation expense (income)	$ 4,828	$ (4,385)

During the three months ended March 31, 2016, the Company granted 975,152 stock options, of which 774,302 were granted in connection with annual merit awards, 140,850 were granted to new hires and 60,000 were granted to members of our board of directors. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions are noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended March 31, 2016 and 2015 was $5.81 per option and $7.49 per option, respectively.

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

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	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Three Months Ended March 31, 2016	For the Three Months Ended March 31, 2015	For the Three Months Ended March 31, 2016	For the Three Months Ended March 31, 2015
Expected volatility	57%	61%	56%	61%
Expected dividends				
Expected life (years)	6.1	6.2	0.5	0.5
Risk-free interest rate	1.6%	1.8%	0.4%	0.1%

At March 31, 2016, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $18.3 million, net of estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.68 years.

During the three months ended March 31, 2016, the Company issued 52,116 shares of common stock to employees under the employee stock purchase plan, or ESPP, resulting in proceeds of approximately $0.6 million.

Restricted Stock Awards

The Company has also made awards of time-based and performance-based restricted common stock to its employees and officers. In the three months ended March 31, 2016, the Company awarded 387,321 shares of time-based restricted common stock to its employees and officers in connection with its annual merit grant. 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 its employees and officers. The performance-based restricted common stock was scheduled to vest upon FDA approval of the GLATOPA Abbreviated New Drug Application, or ANDA, on or before the performance deadline date of March 28, 2015 according to the following 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 that extended the performance deadline date to September 1, 2015 and provided for the forfeiture of 15% of the number of shares originally subject to each award on the 29th of each month, beginning March 29, 2015 until the shares vested or were forfeited in full. 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 is recognizing the compensation cost attributed to the modified awards as follows: the first 50% of the awards was expensed over the period 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 over the period beginning on March 11, 2015 and ending on April 16, 2016, the one year anniversary of FDA approval. Accordingly, approximately $9.1 million of stock compensation cost was recognized in the period between March 11, 2015 and March 31, 2016. As of March 31, 2016, the total remaining unrecognized compensation cost related to the nonvested portion of the modified awards amounted to $0.2 million, which will be recognized in the second quarter of 2016 as the performance condition was achieved in April 2016.

As of March 31, 2016, the total remaining unrecognized compensation cost related to all nonvested time-based and performance-based restricted stock awards amounted to $8.8 million, which is expected to be recognized over the weighted average remaining requisite service period of 2.23 years.

A summary of the status of nonvested shares of restricted stock as of March 31, 2016 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, 2016	761	$	14.61
Granted	387		10.83
Vested	(104)		14.11
Forfeited	(22)		14.07
Nonvested at March 31, 2016	1,022	$	13.24

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Nonvested shares of restricted stock that have time-based or both performance-based and time-based vesting conditions as of March 31, 2016 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	714
Performance-based and time-based	308
Nonvested at March 31, 2016	1,022

7. Equity Financings

In May 2014, the Company entered into an At-the-Market Equity Offering Sales Agreement, or the 2014 ATM Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which the Company was 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 its common stock under this facility. The offering was conducted by the Company pursuant to an effective 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. In the three months ended March 31, 2015, the Company sold approximately 2.6 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately $33.7 million. The Company concluded sales under the 2014 ATM Agreement in April 2015. Between October 2014 and April 2015, the Company sold approximately 5.4 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately $73.5 million.

In April 2015, the Company entered into a new ATM Agreement, or the 2015 ATM 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 the 2015 ATM Agreement. Sales of common stock under this facility have been 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. Between April 2015 and December 2015, the Company sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement, raising aggregate net proceeds of approximately $9.3 million. No shares were sold under the 2015 ATM Agreement in the three months ended March 31, 2016.

8. Commitments and Contingencies

The disclosures relating to the Company s operating lease obligations are included in its Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on February 26, 2016.

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.

M356-Related Litigation

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 the Company and Sandoz Inc. in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for M356. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, 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. In April 2015, Teva and Yeda filed an additional suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit filed in September 2014. In November 2015, Teva and Yeda filed a suit against the Company and Sandoz Inc. in the United States

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District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of M356 until the expiration of this patent. In December 2015, this suit was consolidated with the initial suit filed in September 2014. The Company and Sandoz Inc. have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of the COPAXONE 40 mg/mL patents. A pre-trial claim construction hearing was held in February 2016 and the trial is scheduled to begin in September 2016.

Enoxaparin Sodium Injection-related Litigation

On September 21, 2011, the Company and Sandoz Inc. sued Amphastar and Actavis, 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 and Actavis 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 and Actavis 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 Inc. to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded 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 July 2013, the District Court granted a motion by Amphastar and Actavis 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, which the CAFC denied in May 2014. On November 10, 2015, the CAFC affirmed the District Court summary judgment decision with respect to Actavis, reversed the District Court summary judgment decision with respect to Amphastar, and remanded the case against Amphastar to the District Court. On January 11, 2016, Amphastar filed a petition for rehearing by the CAFC, which was denied on February 17, 2016. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company is not successful in further prosecution or settlement of this action against Amphastar, and Amphastar is 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 Inc. have opposed.

On September 17, 2015, Amphastar filed a complaint against the Company and Sandoz Inc. in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz Inc. sought to prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, the Company and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting the court to reverse and review the District Court s grant of transfer. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and the Company intends to vigorously defend itself in this litigation.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against the Company and Sandoz Inc. in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic enoxaparin sodium injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz Inc. sought to

prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, the Company and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. Hearings on the motions were held in February 2016 on the motion to transfer and in April 2016 on the motion to dismiss, before a United States magistrate. These motions are pending before the magistrate and subject to review by the court. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and it intends to vigorously defend itself in this litigation.

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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, 2015.

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.

Overview

We are a biotechnology company focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for oncology and autoimmune disease.

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 expect to incur annual operating losses over the next several years as we advance our drug development portfolio. As of March 31, 2016, we had an accumulated deficit of approximately $476 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

GLATOPA® Generic COPAXONE® (glatiramer acetate injection) 20 mg/mL

On April 16, 2015, the FDA approved the ANDA for once-daily GLATOPA (glatiramer acetate injection) 20 mg/mL, a generic equivalent of once-daily COPAXONE® 20 mg/mL. GLATOPA is the first AP rated, substitutable generic equivalent of once-daily COPAXONE. Sandoz commenced sales of GLATOPA on June 18, 2015. Under our collaboration agreement with Sandoz AG, we earn 50% of contractually-defined profits on GLATOPA sales. For the three months ended March 31, 2016, we recorded $14.8 million in product revenues from Sandoz sales of GLATOPA.

GLATOPA was formerly referred to as M356. M356 now refers to our generic product candidate for three-times-weekly COPAXONE 40 mg/mL.

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

An ANDA with a Paragraph IV certification for our generic version of three-times-weekly COPAXONE 40 mg/mL, which was filed in February 2014, remains under review by the FDA. Our M356 formulation contains the same drug substance as GLATOPA, which we believe should help streamline the FDA review of the ANDA. To date, we are the only ANDA applicant for the three-times-weekly COPAXONE 40 mg/mL with an approved active pharmaceutical ingredient. If we are successful in our challenge of the patents related to 40 mg/mL COPAXONE, and based on the scheduled September 2016 trial start date and assuming customary patent litigation timelines, we believe M356 could be approved, following expiration regulatory exclusivity and of any 30-month stay, if applicable, and be on the market as early as the first quarter of 2017. In August 2015, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, instituted an Inter Partes Review, or IPR, filed by a third party challenging the validity of several of the same patents relating to 40 mg/mL COPAXONE that are the subject of our patent litigation. Although the IPR decision, which is expected in August 2016, is not binding on the court, we believe the outcome of this IPR could indirectly impact our M356 litigation and launch timelines.

Enoxaparin Sodium Injection Generic LOVENOX®

In June 2015, we and Sandoz amended our collaboration agreement relating to Enoxaparin Sodium Injection, replacing Sandoz obligation to pay us a royalty on net sales with an obligation to pay us 50% of contractually-defined profits on sales. The amendment, which was effective April 1, 2015, better aligned our interests in an evolving market that has seen continued pricing pressure.

Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended March 31, 2016, and therefore we recorded no revenue for Enoxaparin Sodium Injection in the period.

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Biosimilars

M923 Biosimilar HUMIRA® (adalimumab) Candidate

In connection with Baxter s internal corporate restructuring in July 2015, Baxter assigned all of its rights and obligations under the Baxter Collaboration Agreement to Baxalta. In light of the assignment, all references to Baxter and the Baxter Collaboration Agreement have been replaced with references to Baxalta and the Baxalta Collaboration Agreement, respectively. In January 2016, Baxalta and Shire plc announced an agreement under which Shire will combine with Baxalta, subject to shareholder and regulatory approvals.

In February 2015, Baxalta commenced a randomized, double-blind, single-dose study in healthy volunteers to compare the pharmacokinetics, safety, tolerability and immunogenicity of M923 versus EU-sourced and US-sourced HUMIRA. A total of 324 healthy volunteers were enrolled in the study. The volunteers were randomized 1:1:1 to receive a single 40 mg injection of M923, US-sourced HUMIRA, or EU-sourced HUMIRA. The volunteers were followed for 71 days. In December 2015, we announced that M923 met its primary endpoint in the study as the data demonstrated pharmacokinetic bioequivalence to the reference products. In October 2015, Baxalta initiated a pivotal clinical trial of M923 in patients with chronic plaque psoriasis. The trial is a randomized, double-blind, active control, multi-center, global study in patients with chronic plaque psoriasis to compare the safety, efficacy and immunogenicity of M923 with HUMIRA. In April 2016, we and Baxalta completed enrollment in the pivotal clinical trial for M923, and we expect to report data from this trial in the second half of 2016 or early 2017. Baxalta is planning to submit the first regulatory submission for marketing approval for M923 in 2017 and, subject to marketing approval and patent considerations, we expect first commercial launch to be as early as 2018.

M834 Biosimilar ORENCIA® (abatacept) Candidate

On January 8, 2016, we and Mylan entered into the Mylan Collaboration Agreement, which became effective on February 9, 2016, pursuant to which we and Mylan agreed to collaborate exclusively, on a world-wide basis, to develop, manufacture and commercialize six of our biosimilar candidates, including M834. Under the terms of the Mylan Collaboration Agreement, Mylan paid us a non-refundable upfront payment of $45 million in March 2016. In addition, we and Mylan will share equally costs, including development, manufacturing, commercialization and certain legal expenses, and profits (losses) across the six product candidates. We are in the final stages of preclinical and process development work and plan to initiate a clinical trial of M834 in the second half of 2016. We believe there is currently limited biosimilar competition for M834. Subject to development, marketing approval and patent considerations, we expect to be able to launch M834 in the 2020 timeframe to be able to be among the first biosimilars on the market for ORENCIA.

Other Biosimilar Candidates

Under our Mylan collaboration, we and Mylan are also developing five other biosimilar candidates from our portfolio, in addition to M834. We and Mylan will share equally costs and profits (losses) related to these earlier stage product candidates. We and Mylan will share development responsibilities across product candidates, and Mylan will lead commercialization of the products.

As of March 31, 2016, 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 2012, we initiated a Phase 1/2 clinical trial evaluating necuparanib in combination with ABRAXANE® (nab-paclitaxel) plus gemcitabine in patients with advanced metastatic pancreatic cancer. In October 2014, we successfully completed and reported top-line data from Part A, or Phase 1, of the trial, including determining a maximum tolerated dose of 5 mg/kg. In June 2015 at the American Society of Clinical Oncology, or ASCO, annual meeting, we reported more mature data from Phase 1, which continued to show acceptable safety and tolerability and encouraging signals of activity, including the following:

- Adding necuparanib to ABRAXANE and gemcitabine did not appear to increase the toxicity profile associated with ABRAXANE and gemcitabine alone.

- Of the 24 patients who received at least one dose of necuparanib in combination with ABRAXANE plus gemcitabine, the median overall survival was 14.2 months. Also, within a subset of 16 patients who completed one cycle and had at least one scan on treatment, the median overall survival was 15.3 months.

- Of the 15 patients treated with necuparanib in combination with ABRAXANE plus gemcitabine that completed Cycle 1 and had at least one follow-up measurement for CA19.9 (a biomarker predictive of long-term outcome and treatment response in pancreatic cancer), 93% had a greater than 50% decrease from baseline, and 100% had a greater than 20% decrease from baseline.

We believe the safety data and early signals of activity are encouraging and that 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. We believe these results, combined with nonclinical data in other cancer models, and necuparanib s differentiated, multi-targeted mechanism of action, suggest the possibility of combining necuparanib with other chemotherapy and targeted therapy standards of care in a variety of other tumor types. We continue to collect data from Phase 1 of the trial and plan to present final results at ASCO in June 2016.

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We continue to enroll patients in Part B, or Phase 2, of the trial, to evaluate the antitumor activity of necuparanib in combination with ABRAXANE plus gemcitabine, versus ABRAXANE plus gemcitabine alone. We expect data from this randomized trial to be available in the second half of 2017. Subject to successfully completing clinical trials and obtaining marketing approval, we believe necuparanib could be on the market in the 2020-2021 timeframe, or potentially earlier under Fast-Track Designation.

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 M281, our Anti-FcRn program, and M230, our SIF3 program. We have received regulatory clearance for M281 and plan to initiate a Phase 1 dosing study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 in healthy volunteers in the second quarter of 2016. We expect to initiate a clinical trial for M230 in 2017. We are currently identifying and pursuing potential collaboration opportunities to further develop and commercialize 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.

Equity Financings

In May 2014, we entered into an At-the-Market Equity Offering Sales Agreement, or the 2014 ATM Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal. We 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 was conducted by us pursuant to an effective shelf registration statement previously filed with the Securities and Exchange Commission (Reg. No. 333-188227) and a related prospectus supplement. We intend to use the net proceeds from this facility to advance our development pipeline and for general corporate purposes, including working capital. In the three months ended March 31, 2015, we sold approximately 2.6 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately $33.7 million. We concluded sales under the 2014 ATM Agreement in April 2015.

In April 2015, we entered into a new ATM Agreement, or the 2015 ATM Agreement, with Stifel, under which we are authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal. We are required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under the 2015 ATM Agreement. Sales of common stock under this facility are 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. From April 2015 through December 2015, we sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement, raising aggregate net proceeds of approximately $9.3 million. We did not sell any shares of common stock under the 2015 ATM Agreement in the three months ended March 31, 2016.

Results of Operations

Comparison of Three Months Ended March 31, 2016 and 2015

Collaboration Revenue

Collaboration revenue includes both product revenue and research and development revenue earned under our collaborative arrangements. Product revenue includes our contractually-defined profits and/or royalties earned on Sandoz sales of Enoxaparin Sodium Injection and GLATOPA.

GLATOPA® Generic COPAXONE® (glatiramer acetate injection) 20 mg/mL

Sandoz commenced sales of GLATOPA in the United States on June 18, 2015. We earn 50% of contractually-defined profits on Sandoz sales of GLATOPA. A portion of certain GLATOPA legal expenses, including any patent infringement damages, is deducted from our profits in proportion to our 50% profit sharing interest.

For the three months ended March 31, 2016, we recorded $14.8 million in product revenues from Sandoz sales of GLATOPA. We estimate that the number of prescriptions for GLATOPA represents nearly 35% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

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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 in the United States. However, Teva received marketing approval of its three-times-weekly COPAXONE 40 mg/mL in January 2014. Teva s three-times-weekly COPAXONE 40 mg/mL accounts for more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). 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 $4.0 billion in worldwide sales of COPAXONE (20 mg/mL and 40 mg/mL) in 2015, $3.2 billion of which was from the United States.

Enoxaparin Sodium Injection Generic LOVENOX®

Effective April 1, 2015, we began to earn 50% of contractually-defined profits on Sandoz sales of Enoxaparin Sodium Injection.

Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended March 31, 2016, and therefore we recorded no revenue for Enoxaparin Sodium Injection in the period. 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. The decrease in our product revenue was $2.7 million, or 100%, from the 2015 period to the 2016 period and was attributed to the change in our collaboration economics and lower unit sales driven by lower market share and lower prices in response to competitor pricing reductions on enoxaparin.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, we do not anticipate significant Enoxaparin Sodium Injection product revenue in the near future.

Research and Development Revenue

Research and development revenue generally consists of amounts earned by us under our collaborations for:

- Technical development, regulatory and commercial milestones under the Sandoz and Baxalta collaborations;

- Reimbursement of research and development services and reimbursement of development costs under our Sandoz and Baxalta collaborations; and

- Recognition of the arrangement consideration under our Baxalta and Mylan collaborations.

Research and development revenue was $5.1 million and $5.8 million for the three months ended March 31, 2016 and 2015, respectively. The decrease in research and development revenue of $0.7 million, or 12%, from the 2015 period to the 2016 period is due to lower reimbursable FTEs and external costs for M923 as Baxalta has clinical development responsibilities for that program by $1.6 million, partially offset by recognition of arrangement consideration of $0.9 million under our collaboration with Mylan.

We expect collaborative research and development revenue earned by us related to FTE and external expense reimbursement from Baxalta and Sandoz will fluctuate from quarter to quarter in 2016 depending on our research and development activities. We expect to recognize the arrangement consideration under our collaborations with Baxalta and Mylan ratably as revenue over our performance period with 2016 quarterly revenue amounts of approximately $2.4 million and $1.8 million, respectively.

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 nonclinical studies and clinical trials are conducted;

- costs of acquiring reference comparator materials and manufacturing nonclinical 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.

Beginning on February 9, 2016, under the Mylan Collaboration Agreement, we share collaboration expenses with Mylan. A portion of the net amount due from Mylan for its 50% share of collaboration expenses is recorded as a reduction in research and development expenses based on the nature of the cost reimbursement. Collaboration costs for development of the six biosimilar candidates under the collaboration incurred by us are recorded as research and development expense as incurred.

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Research and development expense for the three months ended March 31, 2016 was $28.8 million, compared with $22.7 million for the three months ended March 31, 2015. The increase of $6.1 million, or 27%, from the 2015 period to the 2016 period primarily resulted from increases of: $5.0 million in personnel-related expenses, primarily attributed to the reversal of prior period share-based compensation expense in the first quarter of 2015 associated with performance-based stock awards; $3.3 million in third-party research and process development costs primarily attributable to advance our biosimilar and novel therapeutic programs; $0.6 million in allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment; $0.6 million in clinical trial expenses as the necuparanib Phase 2 clinical trial continued to accrue patients; and $0.3 million in professional fees, driven mainly by temporary labor and regulatory filing fees. These increases were partially offset by a decrease of $3.7 million for Mylan s 50% share of collaboration costs under our cost-sharing collaboration agreement. In March 2015, we amended performance stock awards related to the GLATOPA ANDA approval to reduce the number of shares subject to the awards and to extend the performance period. Upon the amendment, stock compensation previously recognized was reversed and new stock compensation was recognized ratably based on the GLATOPA ANDA approval, which occurred in April 2015. 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 these performance grants. In the first quarter of 2016 research and development expense relating to the performance grants was $0.5 million.

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, 2016 and 2015. 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.

	Phase of Development as of March 31, 2016	Three Months Ended March 31, 2016	2015	Project Inception to March 31, 2016
External Costs Incurred by Product Candidate:				
GLATOPA and M356 Generic COPAXONE® (20 mg/mL and 40 mg/mL)	ANDAs filed(1)	$ 293	$ 147	$ 49,156
Necuparanib Oncology Product Candidate	Phase 2	3,056	2,100	39,931
Biosimilars	Various(2)(3)	4,450	3,896	81,633
Other novel therapeutic programs	Discovery/Nonclinical	2,599	2,147	
Internal Costs		18,359	14,459	
Total Research and Development Expenses(3)		$ 28,757	$ 22,749	

(1) On April 16, 2015, the FDA approved the ANDA for once-daily Glatopa. Sandoz launched Glatopa on June 18, 2015. The ANDA for M356 is under FDA review.

(2) Biosimilars include M923, a biosimilar candidate of HUMIRA® (adalimumab), M834, a biosimilar candidate of ORENCIA® (abatacept), as well as seven other biosimilar candidates. Enrollment in a Baxalta-initiated pivotal clinical trial of M923 in patients with chronic plaque psoriasis is complete. We are in the final stages of preclinical and process development work and plan to initiate a clinical trial of M834 in the second half of 2016. We expect to initiate a Phase 1 dosing study for M281 in the second quarter of 2016. Our other biosimilar candidates are in discovery and process development.

(3) As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately $3.7 million against research and development costs during the three months ended March 31, 2016.

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The increase in our necuparanib external expenditures of $1.0 million, or 46%, from the 2015 period to the 2016 period as we accrue more clinical sites and patients in our Phase 2 clinical trial. Our process development and contract research costs for the programs being developed under our collaboration with Mylan increased by $0.9 million from the 2015 period to the 2016 period. Our external expenditures for M923, in collaboration with Baxalta, decreased by $0.3 million from the 2015 period to the 2016 period as Baxalta has clinical development responsibility for that program. The increase of $0.5 million, 21%, in other novel therapeutics program external expenditures from the 2015 period to the 2016 period was due to increased nonclinical and process development to advance M281 and M230.

Our total operating expenses will be increasing in 2016 due to increased development costs in both our biosimilar and novel therapeutic development programs. The necuparanib Phase 2 study is accruing patients, and our two preclinical programs, M281 and M230, are advancing toward the clinic, with M281 targeted to enter the clinic in the second quarter of 2016 and M230 in 2017. Under the Mylan Collaboration Agreement, we have the operating responsibility for M834 through clinical development, which we expect to initiate in the second half of 2016.

Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

General and Administrative 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.

Beginning on February 9, 2016, under our collaboration agreement with Mylan we share collaboration expenses. A portion of the net amount due from Mylan for its 50% share of collaboration expenses under the cost-sharing arrangement is recorded as a reduction in general and administrative expenses based on the nature of the cost reimbursement. Collaboration costs for certain legal expenses for the six biosimilar candidates under the collaboration incurred by us are recorded as general and administrative expense as incurred.

General and administrative expense for the three months ended March 31, 2016 was $15.6 million, compared with $7.9 million for the three months ended March 31, 2015. The increase of $7.7 million, or 97%, from the 2015 period to the 2016 period was due to increases of: $6.3 million in personnel-related expenses primarily due to the reversal of prior period share-based compensation expense in the first quarter of 2015 associated with performance-based stock awards discussed under Research and Development Expense and $1.4 million in professional fees, driven mainly by increased legal and consulting fees. 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 $0.5 million and $0.1 million for the three months ended March 31, 2016 and 2015, respectively. The increase of $0.4 million from the 2015 period to the 2016 period was caused by higher average investment balances due to 2015 fundraising activities.

Other Income

Other income was $0.1 million for each of the three months ended March 31, 2016 and 2015 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, 2016, we had $362.8 million in cash, cash equivalents and marketable securities and $21.7 million in collaboration receivable, including $14.8 million for our profit share from GLATOPA sales in the first quarter of 2016. 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 Amphastar. Our funds at March 31, 2016 were primarily invested in senior debt of government-sponsored enterprises, commercial paper, overnight repurchase agreements, asset-backed securities, corporate debt securities and United States money market funds, directly or through managed funds, with remaining maturities of 24 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. We do not believe that our cash equivalents and marketable securities were subject to significant market risk at March 31, 2016.

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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 sales of Enoxaparin Sodium Injection and GLATOPA. Since our inception through March 31, 2016, we have received $638 million through private and public issuances of equity securities, including approximately $148 million in net proceeds from our May 2015 public offering of common stock and approximately $83 million under our At-the-Market Equity Offering Sales Agreements, or the ATM Agreements, with Stifel, Nicolaus & Company, Incorporated entered into in May 2014 and April 2015, respectively. As of March 31, 2016, we had received a cumulative total of $677 million under our collaborations with Sandoz, including $469 million in revenues on sales of Enoxaparin Sodium Injection and regulatory and commercial milestones related to that product and $78 million in revenues on sales of GLATOPA and regulatory and commercial milestones related to that product. In addition, we received $84 million under our collaboration with Baxalta, including a $33 million upfront payment, $32 million in reimbursement of research and development services and costs and $19 million in license and milestone payments. In March 2016, we received a $45 million upfront payment from Mylan under the Mylan Collaboration Agreement. We expect to receive $60 million of the total $200 million in contingent milestone payments from Mylan in 2016.

We expect to finance and manage our planned operating and expenditure requirements principally through our current cash, cash equivalents and marketable securities; capital raised through equity financings, including under our ATM Agreements; and future product revenues. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2018.

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Net cash provided by (used in) operating activities	$ 13,923	$ (28,576)
Net cash provided by investing activities	$ 13,489	$ 28,259
Net cash provided by financing activities	$ 558	$ 36,576
Net increase in cash and cash equivalents	$ 27,970	$ 36,259

Cash provided by (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 provided by operating activities was $13.9 million for the three months ended March 31, 2016 reflecting a net loss of $24 million, which was partially offset by non-cash charges of $2.2 million for depreciation and amortization of property, equipment and intangible assets, $4.8 million in shared-based compensation and $0.3 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of $30.7 million and resulted from: an increase in collaboration receivable of $0.6 million, driven by the collection of $17.8 million from Sandoz for fourth quarter 2015 GLATOPA and Enoxaparin Sodium Injection profit share, partially offset by the addition of a $14.8 million receivable from Sandoz for first quarter 2016 GLATOPA profit share, and a receivable of $3.8 million representing the net amount due from Mylan for its 50% share of collaboration expenses under the cost-sharing arrangement. Additional changes include: an increase in prepaid expenses and other current assets of $0.9 million due to the timing of advance payments to vendors for nonclinical studies and other services and the amortization of those payments; an increase in other long-term assets of $0.7 million for advance payments to vendors for agreements with service periods that extend beyond 12 months; a decrease in accounts payable of $0.7 million due to timing of vendor payments; a decrease in accrued expenses of $8.3 million primarily due to the timing of costs for process development services for our biosimilars and novel therapeutics programs; an increase in deferred revenue of $41.6 million, primarily due to receipt of a $45 million upfront payment from Mylan offset by revenue recognized

under the Baxalta and Mylan collaborations; a decrease in other current liabilities of $0.4 million primarily due to adjustments made to the short-term portions of the deferred rent and tenant improvement liabilities to reflect the extension of our 320 Bent Street lease agreement; and an increase in other long-term liabilities of $0.5 million to adjust the long-term portions of the deferred rent and tenant improvement liabilities for the extension of our 320 Bent Street lease agreement.

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 product 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 arrangement consideration under the Baxalta collaboration; and a decrease in other long-term liabilities of $0.2 million, of which $0.1 million represents the amortization of a

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job creation tax award and $0.1 million is the amortization of the tenant improvement allowance over the term of our 320 Bent Street facility lease.

Cash provided by investing activities

Cash provided by investing activities of $13.5 million for the three months ended March 31, 2016 includes cash inflows of $134.4 million from maturities of marketable securities offset by cash outflows of $119.4 million for purchases of marketable securities and $1.5 million for capital equipment and leasehold improvements.

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 financing activities

Cash provided by financing activities of $0.6 million for the three months ended March 31, 2016 consist solely of proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

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 2014 ATM Agreement and $2.9 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations including royalties payable to third parties, purchase commitments to various contractual research and manufacturing organizations 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, 2015, filed with the Securities and Exchange Commission on February 26, 2016 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.

Please refer 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, 2015 filed with the SEC on February 26, 2016.

Please refer to Revenue Recognition within Note 2 *Summary of Significant Accounting Policies* to the accompanying condensed consolidated financial statements for our discussion of our revenue recognition policy for our multiple element arrangements. The notes to our consolidated financial statements are contained in Part I, Item I of this Quarterly Report on Form 10-Q.

New Accounting Standards

Please refer to Note 2 *Summary of Significant Accounting Policies* to the accompanying condensed consolidated financial statements 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

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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, 2016, 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, 2016. 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, 2016, 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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

M356-Related Proceedings

On September 10, 2014, Teva and Yeda filed suit against us and Sandoz Inc. in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for M356. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and seeks declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015, Teva and Yeda filed an additional suit against us and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit filed in September 2014. In November 2015, Teva and Yeda filed a suit against us and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of M356 until the expiration of this patent. In December 2015, this suit was consolidated with the initial suit filed in September 2014. We and Sandoz Inc. have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of the COPAXONE 40 mg/mL patents. A pre-trial claim construction hearing was held in February 2016 and the trial is scheduled to begin in September 2016.

M834-Related Proceedings

On July 2, 2015, we filed a petition for Inter Partes Review, or IPR, with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, to challenge the validity of U.S. Patent No 8,476,239, a patent for ORENCIA owned by Bristol Myers Squibb (BMS). The PTAB issued a decision instituting the IPR proceedings in January 2016, and BMS filed for a rehearing by the full PTAB. Briefings by the parties will take place in 2016, with oral arguments scheduled for September 2016. A final opinion from the PTAB is expected in January 2017.

Enoxaparin Sodium Injection-Related Proceedings

On September 21, 2011, we and Sandoz Inc. sued Amphastar and Actavis 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 and Actavis 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 and Actavis 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 and Actavis appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded 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 July 2013, the District Court granted a motion by Amphastar and Actavis for summary judgment. We 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, which the CAFC denied in May 2014. On November 10, 2015, the CAFC affirmed the District Court summary judgment decision with respect to Actavis, reversed the District Court summary judgment decision with respect to Amphastar, and remanded the case against Amphastar to the District Court. On January 11, 2016, Amphastar filed a petition for rehearing by the CAFC, which was denied on February 17, 2016.

In the event that we are not successful in further prosecution or settlement of this action against Amphastar, and Amphastar is able to prove it 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 Inc. have opposed. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz Inc. will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against us and Sandoz Inc. in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz Inc. sought to prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, we and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed

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a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that court to reverse and review the District Court s grant of transfer. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourself in this litigation.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital (NGH) filed a class action suit against us and Sandoz Inc. in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic enoxaparin sodium injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz Inc. sought to prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, we and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. Hearings on the motions were held in February 2016 and April 2016, respectively. These motions are pending before the court. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourself in this litigation.

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Item 1A. RISK FACTORS

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

Risks Relating to Our Business

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

We have incurred significant losses since our inception in May 2001. At March 31, 2016, our accumulated deficit was $476.4 million. We may incur annual operating losses over the next several years as we expand our drug development, commercialization 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.

Even if M356 (our generic product candidate for three-times-weekly COPAXONE 40 mg/mL) is approved by the FDA, if Teva is successful in the current M356 ANDA-related patent infringement litigation, we and Sandoz may not launch M356 until the relevant COPAXONE patents expire, or we may have to pay significant damages if we launch before those patents expire and they are ultimately determined to be enforceable, valid and infringed. In addition, Teva may allege that we and Sandoz, in manufacturing and selling GLATOPA and/or M356, are infringing COPAXONE patents other than those at issue in our current M356 patent litigation. 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 decrease or halt GLATOPA sales or future M356 sales, if any, prior to a successful defense of such litigation or expiration of any such patents, and we and Sandoz may incur significant damages, reducing our profits and having a material adverse effect on our business.

Should Teva succeed in the current M356 ANDA-related patent infringement litigation, the launch of M356, if approved, may not occur until the patents expire, which would impair our ability to commercialize M356 and would harm our business and financial condition. If M356 is approved by the FDA prior to a decision in the patent infringement litigation, and we and Sandoz launch prior to such decision, we may not be able to utilize M356 product revenue until the conclusion of the litigation, and if Teva is ultimately successful, we and Sandoz may be liable for significant damages, including damages in excess of M356 product revenue, 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 M356 prior to a favorable outcome of the patent infringement litigation. 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 manufacturing and selling M356 and prohibiting the use of previously manufactured product for commercial sale until a favorable outcome of the litigation or the expiration of the patents.

Teva may also assert that our manufacturing and sale of M356 and/or GLATOPA infringes COPAXONE-related patents other than those at issue in the current M356 ANDA-related patent infringement litigation, including patents that may issue in the future. If so, we would expect to incur significant expenses under the terms of our collaboration with Sandoz to respond to and litigate these claims. Furthermore, we may be ordered to pay damages from the sale of M356 and/or GLATOPA if we are found to have infringed Teva s patents. Litigation concerning intellectual property and proprietary technologies can be protracted and expensive, and can distract management and other key personnel from running our business.

If other generic versions of the brand name drugs, or other biosimilars of the reference products, for which we have products or product candidates, including GLATOPA, M356, M923 and M834, are approved and successfully commercialized, our business would suffer.

Generic versions of our products can 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, Mylan

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announced that the FDA had accepted for filing its ANDAs for generic versions of COPAXONE and Synthon announced that it submitted ANDAs to the FDA for generic versions of COPAXONE. A launch of an additional generic version of COPAXONE could significantly reduce anticipated revenue from GLATOPA.

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, M923 and M834 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 alternative version of a name brand drug or reference product, such as COPAXONE or HUMIRA, is developed that has a new product profile and labeling, the alternative version of the product could significantly reduce the market share of the original name brand drug or reference product, and may cause a significant decline in sales or potential sales of our corresponding generic or biosimilar product.

Brand companies may develop alternative versions of a reference brand product as part of a life cycle extension strategy, and may obtain approval of the alternative version under a supplemental new drug application, for a drug, or biologics license application for a biologic. The alternative version may offer patients added benefits such as a more convenient form of administration or dosing regimen. Should the brand company succeed in obtaining an approval of an alternative 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, Teva s three-times-weekly COPAXONE 40 mg/mL, which launched in early 2014, accounts for more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). 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 alternative 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 alternative 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 name brand drug or reference product, such as COPAXONE, HUMIRA or ORENCIA, significantly declines, sales or potential sales of our corresponding 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.

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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. If we are unable to fund our obligations under our collaboration agreements, we may breach those agreements and our collaboration partners could terminate those agreements.

As of March 31, 2016, we had cash, cash equivalents and marketable securities totaling approximately $362.8 million. For the three months ended March 31, 2016, we had a net loss of $24 million and our operations provided cash of $13.9 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 GLATOPA;

- the successful commercialization of M356 and our other product candidates;

- the cost of advancing our product candidates and funding our development programs, including the costs of nonclinical and clinical studies and obtaining regulatory approvals;

- the receipt of milestone payments under our Baxalta Collaboration Agreement and continuation payments under our Mylan Collaboration Agreement;

- the continuation of activities under our Baxalta Collaboration Agreement without disruption following the combination of Baxalta and Shire plc;

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

- the cost of litigation, including with Amphastar 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 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 cost of acquiring and/or in-licensing 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, capital raised through our collaboration agreements and 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 2018. 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 may not be able to fund our obligations under one or more of our collaboration agreements, which could enable one or more of our collaborators to terminate their agreements with us, and therefore harm our business, financial condition and results of operations.

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 our biosimilar programs. In the future, we may also find it necessary to form similar

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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 arrangements may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own. These alliances may also 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 future GLATOPA product revenue is dependent on the continued successful commercialization of GLATOPA.

Our near-term ability to generate GLATOPA product revenue depends, in large part, on Sandoz continued ability to manufacture and commercialize GLATOPA, maintain pricing levels and market share and compete with Teva s three-times-weekly COPAXONE 40 mg/mL, which currently accounts for more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). Because GLATOPA is only a substitutable generic version of the once-daily 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. In addition, other competitors may in the future receive approval to market generic versions of the 20 mg/mL formulation of COPAXONE which would further impact our product revenue, which is based on a fifty-percent contractual profit share and, as a result, our business, including our near-term financial results and our ability to utilize GLATOPA revenue to fund future discovery and development programs, may suffer.

Any future 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 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 and profits from Enoxaparin Sodium Injection, and therefore our product revenue. Furthermore, other competitors may in the future receive approval to market generic enoxaparin products which would further impact our product revenue, which is based on a fifty-percent contractual profit share.

Due to these circumstances, the resulting market price for our Enoxaparin Sodium Injection product has substantially decreased and may decrease further. In the year ended December 31, 2015, we received $5.1 million in product revenue from Sandoz sales of Enoxaparin Sodium Injection, and we do not anticipate significant enoxaparin revenue in the near term. As a result, our business, including our near-term financial results, may suffer.

If our patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful or Amphastar or others are successful in anti-trust lawsuits against us relating to Enoxparin Sodium Injection, we may be liable for damages and our business may be materially harmed.

In the event that we are not successful in our continued prosecution of our suit against Amphastar and Amphastar is able to prove it suffered damages as a result of the preliminary injunction preventing it from selling its enoxaparin product in the United States 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 is successful in their motion to increase the amount of the security bond. Moreover, if Amphastar or others are successful in the anti-trust lawsuits against us for asserting our enoxaparin patent rights, they may be able to recover damages incurred as a result of enforcement of our patent rights, thereby negatively affecting our financial condition and results of operations.

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If efforts by manufacturers of brand name drugs and reference 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;

- seeking to restrict biosimilar commercialization options by making mandatory the optional right to adjudicate patent rights under Section 351(l) of the Biologics Price, Competition and Innovation Act or restricting access by biosimilar and generic applicants to the use of inter partes patent review proceedings at the U.S. Patent Office to challenge invalid biologic patent rights;

- 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 or to influence the adoption of policy with regard to the submission of 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, payers 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 federal reimbursement policies that do not promote adoption of biosimilars and interchangeable biologics;

- 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. For example, Teva Neuroscience, Inc. filed eight Citizen Petitions regarding GLATOPA, all of which have been denied, dismissed or withdrawn. Teva also sought 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. Teva may seek to file additional Citizen Petitions pertaining to the 40mg M356 ANDA, and seek to delay or prevent the FDA approval of the 40mg M356 ANDA, which could 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.

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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. 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, payers 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 positions.

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

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

Generic pharmaceutical biosimilars products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. The distribution of such products is also managed by pharmacy benefit management firms such as Express Scripts or CVS. These purchasers and pharmacy benefit management firms rely on competitive bidding, discounts and rebates across their purchasing arrangements. We also believe that we, in collaboration with commercial collaboration partners, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products to establish and maintain these relationships. The GPOs, pharmacy benefit management firms and other customers 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 products to certain market segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by GPOs, pharmacy benefit management firms, and customers, including wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. 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 payers. Acceptance of our products will be a function of our products being clinically useful, being cost effective and demonstrating superior or biosimilar 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 payer 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.

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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 development and commercialization of multiple pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.

As we advance an increasing number of 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 lease additional or alternative facilities and manage additional relationships with various collaborative partners, suppliers and other organizations. The market for laboratory and office facilities is highly competitive near our current location. If we are not successful in leasing additional or alternative space in our current area and have to move our facilities, the timing of our development programs could be disrupted.

In addition, 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:

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- 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 product candidate. If we are not able to obtain regulatory approval for the commercial sale of our M356 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. Our application for M356 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:

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- contains the same active ingredients as COPAXONE 40 mg/mL;

- is of the same dosage form, strength and route of administration as COPAXONE 40 mg/mL, and has the same labeling as the approved labeling for COPAXONE 40 mg/mL, with certain exceptions; and

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

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

Determination of therapeutic equivalence of M356 to COPAXONE 40 mg/mL will be based, in part, on our demonstration of the chemical equivalence of our versions to their respective reference listed drugs. The FDA may not agree that we have adequately characterized M356 or that M356 and COPAXONE 40 mg/mL are chemical equivalents. In that case, the FDA may require additional information, including nonclinical or clinical trial results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product s safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. We cannot predict whether M356 will receive FDA approval as therapeutically equivalent to COPAXONE 40 mg/mL.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of COPAXONE 40 mg/mL, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of M356 could be delayed or prevented or become more expensive. Delays in any part of the process or our inability to obtain regulatory approval for M356 could adversely affect our operating results by restricting or significantly delaying our introduction of M356.

Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of biosimilars has been enacted, the standards for determining biosimilarity and interchangeability for biosimilars are only just being implemented by the FDA. Therefore, substantial uncertainty remains about the potential value of our scientific approach and regulatory strategy for biosimilar development.

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 under the Biologics Price Competition and Innovation Act, or BPCI Act. For example, the FDA only recently issued 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 limited number of biosimilar applications have been accepted for review by the FDA, and one application has been approved for a biosimilar under the 351(k) pathway. The 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 substitutable at the retail pharmacy level without the intervention of a physician. The 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 biosimilarity and/or interchangeability, reduces the need for large scale clinical trials or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a reference 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 within the context of the biosimilar meeting and application review process. 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 nonclinical data may not be successful or may take longer than strategies that rely more heavily on clinical trial data.

The 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 pre-approval 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;

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- 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 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 legislation also creates the risk that, as brand and biosimilar companies gain experience with the 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 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 2016 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.

Our opportunity to realize value from the potential of the biosimilars market is difficult and challenging due to the significant scientific and development expertise required to develop and consistently manufacture complex protein biologics.

The market potential of biosimilars may be difficult to realize, in large part due to the challenges of successfully developing and manufacturing biosimilars. Biologics are therapeutic proteins and are much more complex and much more difficult to characterize and replicate than small-molecule, chemically synthesized drugs. Proteins tend to be 100 to 1000 times larger than conventional drugs, and are more susceptible to physical factors such as light, heat and agitation. They also have greater structural complexity. Protein molecules differ from one another primarily in their sequence of amino acids, which results in folding of the protein into a specific three-dimensional structure that determines its activity. Although the sequence of amino acids in a protein is consistently replicated, there are a number of changes that can occur following synthesis that create inherent variability. Chief among these is the glycosylation, or the attachment of sugars at certain amino acids. Glycosylation is critical to protein structure and function, and thoroughly characterizing and matching the glycosylation profile of a targeted biologic is essential and poses significant scientific and technical challenges. Furthermore, it is often challenging to consistently manufacture proteins with complex glycosylation profiles, especially on a commercial scale. Protein-based therapeutics are inherently heterogeneous and their structure is highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots of the same product produced at the same facility. The physicochemical complexity and size of biologics creates significant technical and scientific challenges in their replication as biosimilar products. Accordingly, the technical complexity involved and expertise and technical skill required to successfully develop and manufacture biosimilars poses significant barriers to entry. Any difficulties encountered in developing and producing, or any inability to develop and produce, biosimilars could adversely affect our business, financial condition and results of operations.

Even if we are able to obtain regulatory approval for our generic and biosimilar 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 corresponding name brand drug or reference product. If our generic or biosimilar products are not substitutable at the pharmacy level for their corresponding name brand drug or reference product, 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.

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If our nonclinical studies and clinical trials for our novel product candidates, including necuparanib, are not successful, we will not be able to obtain regulatory approval for commercial sale of those product 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.

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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 payers 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 payers, both in the United States and in foreign markets. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer 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 payer 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 payer. 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 payer will reimburse the use of any drug product incorporating new technology. Even when a payer determines that a product is eligible for reimbursement, the payer 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

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product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payers may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payers, 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 payers determine whether or not 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 proposed to group all non-interchangeable biosimilars of a reference biologic under a single, separate reimbursement code from the code for the reference biologic. CMS has not determined that interchangeable biologic products should be under the same reimbursement code as their reference biologics. If separate codes are instituted, the value of interchangeability could be reduced or significantly impaired. 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 payers 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 payers 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 payers.

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 Act 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

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profitability. In addition, litigation may prevent some or all of the legislation from taking effect. Consequently, there is uncertainty regarding implementation of the new legislation.

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

In some foreign countries, particularly the countries of the European Union, the pricing and/or reimbursement of prescription pharmaceuticals 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 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. Until the backlog of ANDA filings is reduced, 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.

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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.

While the United States Court of Appeals for the Federal Circuit ruled that the practice of our patented commercial manufacturing test by Amphaster did not fall within the scope of the safe harbor from patent infringement under federal patent law, 35 USC section 271(e)(1), Amphastar may challenge the ruling and there may remain uncertainty in the future regarding enforcement of our patents protecting manufacturing test methods. Additional information about this litigation is set forth under Part II, Item 3 *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

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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 2006 Sandoz Collaboration Agreement is important to our business. If Sandoz AG fails to adequately perform under this collaboration, or if we or Sandoz AG terminate all or a portion of this collaboration, the development and commercialization of some of our products and product candidates, including GLATOPA and M356, would be impacted, delayed or terminated and our business would be adversely affected.

Either we or Sandoz AG may terminate the 2006 Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. For some of the products, for any termination of the 2006 Sandoz Collaboration Agreement other than a termination by Sandoz AG 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 AG 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 AG terminates the 2006 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 AG 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 AG terminates due to our uncured breach or bankruptcy, Sandoz AG 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 2006 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 2006 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 agreement, we are dependent upon Sandoz AG to successfully continue to commercialize GLATOPA and are significantly dependent on Sandoz AG to successfully commercialize M356. We do not fully control Sandoz AG s commercialization activities or the resources it allocates to our products. While the 2006 Sandoz Collaboration Agreement contemplates joint decision making and alignment, our interests and Sandoz AG s interests may differ or conflict from time-to-time or we may disagree with Sandoz AG s level of effort

or resource allocation. Sandoz AG may internally prioritize our products differently than we do or it may fail to allocate sufficient resources to effectively or optimally commercialize our products and alignment may only be achieved through dispute resolution. If these events were to occur, our business would be adversely affected.

The Baxalta Collaboration Agreement is important to our business. If we or Baxalta fail to adequately perform under the Agreement, or if we or Baxalta 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 Baxalta Collaboration Agreement may be terminated:

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

- by Baxalta for its convenience;

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- by us in the event Baxalta 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 Baxalta Collaboration Agreement, in event of such a breach by Baxalta; 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 Baxalta Collaboration Agreement were terminated by Baxalta for convenience or if Baxalta elects to terminate the Baxalta Collaboration Agreement with respect to M923 in the specified time frame or if we terminate the Baxalta Collaboration Agreement for breach by Baxalta, 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 M923. Any alternative collaboration could 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 Baxalta terminates the Baxalta Collaboration Agreement due to our uncured breach, Baxalta 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 Baxalta Collaboration Agreement, we are dependent upon Baxalta to successfully conduct clinical trials for, and if approved, commercialize M923. We do not control Baxalta s administration of the clinical trials, commercialization activities or the resources it allocates to M923. Our interests and Baxalta s interests may differ or conflict from time to time, or we may disagree with Baxalta s level of effort or resource allocation. Baxalta 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.

The Mylan Collaboration Agreement is important to our business. If we or Mylan fail to adequately perform under the Agreement, or if we or Mylan terminate the Agreement, the development and commercialization of one or more of our biosimilar candidates, including M834, could be delayed or terminated and our business would be adversely affected.

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party shall have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries. In the case of a termination for convenience, the other party shall have the right to continue. If a termination occurs, the licenses granted to the non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that has the right to continue the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

If the Mylan Collaboration Agreement was terminated and we had the right to continue the development and commercialization of one or more terminated products, to fully exercise that right, 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 those products. Any alternative collaboration

could be on less favorable terms to us. In addition, we may need to seek additional financing to support the development and commercialization of any terminated products, or alternatively we may decide to discontinue one or more terminated products, which could have a material adverse effect on our business. If the Mylan Collaboration Agreement was terminated and Mylan had the right to continue the development and commercialization of one or more terminated products, we would have no influence or input into those activities.

Under the Mylan Collaboration Agreement, we are dependent upon Mylan to successfully perform its responsibilities and activities, including conducting clinical trials for certain products and leading the commercialization of products. We do not control Mylan s execution of its responsibilities, including commercialization activities, or the resources it allocates to our products. Our interests and Mylan s interests may differ or conflict from time to time, or we may disagree with Mylan s level of effort or resource allocation. Mylan may internally prioritize our products differently than we do or it may not allocate sufficient resources to effectively or optimally execute its responsibilities or activities. 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 and GLATOPA, sufficient quantities of such product must also be produced in order to satisfy demand. If these contract manufacturers are

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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, a change in senior executive management within, or a change in control of Sandoz, Baxalta or Mylan, or any future 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, 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. For example, in January 2016, Baxalta and Shire plc announced an agreement under which Shire will combine with Baxalta, subject to shareholder and regulatory approvals. Following such combination, we will become dependent on Shire plc to allocate resources for future development and commercialization of M923, and there could be changes or delays in the timing of the M923 program in connection with the integration of Baxalta and Shire plc.

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

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- 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:

- 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 GLATOPA to sustain profitable sales or market share that meet expectations of securities analysts;

- other adverse FDA decisions relating to our GLATOPA or M356 programs, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M356 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, Amphastar in our patent litigation suits, a settlement related to any case; or a decision in favor of Amphastar or others in the anti-trust suits filed against us;

- announcements by other companies regarding the status of their ANDAs for generic versions of COPAXONE;

- FDA approval of other companies ANDAs for generic versions of COPAXONE;

- marketing and/or launch of other companies generic versions of 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 such as M356 or biosimilars such as M923 or M834;

- 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 sale of the product or to meet market demand;

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

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

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

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

- termination of any of our 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 Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
*10.1	Non-Employee Director Compensation Summary				
*+10.2	Collaboration Agreement, by and between Momenta Pharmaceuticals, Inc. and Mylan Ireland Limited, executed as of January 8, 2016.				
*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.

\+ Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

The following materials from the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at March 31, 2016 and December 31, 2015, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2016 and 2015, (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015, 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 6, 2016

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

Date: May 6, 2016

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