

# MOMENTA PHARMACEUTICALS INC

## **FORM 10-Q** (Quarterly Report)

Filed 08/05/16 for the Period Ending 06/30/16

Address	675 WEST KENDALL STREET CAMBRIDGE, MA 02142
Telephone	617 491-9700
CIK	0001235010
Symbol	MNTA
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(MARK ONE)

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

For the quarterly period ended June 30, 2016

or

**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**

(State or Other Jurisdiction of  
Incorporation or Organization)

**04-3561634**

(I.R.S. Employer Identification No.)

**675 West Kendall Street, Cambridge, MA**

(Address of Principal Executive Offices)

**02142**

(Zip Code)

**(617) 491-9700**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of July 29, 2016, there were 70,744,044 shares of the registrant's common stock, par value \$0.0001 per share, outstanding.

---

---

MOMENTA PHARMACEUTICALS, INC.

	<u>Page</u>
<a href="#"><b>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</b></a>	3
<a href="#"><b>PART I. FINANCIAL INFORMATION</b></a>	4
<a href="#">Item 1. <u>Financial Statements (unaudited)</u></a>	4
<a href="#">    <u>Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015</u></a>	4
<a href="#">    <u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2016 and 2015</u></a>	5
<a href="#">    <u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2016 and 2015</u></a>	6
<a href="#">    <u>Notes to Unaudited, Condensed Consolidated Financial Statements</u></a>	7
<a href="#">Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a>	25
<a href="#">Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u></a>	36
<a href="#">Item 4. <u>Controls and Procedures</u></a>	37
<a href="#"><b>PART II. OTHER INFORMATION</b></a>	38
<a href="#">Item 1. <u>Legal Proceedings</u></a>	38
<a href="#">Item 1A. <u>Risk Factors</u></a>	39
<a href="#">Item 6. <u>Exhibits</u></a>	62
<a href="#"><b>SIGNATURES</b></a>	63

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

## 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,” “approach,” “believe,” “can,” “contemplate,” “continue,” “could,” “ensure,” “estimate,” “expect,” “intend,” “likely,” “may,” “might,” “objective,” “opportunity,” “plan,” “potential”, “predict,” “project,” “pursue,” “seek,” “schedule,” “should,” “strategy,” “target,” “typically,” “will,” “would,” 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 and product candidates; development, manufacture and commercialization of our products and product candidates; efforts to seek and manage relationships with collaboration partners, including without limitation for our biosimilar programs; the timing of clinical trials and the availability of results; the timing of launch of products and product candidates; GLATOPA® (glatiramer acetate injection) market share, market potential and product revenues; M356 launch timing and market potential; the timing, merits, strategy, impact and outcome of litigation and legal proceedings; collaboration revenues and research and development revenues; manufacturing, including but not limited to our intent to rely on contract manufacturers; regulatory filings, reviews and approvals; the sufficiency of our current capital resources and projected milestone payments and product revenues for future operations; our future financial position, including but not limited to our future operating losses, our potential future profitability, our future expenses, the composition and mix of our cash, cash equivalents and marketable securities, our future revenues and our future liabilities; our funding transactions and our intended uses of proceeds thereof; Enoxaparin Sodium Injection product revenues and market potential; product candidate development costs; receipt of contingent milestone payments; accounting policies, estimates and judgments; our estimates regarding the fair value of our investment portfolio; the market risk of our cash equivalents, marketable securities, and derivative, foreign currency and other financial instruments; rights, obligations, terms, conditions and allocation of responsibilities and decisionmaking under our collaboration agreements; the regulatory pathway for biosimilars; our strategy, including but not limited to our regulatory strategy, and scientific approach; the importance of key customer distribution arrangements; market potential and acceptance of our products and product candidates; future capital requirements; reliance on our collaboration partners and other third parties; the competitive landscape; changes in, impact of and compliance with laws, rules and regulations; product reimbursement policies and trends; pricing of pharmaceutical products, including our products and product candidates; our stock price; our intellectual property strategy and position; sufficiency of insurance; attracting and retaining qualified personnel; our internal controls and procedures; acquisitions or investments in companies, products and technologies; entering into license arrangements; marketing plans; financing our planned operating and capital expenditure; leasing additional facilities; materials used in our research and development; issuance of shares to satisfy the Parivid milestone payment; unblinding the data from the Phase 2 trial of necuparanib, confirming the futility analysis of necuparanib, and determining next steps for the necuparanib program; dilution; royalty rates; and vesting of equity awards.

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

## PART I. FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS

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

	June 30, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 88,224	\$ 61,461
Marketable securities	248,692	288,583
Collaboration receivable	35,862	21,185
Prepaid expenses and other current assets	4,085	3,479
Total current assets	376,863	374,708
Property and equipment, net	21,796	21,896
Restricted cash	20,660	20,660
Intangible assets, net	5,498	3,528
Other long-term assets	936	248
<b>Total assets</b>	<b>\$ 425,753</b>	<b>\$ 421,040</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 12,139	\$ 4,053
Accrued expenses	15,688	24,499
Deferred revenue	17,144	9,770
Other current liabilities	122	460
Total current liabilities	45,093	38,782
Deferred revenue, net of current portion	42,189	12,213
Other long-term liabilities	3,832	69
<b>Total liabilities</b>	<b>91,114</b>	<b>51,064</b>
Commitments and contingencies (Note 8)		
<b>Stockholders' Equity:</b>		
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, 70,921 shares issued and 70,692 shares outstanding at June 30, 2016 and 69,077 shares issued and 68,958 outstanding at December 31, 2015	7	7
Additional paid-in capital	834,829	824,385
Accumulated other comprehensive income	286	4
Accumulated deficit	(497,370)	(452,372)
Treasury stock, at cost, 229 shares at June 30, 2016 and 119 shares at December 31, 2015	(3,113)	(2,048)
<b>Total stockholders' equity</b>	<b>334,639</b>	<b>369,976</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 425,753</b>	<b>\$ 421,040</b>

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Collaboration revenues:</b>				
Product revenue	\$ 20,692	\$ 19,305	\$ 35,492	\$ 22,027
Research and development revenue	5,738	25,595	10,788	31,436
Total collaboration revenue	26,430	44,900	46,280	53,463
<b>Operating expenses:</b>				
Research and development*	33,173	33,983	61,930	56,733
General and administrative*	14,896	13,329	30,543	21,219
Total operating expenses	48,069	47,312	92,473	77,952
Operating loss	(21,639)	(2,412)	(46,193)	(24,489)
<b>Other income:</b>				
Interest income	591	122	1,071	234
Other income	62	68	124	156
Total other income	653	190	1,195	390
Net loss	\$ (20,986)	\$ (2,222)	\$ (44,998)	\$ (24,099)
Basic and diluted net loss per share	\$ (0.31)	\$ (0.04)	\$ (0.66)	\$ (0.41)
Weighted average shares used in computing basic and diluted net loss per share	68,532	61,680	68,409	58,106
<b>Comprehensive loss:</b>				
Net loss	\$ (20,986)	\$ (2,222)	\$ (44,998)	\$ (24,099)
Net unrealized holding gains on available-for-sale marketable securities	149	18	282	36
Comprehensive loss	\$ (20,837)	\$ (2,204)	\$ (44,716)	\$ (24,063)

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

Research and development	\$ 2,319	\$ 3,125	\$ 4,384	\$ 910
General and administrative	\$ 2,670	\$ 3,491	\$ 5,433	\$ 1,321

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

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

	Six Months Ended June 30,	
	2016	2015
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (44,998)	\$ (24,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash items:		
Depreciation and amortization	3,804	3,963
Share-based compensation expense	9,817	2,231
Amortization of premium on investments	429	563
Amortization of intangibles	898	530
Changes in operating assets and liabilities:		
Collaboration receivable	(14,677)	(25,791)
Prepaid expenses and other current assets	(606)	934
Other long-term assets	(688)	—
Accounts payable	8,086	(5,538)
Accrued expenses	(8,811)	6,997
Deferred revenue	37,350	(4,130)
Other current liabilities	(338)	61
Other long-term liabilities	895	(301)
Net cash used in operating activities	(8,839)	(44,580)
<b>Cash Flows from Investing Activities:</b>		
Purchases of property and equipment	(3,704)	(1,360)
Purchases of marketable securities	(221,982)	(68,040)
Proceeds from maturities of marketable securities	261,726	92,334
Net cash provided by investing activities	36,040	22,934
<b>Cash Flows from Financing Activities:</b>		
Proceeds from public offering of common stock, net of issuance costs	—	148,439
Net proceeds from issuance of common stock under ATM facilities	—	64,503
Proceeds from issuance of common stock under stock plans	627	21,210
Repurchase of common stock pursuant to share surrender	(1,065)	(2,048)
Net cash (used in) provided by financing activities	(438)	232,104
Increase in cash and cash equivalents	26,763	210,458
Cash and cash equivalents, beginning of period	61,461	61,349
Cash and cash equivalents, end of period	\$ 88,224	\$ 271,807
<b>Non-Cash Investing Activity:</b>		
Intangible asset and shares due to Parivid	\$ 2,868	\$ —

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

**MOMENTA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED, CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. The Company**

***Business***

Momenta Pharmaceuticals, Inc., 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 June 30, 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 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.

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

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 and six months ended June 30, 2016 and 2015 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Weighted-average anti-dilutive shares related to:				
Outstanding stock options	7,156	3,814	6,908	5,167
Restricted stock awards	1,323	501	829	593

Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per share is the same for the three and six months ended June 30, 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, 1,430,460 performance-based restricted common stock awards that were granted between April and June of 2016 had not vested as of June 30, 2016, and were excluded from diluted shares outstanding as the vesting conditions for the awards, discussed further in Note 6 “*Share-Based Payments - Restricted Stock Awards*,” had not been met as of June 30, 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 June 30, 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 June 30, 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	\$ 84,682	\$ 59,682	\$ 25,000	\$ —
Marketable securities:				
Corporate debt securities	40,602	—	40,602	—
Commercial paper obligations	94,376	—	94,376	—
Asset-backed securities	113,714	—	113,714	—
<b>Total</b>	<b>\$ 333,374</b>	<b>\$ 59,682</b>	<b>\$ 273,692</b>	<b>\$ —</b>

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	—
<b>Total</b>	<b>\$ 342,660</b>	<b>\$ 30,077</b>	<b>\$ 312,583</b>	<b>\$ —</b>

[Table of Contents](#)

There have been no impairments of the Company's assets measured and carried at fair value during the three and six months ended June 30, 2016 and 2015. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three and six months ended June 30, 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.

**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 June 30, 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 June 30, 2016 and December 31, 2015 (in thousands):

<b>As of June 30, 2016</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Cash, money market funds and overnight repurchase agreements	\$ 88,224	\$ —	\$ —	\$ 88,224
Corporate debt securities due in one year or less	40,611	—	(9)	40,602
Commercial paper obligations due in one year or less	94,150	226	—	94,376
Asset-backed securities due in one year or less	113,645	71	(2)	113,714
<b>Total</b>	<b>\$ 336,630</b>	<b>\$ 297</b>	<b>\$ (11)</b>	<b>\$ 336,916</b>
Reported as:				
Cash and cash equivalents	\$ 88,224	\$ —	\$ —	\$ 88,224
Marketable securities	248,406	297	(11)	248,692
<b>Total</b>	<b>\$ 336,630</b>	<b>\$ 297</b>	<b>\$ (11)</b>	<b>\$ 336,916</b>

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
<b>Total</b>	<b>\$ 350,040</b>	<b>\$ 126</b>	<b>\$ (122)</b>	<b>\$ 350,044</b>
<b>Reported as:</b>				
Cash and cash equivalents	\$ 61,461	\$ —	\$ —	\$ 61,461
Marketable securities	288,579	126	(122)	288,583
<b>Total</b>	<b>\$ 350,040</b>	<b>\$ 126</b>	<b>\$ (122)</b>	<b>\$ 350,044</b>

At June 30, 2016 and December 31, 2015, the Company held 19 and 66 marketable securities, respectively, that were in a continuous unrealized loss position for less than one year. At June 30, 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 June 30, 2016 and December 31, 2015 (in thousands):

	As of June 30, 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	\$ 38,701	\$ (9)	\$ 70,657	\$ (84)
Commercial paper obligations due in one year or less	\$ —	\$ —	\$ 33,734	\$ (8)
Asset-backed securities due in one year or less	\$ 11,756	\$ (2)	\$ 61,337	\$ (30)

### **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 No. 2014-9, 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 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, Balance Sheet Classification of Deferred Taxes (Topic 740). 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 February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the impact of adopting this new accounting standard on its financial position and results of operations.

In March 2016, the FASB issued ASU No. 2016-8, 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. 2014-9.

In March 2016, the FASB issued ASU No. 2016-9, 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**

In April 2007, the Company entered into an asset purchase agreement with Parivid, LLC, or Parivid, a provider of data integration and analysis services, and S. Raguram, the principal owner of Parivid. Pursuant to the asset purchase agreement, the Company acquired certain of the assets and assumed certain of the liabilities of Parivid related to the acquired assets in exchange for \$2.5 million in cash paid at closing and certain contingent milestone payments in a combination of cash and/or stock in the manner and on the terms and conditions set forth in the asset purchase agreement if certain milestones are achieved within fifteen years of the date of the asset purchase agreement. The asset purchase agreement was amended in August 2009 and in July 2011. Between 2009 and 2011, the Company made cash payments to Parivid of \$7.3 million and issued 91,576 shares of its common stock valued at \$10.92 per share to Parivid in satisfaction of certain Enoxaparin Sodium Injection-related milestones under the amended asset purchase agreement. As of June 18, 2016, the one-year anniversary of the commercial launch of GLATOPA, GLATOPA remained the sole generic COPAXONE 20 mg/mL product on the U.S. market, triggering the final milestone payment under the amended asset purchase agreement. In connection with the final milestone, in June 2016, the Company recorded an intangible asset and a non-current liability of \$2.9 million. The Company plans to issue 265,605 shares of its common stock to Parivid in the third quarter of 2016 to satisfy the GLATOPA-related milestone.

Intangible assets consist solely of the core developed technology assets acquired from Parivid. The intangible developed technology assets are being amortized over the estimated useful life of the GLATOPA developed technology of approximately six years. The Company will amortize its intangibles through June of 2021. As of June 30, 2016 and December 31, 2015, intangible assets, net of accumulated amortization, were as follows (in thousands):

	June 30, 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	\$ 13,295	\$ (7,797)	\$ 5,498	\$ 10,427	\$ (6,899)	\$ 3,528

The weighted-average amortization period for the Company's intangible assets is six 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 \$0.6 million and \$0.3 million for the three months ended June 30, 2016 and 2015, respectively. Amortization expense was approximately \$0.9 million and \$0.5 million for the six months ended June 30, 2016 and 2015, respectively.

The Company expects to incur amortization expense of approximately \$1.1 million per year for each of the next five years.

#### 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.

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 February 2027 and during any lease term extensions and therefore is classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

#### 5. Collaboration and License Agreements

At June 30, 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.

	<b>For the Three Months Ended June 30, 2016</b>				
	<b>2003 Sandoz Collaboration Agreement</b>	<b>2006 Sandoz Collaboration Agreement</b>	<b>Baxalta Collaboration Agreement</b>	<b>Mylan Collaboration Agreement (1)</b>	<b>Total Collaborations</b>
<b>Collaboration revenues:</b>					
Product revenue	\$ —	\$ 20,692	\$ —	\$ —	\$ 20,692
<b>Research and development revenue:</b>					
Recognition of upfront payments and license payments	—	—	2,442	1,843	4,285
Research and development services and external costs under Sandoz and Baxalta collaborations	61	739	653	—	1,453
<b>Total research and development revenue</b>	<b>\$ 61</b>	<b>\$ 739</b>	<b>\$ 3,095</b>	<b>\$ 1,843</b>	<b>\$ 5,738</b>
<b>Total collaboration revenues</b>	<b>\$ 61</b>	<b>\$ 21,431</b>	<b>\$ 3,095</b>	<b>\$ 1,843</b>	<b>\$ 26,430</b>
<b>Operating expenses:</b>					
Research and development expense(2)(3)	\$ —	\$ 1,001	\$ 164	\$ 8,408	\$ 9,573
General and administrative expense(2)(3)	\$ 469	\$ 180	\$ 42	\$ 452	\$ 1,143
<b>Total operating expenses</b>	<b>\$ 469</b>	<b>\$ 1,181</b>	<b>\$ 206</b>	<b>\$ 8,860</b>	<b>\$ 10,716</b>

	<b>For the Three Months Ended June 30, 2015</b>			
	<b>2003 Sandoz Collaboration Agreement</b>	<b>2006 Sandoz Collaboration Agreement</b>	<b>Baxalta Collaboration Agreement</b>	<b>Total Collaborations</b>
<b>Collaboration revenues:</b>				
Product revenue	\$ 121	\$ 19,184	\$ —	\$ 19,305
<b>Research and development revenue:</b>				
Milestone payments	—	20,000	—	20,000
Recognition of upfront payments and license payments	—	—	2,442	2,442
Research and development services and external costs	130	794	2,229	3,153
<b>Total research and development revenue</b>	<b>\$ 130</b>	<b>\$ 20,794</b>	<b>\$ 4,671</b>	<b>\$ 25,595</b>
<b>Total collaboration revenues</b>	<b>\$ 251</b>	<b>\$ 39,978</b>	<b>\$ 4,671</b>	<b>\$ 44,900</b>
<b>Operating expenses:</b>				
Research and development expense(2)	\$ 177	\$ 282	\$ 517	\$ 976
General and administrative expense(2)	\$ 112	\$ 33	\$ 227	\$ 372
<b>Total operating expenses</b>	<b>\$ 289</b>	<b>\$ 315</b>	<b>\$ 744</b>	<b>\$ 1,348</b>

- (1) The Mylan Collaboration Agreement, as defined below, became effective on February 9, 2016.
- (2) The amounts generally 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 \$8.4 million against research and development costs and \$0.5 million against general and administrative costs during the three months ended June 30, 2016. During the six months ended June 30, 2016, the Company offset approximately \$12.1 million against research and development costs and \$0.6 million against general and administrative costs.

<b>For the Six Months Ended June 30, 2016</b>					
	<b>2003 Sandoz Collaboration Agreement</b>	<b>2006 Sandoz Collaboration Agreement</b>	<b>Baxalta Collaboration Agreement</b>	<b>Mylan Collaboration Agreement (1)</b>	<b>Total Collaborations</b>
<b>Collaboration revenues:</b>					
Product revenue	\$ —	\$ 35,492	\$ —	\$ —	\$ 35,492
<b>Research and development revenue:</b>					
Recognition of upfront payments and license payments	—	—	4,884	2,765	7,649
Research and development services and external costs under Sandoz and Baxalta collaborations	138	1,384	1,617	—	3,139
Total research and development revenue	\$ 138	\$ 1,384	\$ 6,501	\$ 2,765	\$ 10,788
<b>Total collaboration revenues</b>	<b>\$ 138</b>	<b>\$ 36,876</b>	<b>\$ 6,501</b>	<b>\$ 2,765</b>	<b>\$ 46,280</b>
<b>Operating expenses:</b>					
Research and development expense(2)(3)	\$ —	\$ 1,294	\$ 478	\$ 12,088	\$ 13,860
General and administrative expense(2)(3)	\$ 1,533	\$ 275	\$ 324	\$ 564	\$ 2,696
<b>Total operating expenses</b>	<b>\$ 1,533</b>	<b>\$ 1,569</b>	<b>\$ 802</b>	<b>\$ 12,652</b>	<b>\$ 16,556</b>

<b>For the Six Months Ended June 30, 2015</b>					
	<b>2003 Sandoz Collaboration Agreement</b>	<b>2006 Sandoz Collaboration Agreement</b>	<b>Baxalta Collaboration Agreement</b>	<b>Total Collaborations</b>	
<b>Collaboration revenues:</b>					
Product revenue	\$ 2,843	\$ 19,184	\$ —	\$ 22,027	
<b>Research and development revenue:</b>					
Milestone payments	—	20,000	—	20,000	
Recognition of upfront payments and license payments	—	—	4,130	4,130	
Research and development services and external costs	381	1,478	5,447	7,306	
Total research and development revenue	\$ 381	\$ 21,478	\$ 9,577	\$ 31,436	
<b>Total collaboration revenues</b>	<b>\$ 3,224</b>	<b>\$ 40,662</b>	<b>\$ 9,577</b>	<b>\$ 53,463</b>	
<b>Operating expenses:</b>					
Research and development expense(2)	\$ 208	\$ 429	\$ 1,125	\$ 1,762	
General and administrative expense(2)	\$ 222	\$ 110	\$ 633	\$ 965	
<b>Total operating expenses</b>	<b>\$ 430</b>	<b>\$ 539</b>	<b>\$ 1,758</b>	<b>\$ 2,727</b>	

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

(2) The amounts generally 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 \$8.4 million against research and development costs and \$0.5 million against general and administrative costs during the three months ended June 30, 2016. During the six months ended June 30, 2016, the Company offset approximately \$12.1 million against research and development costs and \$0.6 million against general and administrative costs.

### **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 and six months ended June 30, 2016, and therefore the Company did not record product revenue for Enoxaparin Sodium Injection in those periods. See “Product revenue” in the table above for product revenue earned by the Company in the three and six months ended June 30, 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.

### **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 borne 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 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 June 30, 2016, the Company recorded \$20.7 million in product revenues from Sandoz’ sales of GLATOPA. For the six months ended June 30, 2016, the Company recorded \$35.5 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. On June 3, 2016, Baxalta Incorporated and Shire plc, or Shire, announced the completion of the combination of Baxalta Incorporated and Shire. As a result of the combination, Baxalta Incorporated is a wholly-owned subsidiary of Shire.

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.

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 Baxalta Collaboration 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. While under the Baxalta Collaboration Agreement, 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 and expense of the clinical trial program required for regulatory approval. To date, the expenditures by Baxalta in the clinical trial program may have significantly reduced, or potentially eliminated, this potential milestone payment.

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 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 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 years. As of June 30, 2016, \$17.1 million of revenue was deferred under this agreement, of which \$9.8 million was included in current liabilities and \$7.3 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 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, and \$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 June 30, 2016, of the \$45 million in total arrangement consideration, \$2.7 million was recognized as research and development revenue and \$7.4 million was included in current liabilities and \$34.9 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, in part, 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 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 six months ended June 30, 2016, the Company reduced research and development expenses by \$12.1 million and general and administrative expenses by \$0.6 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 and six months ended June 30, 2016 and 2015 (in thousands):

Share-based compensation expense (income)	For the Three Months Ended June 30, 2016	For the Three Months Ended June 30, 2015	For the Six Months Ended June 30, 2016	For the Six Months Ended June 30, 2015
Outstanding employee and non-employee stock option grants	\$ 2,372	\$ 2,647	\$ 5,130	\$ 5,016
Outstanding restricted stock awards	2,514	3,877	4,472	(2,973)
Employee stock purchase plan	103	92	215	188
Total compensation expense	\$ 4,989	\$ 6,616	\$ 9,817	\$ 2,231

During the six months ended June 30, 2016, the Company granted 1,230,202 stock options, of which 774,302 were granted in connection with annual merit awards, 269,900 were granted to new hires and 55,000 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 June 30, 2016 and 2015 was \$5.85 per option and \$11.00 per option, respectively. The weighted average grant date fair value of option awards granted during the six months ended June 30, 2016 and 2015 was \$5.82 per option and \$7.84 per option, respectively.

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

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Three Months Ended June 30, 2016	For the Three Months Ended June 30, 2015	For the Three Months Ended June 30, 2016	For the Three Months Ended June 30, 2015
Expected volatility	62%	54%	57%	61%
Expected dividends	—	—	—	—
Expected life (years)	5.8	5.4	0.5	0.5
Risk-free interest rate	1.5%	2.1%	0.5%	0.1%

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Six Months Ended June 30, 2016	For the Six Months Ended June 30, 2015	For the Six Months Ended June 30, 2016	For the Six Months Ended June 30, 2015
Expected volatility	58%	60%	56%	61%
Expected dividends	—	—	—	—
Expected life (years)	6.1	6.1	0.5	0.5
Risk-free interest rate	1.5%	1.8%	0.4%	0.1%

At June 30, 2016, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to \$16.3 million, net of estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.7 years.

During the six months ended June 30, 2016, the Company issued 52,116 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 six months ended June 30, 2016, the Company awarded 434,821 shares of time-based restricted common stock to its employees and officers. 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 April and June of 2016, the Company awarded 1,535,160 shares of performance-based restricted common stock to employees and officers. The vesting of the shares is subject to achieving up to two of three possible company-wide milestones on or before April 13, 2019. Upon achieving each of the first and second milestones, 25% of the shares will vest on the milestone achievement date, and an additional 25% of the shares will vest on the one-year anniversary of such achievement date, subject to a minimum one year vesting period from the date of grant and a requirement that recipients are employees on any applicable vesting date. Each quarter the Company evaluates the probability of achieving the milestones on or before April 13, 2019, and its estimate of the implicit service period over which the fair value of the awards will be recognized and expensed. The Company determined that it is probable that the performance conditions will be achieved and therefore is expensing the fair value of the shares over the implicit service period using the accelerated attribution method. In the second quarter of 2016, the Company recognized approximately \$ 1.7 million of stock compensation costs related to the awards.

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 recognized the compensation cost attributed to the modified awards as follows: the first 50% of the awards were 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 were expensed over the period beginning on March 11, 2015 and ending on April 16, 2016, the one year anniversary of FDA approval. Accordingly, approximately \$9.4 million of stock compensation cost for awards that were earned and vested was recognized in the period between March 11, 2015 and June 30, 2016.

As of June 30, 2016, the total remaining unrecognized compensation cost related to all nonvested time-based and performance-based restricted stock awards amounted to \$17.6 million, which is expected to be recognized over the weighted average remaining requisite service period of 3.2 years.

A summary of the status of nonvested shares of restricted stock as of June 30, 2016 and the changes during the six 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	1,969	10.01
Vested	(449)	14.49
Forfeited	(186)	11.13
Nonvested at June 30, 2016	2,095	\$ 10.62

Nonvested shares of restricted stock that have time-based or both performance-based and time-based vesting conditions as of June 30, 2016 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	665
Performance-based and time-based	1,430
Nonvested at June 30, 2016	2,095

## 7. Equity Financings

In May 2015, the Company sold an aggregate of 8,337,500 shares of its common stock through an underwritten public offering at a price to the public of \$19.00 per share. As a result of the offering, which included the full exercise of the underwriters’ option to purchase additional shares, the Company received aggregate net proceeds of approximately \$148.4 million, after deducting underwriting discounts and commissions and other offering expenses.

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 2.00% 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 on Form S-3 previously filed with the SEC (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. 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. The Company concluded sales under the 2014 ATM Agreement in April 2015.

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 on Form S-3 previously filed with the SEC (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 six months ended June 30, 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 SEC 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 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 District Court trial is scheduled to begin on July 10, 2017. 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 May 17, 2016, Amphastar filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, or the Court. The Court invited a response from Momenta and Sandoz Inc., which was filed on August 1, 2016. The Court is expected to issue its decision on whether to grant Amphastar's petition in the Fall of 2016.

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 that the court reverse and review the District Court's grant of transfer, and in May 2016, the writ requested by Amphastar was denied. On July 27, 2016, the Company's and Sandoz Inc.'s motion to dismiss was granted by the District Court, and the case was dismissed.

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 before a U.S. magistrate in April 2016 and February 2016, respectively. 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.

## **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 June 30, 2016, we had an accumulated deficit of approximately \$ 497 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 June 30, 2016, we recorded \$ 20.7 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 FDA-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 of 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 six months ended June 30, 2016, and therefore we recorded no revenue for Enoxaparin Sodium Injection in the period.

### **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. On June 3, 2016, Baxalta Incorporated and Shire announced the completion of the combination of Baxalta Incorporated and Shire. As a result of the combination, Baxalta Incorporated is a wholly owned subsidiary of Shire.

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 late 2016. 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. 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 of ORENCIA on the market.

#### ***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 June 30, 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***

On August 3, 2016, we discontinued further accrual of our Part B, or Phase 2, portion of our Phase 1/2 clinical trial evaluating necuparanib in combination with nab-paclitaxel (ABRAXANE®) and gemcitabine in patients with advanced metastatic pancreatic cancer. The decision to discontinue enrollment was based on the recommendation of the independent Data Safety Monitoring Board, or DSMB, for the trial following the outcome of a planned interim futility analysis. In making its recommendation, the DSMB did not cite any new safety concerns and no new toxicities were observed that necessitated immediate discontinuation of study drug in patients; however, the DSMB determined that necuparanib in combination with nab-paclitaxel and gemcitabine did not show a sufficient level of efficacy to warrant continued enrollment. We plan to unblind the data from the Phase 2 trial, confirm the futility analysis and determine the next steps for the necuparanib program.

##### ***Other Novel Therapeutic Programs***

We are continuing to advance M281, our Anti-FcRn program, and M230, our selective immunomodulator of Fc receptors, or SIF3, program. We initiated a Phase 1 dosing study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 in healthy volunteers in June 2016, and we expect to report data from this trial in the second half of 2017. 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 2015, we sold an aggregate of 8,337,500 shares of our common stock through an underwritten public offering at a price to the public of \$19.00 per share. As a result of the offering, which included the full exercise of the underwriters' option to purchase additional shares, we received aggregate net proceeds of approximately \$148.4 million, after deducting underwriting discounts and commissions and other offering expenses.

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 \$75.0 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 on Form S-3 previously filed with the SEC (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. Between October 2014 and April 2015, we sold approximately 5.4 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately \$73.5 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 \$75.0 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. From April 2015 through December 2015, we sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement pursuant to an effective shelf registration statement previously filed with the SEC (Reg. No. 333-188227) and a related prospectus supplement, 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 six months ended June 30, 2016.

## Results of Operations

### Comparison of Three Months Ended June 30, 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 June 30, 2016, we recorded \$ 20.7 million in product revenues from Sandoz' sales of GLATOPA. For the three months ended June 30, 2015, we recorded \$ 19.2 million in product revenues from Sandoz's sales of GLATOPA net of a deduction of \$9.0 million for reimbursement to Sandoz of 50% of pre-launch GLATOPA-related legal expenses incurred by Sandoz since 2008. In the second quarter of 2016, our share of Sandoz's profits was \$20.7 million compared with \$28.2 million in the second quarter of 2015. The decrease in our share of Sandoz's profits of \$7.5 million, or 27%, from the 2015 period to the 2016 period is driven in part by the shipment of initial trade inventories of GLATOPA in June 2015. We estimate that the number of prescriptions for GLATOPA represents nearly 38% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

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 approximately 77% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/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 June 30, 2016, and therefore we recorded no revenue for Enoxaparin Sodium Injection in the period. For the three months ended June 30, 2015, we recorded \$ 0.1 million in profit share, net of a \$0.1 million claw-back adjustment of pre-launch development expenses. The decrease in our product revenue was \$0.1 million, or 100%, from the 2015 period to the 2016 period and was attributed to lower unit sales driven by lower market share.

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 \$ 5.7 million and \$ 25.6 million for the three months ended June 30, 2016 and 2015, respectively. The decrease in research and development revenue of \$19.9 million, or 78%, from the 2015 period to the 2016 period was primarily due to \$20 million in milestone payments earned in the second quarter of 2015 upon GLATOPA's being the sole generic of COPAXONE 20 mg/mL to receive FDA approval in April 2015 and upon first commercial sale of GLATOPA in June 2015.

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.

Research and development expense for the three months ended June 30, 2016 was \$ 33.2 million, compared with \$ 34.0 million for the three months ended June 30, 2015. The decrease of \$0.8 million, or 2%, from the 2015 period to the 2016 period was due to decreases of \$0.8 million in stock-based compensation expense and \$8.4 million representing Mylan's 50% share of biosimilar program collaboration costs, which was offset by increases of: \$4.4 million in third-party development costs for M281 and certain of the biosimilar programs under our collaboration with Mylan; \$2.2 million in non-clinical expenses to advance our novel autoimmune programs; \$1.0 million in personnel-related expenses; \$0.7 million in necuparanib Phase 2 clinical trial costs; and \$0.1 million in other expenses.

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, in thousands, 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 June 30, 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 June 30, 2016	Three Months Ended June 30,		Project Inception to June 30, 2016
		2016	2015	
<b>External Costs Incurred by Product Candidate:</b>				
GLATOPA and M356—Generic COPAXONE® (20 mg/mL and 40 mg/mL)	ANDAs filed(1)	\$ 1,001	\$ 282	\$ 50,157
Necuparanib—Oncology Product Candidate	Phase 2	2,235	3,004	42,166
Biosimilars	Various(2)	10,170	6,482	91,803
Other novel therapeutic programs	Various(3)	7,263	3,253	
Internal Costs		20,912	20,962	
Subtotal		\$ 41,581	\$ 33,983	
Less: Reimbursable from Mylan(4)		(8,408)	—	
<b>Total Research and Development Expenses(4)</b>		<b>\$ 33,173</b>	<b>\$ 33,983</b>	

(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 five 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. Our other biosimilar candidates are in discovery and process development.

(3) Other novel therapeutic programs include M281, for which a Phase 1 dosing study was initiated in 2016; M230, for which we expect to initiate a clinical trial in 2017; h5IVIg; as well as other discovery and non-clinical stage programs.

(4) As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately \$8.4 million against research and development costs during the three months ended June 30, 2016.

GLATOPA and M356 external expenditures increased by \$0.7 million, or 255% from the 2015 period to the 2016 period as we continued to support our M356 40 mg/mL ANDA filing. The decrease in our necuparanib external expenditures of \$0.8 million, or 26%, from the 2015 period to the 2016 period was due to maturation of the Phase 2 clinical trial. External expenditures for our biosimilars programs increased by \$3.7 million, or 57%, from the 2015 period to the 2016 period due to an increase of \$4.0 million in development costs as we advanced the biosimilars programs, including M834, under our collaboration with Mylan. This increase was offset by a decrease of \$0.3 million for M923, reflecting that Baxalta has clinical development responsibility for that program. The increase of \$4.0 million, or 123%, in other novel therapeutic program external expenditures from the 2015 period to the 2016 period was due to increased nonclinical and process development to advance M281 into the clinic and M230 towards the clinic.

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 June 30, 2016 was \$ 14.9 million, compared with \$ 13.3 million for the three months ended June 30, 2015 . The increase of \$ 1.6 million, or 12% , from the 2015 period to the 2016 period was due to an increase of \$2.1 million in professional fees driven mainly by legal expenses, consulting fees and recruiting expenses. These increases were offset by a decrease of \$0.5 million representing Mylan's 50% share of collaboration costs under the cost-sharing provisions of the Mylan Collaboration Agreement.

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 \$ 0.6 million and \$ 0.1 million for the three months ended June 30, 2016 and 2015, respectively. The increase of \$ 0.5 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 June 30, 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.

### **Comparison of Six Months Ended June 30, 2016 and 2015**

#### ***Collaboration Revenue***

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

For the six months ended June 30, 2016 , we recorded \$ 35.5 million in product revenues from Sandoz' sales of GLATOPA. For the six months ended June 30, 2015 , we recorded \$ 19.2 million in product revenues from Sandoz' sales of GLATOPA net of a deduction of \$9.0 million for reimbursement to Sandoz of 50% of pre-launch GLATOPA-related legal expenses incurred by Sandoz since 2008. Our share of Sandoz's profits for the six months ended June 30, 2016 was \$35.5 million, compared with \$28.2 million in June 2015, the month Sandoz launched GLATOPA. The increase in our share of

Sandoz's profits of \$7.3 million, or 26%, from the 2015 period to the 2016 period was primarily due to higher GLATOPA units sold.

*Enoxaparin Sodium Injection—Generic LOVENOX®*

Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the six months ended June 30, 2016, and therefore we recorded no revenue for Enoxaparin Sodium Injection in the period. For the six months ended June 30, 2015, we earned \$2.8 million in product revenue consisting of \$0.1 million in second quarter profits, net of a claw-back adjustment of \$0.1 million, and \$2.7 million in royalties earned in the first quarter on Sandoz's reported net sales of Enoxaparin Sodium Injection of \$25.9 million. The decrease in our product revenue was \$2.8 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.

***Research and Development Revenue***

Research and development revenue was \$ 10.8 million and \$ 31.4 million for the six months ended June 30, 2016 and 2015, respectively. The decrease in research and development revenue of \$20.6 million, or 66%, from the 2015 period to the 2016 period was primarily due to \$20.0 million in milestone payments we earned in the second quarter of 2015 upon GLATOPA's being the sole generic of COPAXONE 20 mg/mL to receive FDA approval in April 2015 and upon first commercial sale of GLATOPA in June 2015.

***Research and Development Expense***

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.

Research and development expense for the six months ended June 30, 2016 was \$ 61.9 million, compared with \$ 56.7 million for the six months ended June 30, 2015. The increase of \$5.2 million, or 9%, from the 2015 period to the 2016 period primarily resulted from increases of: \$11.2 million in third-party research and process development costs primarily attributable to advance our biosimilar and novel autoimmune programs; \$5.1 million in personnel-related expenses, of which \$1.6 million is due to increased headcount and \$3.5 million is primarily attributed to the reversal of prior period share-based compensation expense in the first quarter of 2015 associated with performance-based restricted stock awards that decreased the amount of research and development expenses we recorded; \$0.7 million in allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment; and \$0.3 million in intangible amortization. These increases were partially offset by a decrease of \$12.1 million for Mylan's 50% share of collaboration costs under the cost-sharing provisions of the Mylan 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 six months of 2015 research and development expense included a stock compensation credit of \$5.1 million and expense of \$3.0 million relating to the performance grants. In the first six months of 2016 research and development expense relating to the performance grants was \$0.6 million.

The following table sets forth, in thousands, 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 six months ended June 30, 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 June 30, 2016	Six Months Ended June 30,		Project
		2016	2015	Inception to June 30, 2016
<b>External Costs Incurred by Product Candidate:</b>				
GLATOPA and M356—Generic COPAXONE® (20 mg/mL and 40 mg/mL)	ANDAs filed(1)	\$ 1,294	\$ 429	\$ 50,157
Necuparanib—Oncology Product Candidate	Phase 2	5,290	5,104	42,166
Biosimilars	Various(2)	16,356	10,378	91,803
Other novel therapeutic programs	Various(3)	9,862	5,400	
Internal Costs		41,216	35,422	
Subtotal		\$ 74,018	\$ 56,733	
Less: Reimbursable from Mylan(4)		(12,088)	—	
Total Research and Development Expenses(4)		\$ 61,930	\$ 56,733	

- (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 five 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. Our other biosimilar candidates are in discovery and process development.
- (3) Other novel therapeutic programs include M281, for which a Phase 1 dosing study was initiated in 2016; M230, for which we expect to initiate a clinical trial in 2017; hslVlg; as well as other discovery and non-clinical stage programs.
- (4) As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately \$12.1 million against research and development costs during the six months ended June 30, 2016 .

GLATOPA and M356 external expenditures increased by \$0.9 million, or 202%, from the 2015 period to the 2016 period as we continued to support our M356 40 mg/mL ANDA filing. Necuparanib external expenditures increased by \$0.2 million from the 2015 period to the 2016 period as we accrued patients in our Phase 2 clinical trial. External expenditures for our biosimilars programs increased by \$6.0 million, or 58%, from the 2015 period to the 2016 period due to an increase of \$6.6 million in development costs as we advanced the biosimilars programs, including M834, under our collaboration with Mylan. This increase was offset by a decrease of \$0.6 million for M923, reflecting that Baxalta has clinical development responsibility for that program. The increase of \$4.5 million, or 83%, in other novel therapeutic programs external expenditures from the 2015 period to the 2016 period was due to increased nonclinical and process development to advance M281 and M230. Finally, internal costs grew by \$5.8 million, or 16%, from the 2015 period to the 2016 period as we increased our headcount.

### **General and Administrative 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 six months ended June 30, 2016 was \$ 30.5 million , compared with \$ 21.2 million for the six months ended June 30, 2015 . The increase of \$ 9.3 million , or 44% , from the 2015 period to the 2016 period was primarily due to increases of \$6.4 million in personnel-related expenses, of which \$2.3 million is due to increased headcount and \$4.1 million is primarily due to the reversal of prior period share-based compensation expense in the first quarter of 2015 associated with performance-based stock awards that decreased the amount of general and administrative expenses we recorded (discussed under “ -- *Research and Development Expense* ”), and \$3.5 million in increased professional fees, driven mainly by consulting, legal and recruiting expenses. These increases were partially offset by a decrease of \$0.6 million for Mylan’s 50% share of collaboration costs under the cost-sharing provisions of the Mylan Collaboration Agreement. In the first six months of 2015, general and administrative expense included a stock compensation credit of \$5.4 million and an

expense of \$3.1 million relating to the performance grants. In the first six months of 2016 general and administrative expense relating to the performance grants was \$0.7 million.

#### ***Interest Income***

Interest income was \$ 1.1 million and \$0.2 million for the six months ended June 30, 2016 and 2015, respectively. The increase of \$0.9 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 six months ended June 30, 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 June 30, 2016 , we had \$336.9 million in cash, cash equivalents and marketable securities and \$ 35.9 million in collaboration receivables, including \$ 20.7 million for our profit share from GLATOPA sales in the three months ended June 30, 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 June 30, 2016 were primarily invested in 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 12 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. We do not believe that our cash equivalents and marketable securities were subject to significant market risk at June 30, 2016 .

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 June 30, 2016 , we have received \$638.0 million through private and public issuances of equity securities, including approximately \$148.0 million in net proceeds from our May 2015 public offering of common stock and approximately \$83.0 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 June 30, 2016 , we had received a cumulative total of \$693.0 million under our collaborations with Sandoz, including \$469.0 million in revenues on sales of Enoxaparin Sodium Injection and regulatory and commercial milestones related to that product, and \$99.0 million in revenues on sales of GLATOPA and regulatory and commercial milestones related to that product. In addition, we received \$85.0 million under our collaboration with Baxalta, including a \$33.0 million upfront payment, \$33.0 million in reimbursement of research and development services and costs and \$19.0 million in license and milestone payments. In March 2016, we received a \$45.0 million upfront payment from Mylan under the Mylan Collaboration Agreement. We expect to receive in 2016 \$60.0 million of the up to \$200.0 million in contingent milestone payments from Mylan under the Mylan Collaboration Agreement, such payments representing Mylan's funding of its share of collaboration expenses.

We expect to fund our planned operating and expenditure requirements through a combination of current cash, cash equivalents and marketable securities; equity financings, including sales of common stock under our 2015 ATM Agreement; and milestone payments and product revenues under existing collaboration agreements. We may also seek funding from new collaborations and strategic alliances, debt financings and other financial arrangements. Future funding transactions may or may not be similar to our prior funding transactions. There can be no assurance that future funding transactions will be available on favorable terms, or at all. We currently believe that our current capital resources and projected milestone payments and product revenues will be sufficient to meet our operating requirements through at least the end of 2018.

In February 2016, we filed a shelf registration statement on Form S-3 (Reg No. 333-209813) with the SEC registering the offer, sale and issuance, from time to time, of common stock, preferred stock, debt securities and warrants. Our prior shelf registration statement on Form S-3 (Reg No. 333-188227) expired in April 2016.

	Six Months Ended June 30,	
	2016	2015
	(in thousands)	
Net cash used in operating activities	\$ (8,839)	\$ (44,580)
Net cash provided by investing activities	\$ 36,040	\$ 22,934
Net cash (used in) provided by financing activities	\$ (438)	\$ 232,104
Net increase in cash and cash equivalents	\$ 26,763	\$ 210,458

***Cash provided by (used in) operating activities***

The cash provided by or used in operating activities generally approximates our net loss adjusted for non-cash items and changes in operating assets and liabilities.

Cash used in operating activities was \$8.8 million for the six months ended June 30, 2016 reflecting a net loss of \$45.0 million, which was partially offset by non-cash charges of \$4.7 million for depreciation and amortization of property, equipment and intangible assets, \$ 9.8 million in shared-based compensation and \$ 0.4 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of \$21.2 million and resulted from: an increase in collaboration receivable of \$ 14.7 million driven primarily by a receivable of \$12.7 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 \$ 0.6 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; an increase in accounts payable of \$ 8.1 million and a decrease in accrued expenses of \$ 8.8 million due to the timing of vendor payments; an increase in deferred revenue of \$37.4 million, primarily due to receipt of a \$45.0 million upfront payment from Mylan offset by revenue recognized under the Baxalta and Mylan collaborations; a decrease in other current liabilities of \$0.3 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 \$0.9 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 \$ 44.6 million for the six months ended June 30, 2015 reflecting a net loss of \$24.1 million, which was partially offset by non-cash charges of \$4.5 million for depreciation and amortization of property, equipment and intangible assets, \$2.2 million in shared-based compensation and \$0.6 million for amortization of purchased premiums on our marketable securities. In addition, the net change in our operating assets and liabilities used cash of \$27.8 million and resulted from: an increase in collaboration receivable of \$ 25.8 million, driven primarily by a receivable of \$19.2 million from Sandoz for second quarter 2015 GLATOPA profit share and a receivable of \$10.0 million for a GLATOPA commercial milestone offset by lower reimbursable FTEs and costs for M923; a decrease in prepaid expenses and other current assets of \$0.9 million due to the timing of advance payments to vendors for services and the amortization of those payments; a decrease in accounts payable of \$5.5 million due to timing of vendor payments; an increase in accrued expenses of \$7.0 million primarily due to process development services for our biosimilars programs; a decrease in deferred revenue of \$4.1 million, due to higher quarterly amortization of revenue from the \$33.0 million Baxalta upfront payment in 2012 and a \$7.0 million M834 pre-defined “minimum development criteria” license payment in 2014; and a decrease in other long-term liabilities of \$0.3 million, of which \$0.1 million represents the amortization of a job creation tax award and \$0.1 million is the amortization of the tenant improvement allowance over the term of our facility lease.

***Cash provided by (used in) investing activities***

Cash provided by investing activities of \$36.0 million for the six months ended June 30, 2016 includes cash inflows of \$261.7 million from maturities of marketable securities offset by cash outflows of \$222.0 million for purchases of marketable securities and \$3.7 million for capital equipment and leasehold improvements.

Cash provided by investing activities of \$22.9 million for the six months ended June 30, 2015 includes cash inflows of \$92.3 million from maturities of marketable securities partially offset by cash outflows of \$68.0 million for purchases of marketable securities and \$1.4 million for capital equipment and leasehold improvements.

***Cash provided by (used in) financing activities***

Cash used in financing activities of \$0.4 million for the six months ended June 30, 2016 consists of \$1.0 million of cash paid to tax authorities in connection with the vesting of employee performance-based restricted stock partially offset by \$0.6 million in 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 \$232.1 million for the six months ended June 30, 2015 includes \$148.4 million of net proceeds from the sale of 8.3 million shares of our common stock through an underwritten public offering, \$64.5 million of net proceeds from the sale of 4.3 million shares of our common stock under our ATM Agreements and \$21.2 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan, for total proceeds of \$234.1 million. Total proceeds were partially offset by \$2.0 million of cash paid to tax authorities in connection with the vesting of employee performance-based restricted stock.

### **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 SEC 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 condensed 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 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 June 30, 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 June 30, 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 June 30, 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 June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. LEGAL PROCEEDINGS

#### *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 IPR with the PTAB to challenge the validity of U.S. Patent No 8,476,239, a patent for ORENCIA owned by Bristol Myers Squibb, or 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. The District Court trial is scheduled to begin on July 10, 2017. On May 17, 2016, Amphastar filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, or the Court. The Court invited a response from Momenta and Sandoz Inc., which was filed with the Court on August 1, 2016. The Court is expected to issue its decision on whether to grant Amphastar's petition in the Fall of 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 a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that the court reverse and review the District Court's grant of transfer, and in May 2016, the writ requested by Amphastar was denied. On July 27, 2016, our and Sandoz Inc.'s motion to dismiss was granted by the District Court, and the case was dismissed.

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 before a U.S. magistrate in April 2016 and February 2016, respectively. These motions are pending before the magistrate and subject to review by 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.

#### **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 June 30, 2016, our accumulated deficit was \$497 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 or Teva appeals a loss at trial, Sandoz may defer launch of M356 until the relevant COPAXONE patents expire or are ultimately determined not to be valid, unenforceable or not infringed. Otherwise, we may have to reimburse Sandoz for significant damages from contractual profits if Sandoz launches 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 from contractual profits 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 contractual 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 Sandoz launches prior to such decision, 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 by Sandoz. 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.***

Pricing and market share of generic and biosimilar products may decline, often dramatically, as other generics or biosimilars of the same brand name drug or reference product, respectively, enter the market. Competing generics include brand name manufacturers' "authorized generics" of their own brand name products. Generally, earlier-to-market generics and biosimilars are better able to gain significantly greater market share than later-to-market competing generics and biosimilars, respectively. Accordingly, revenue and profits from GLATOPA and, if approved, our generic and biosimilar product candidates, may be significantly reduced based on the timing and number of competing generics and biosimilars, respectively. We expect GLATOPA and, if approved, certain of our generic and biosimilar product candidates may face intense and increasing competition from other generics and biosimilars. For example, Mylan announced that the FDA had accepted for filing its ANDAs for generic versions of COPAXONE, and Synthron 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.

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 approximately 77% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/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.

***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 June 30, 2016, we had cash, cash equivalents and marketable securities totaling approximately \$336.9 million. For the six months ended June 30, 2016, we had a net loss of \$45.0 million and our operations used cash of \$8.8 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 Incorporated and Shire;
- the timing of FDA approval of the products of our competitors;

## [Table of Contents](#)

- 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, and milestone payments and product revenues under existing collaboration agreements. 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 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 approximately 77% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/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 third parties are successful in anti-trust litigation against us relating to Enoxaparin 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 third parties are successful in anti-trust litigation 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.

***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 40 mg/mL M356 ANDA, and seek to delay or prevent the FDA approval of the 40 mg/mL 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.

***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.

We face, and will continue to face, competition with regard to our products and, if approved, our product candidates, based on many different factors, including:

- the safety and effectiveness of our products;
- with regard to our generic products and our generic and 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.

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

Drug 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, or offered to, GPOs, pharmacy benefit management firms, and customers, including wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our or our competitors' products. For example, if pharmacy benefit management firms, distributors and other customers contract with Teva for net price discounts or rebates on COPAXONE 20 mg/mL and 40 mg/mL in exchange for exclusivity or preferred status for COPAXONE prior to approval and launch of M356, our opportunity to capture market share would be significantly restricted for the term of these contracts even after a launch of M356. If we or our collaborators are

unable to establish and maintain competitive 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 sameness, in the case of our generic product candidate, and biosimilarity or interchangeability, in the case of our biosimilar product candidates, 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.

***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:

- 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:

- 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 version 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;
- 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.

***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.

***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 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 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 the U.S. Patent and Trademark Office, or U.S. PTO, or become involved in opposition, derivation, reexamination, IPR or interference proceedings challenging our patent rights or the patent rights of others. For example, several of our European patents are being challenged in opposition proceedings before the European Patent Office. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the U.S. PTO 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 Amphistar did not fall within the scope of the safe harbor from patent infringement under federal patent law, 35 USC section 271(e)(1), Amphistar is seeking to challenge the ruling at the U.S. Supreme Court, 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 1 “*Legal Proceedings*” in this Quarterly Report on Form 10-Q. The uncertainty regarding the scope of the safe harbor may impair our ability to enforce certain of our patent rights and reduce the likelihood of enforcing certain of our patent rights to protect our innovations and our products. Accordingly, we do not know the degree of future enforceability for some of our proprietary rights.

The breadth of patent claims allowed in any patents issued to us or to others may be unclear. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and/or opposition proceedings, and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage. Moreover, once they have issued, our patents and any patent for which we have licensed or may license rights may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited, other companies will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

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

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

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

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

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

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

***If we remain involved in patent litigation or other proceedings to determine or enforce our intellectual property rights, we could incur substantial costs which could adversely affect our business.***

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

***We in-license a portion of our proprietary technologies and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to develop our product candidates.***

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

### **Risks Relating to Our Dependence on Third Parties**

***The 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;
- 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 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 June 2016, Baxalta Incorporated and Shire announced the completion of a combination of Baxalta Incorporated and Shire. As a result of such combination, we are dependent on Shire 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 Incorporated and Shire. Similar changes with respect to any of our other collaborators may negatively impact our business operations.

#### **General Company Related Risks**

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and our by-laws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified board of directors;
- a prohibition on actions by our stockholders by written consent; and
- limitations on the removal of directors.

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

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

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

- 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, including without limitation, a decision in the M356 patent litigation or a competitors' related patent litigation that prevents the launch or delays the launch of our M356 product;
- 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 third parties in anti-trust litigation 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;

## [Table of Contents](#)

- 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;
- 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.

**Item 6. EXHIBITS**

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
+*10.1	Amendment No. 4, dated May 26, 2016, to the Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant, as amended.				
*10.2	Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan (as amended and restated).				
*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 Extension Calculation Linkbase Document.				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
*101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
*101.PRE	XBRL Taxonomy Extension Presentation 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 June 30, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at June 30, 2016 and December 31, 2015, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2016 and 2015, (iii) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015, and (iv) Notes to Unaudited, Condensed Consolidated Financial Statements.

**SIGNATURES**

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

Date: August 5, 2016

Momenta Pharmaceuticals, Inc.

By: /s/ Craig A. Wheeler

Craig A. Wheeler, President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 5, 2016

By: /s/ Richard P. Shea

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

Confidential Treatment Requested by Momenta Pharmaceuticals, Inc.

**AMENDMENT NO. 4**  
**to the COLLABORATION AND LICENSE AGREEMENT**

This Amendment No. 4 (this “Amendment No. 4”) to the Collaboration and License Agreement (the “Agreement”) by and between **Sandoz AG**, a Swiss corporation with offices located at Lichtstraße 35, CH 4056 Basel BS, Switzerland (“Sandoz”) and **Momenta Pharmaceuticals, Inc.**, a Delaware company with offices located at 675 West Kendall Street, Cambridge, MA 02142 (“Momenta”) is made effective as of May 26, 2016 (the “Amendment No. 4 Effective Date”). Sandoz and Momenta may hereafter be referred to collectively as the “Parties” and individually as a “Party”.

**WHEREAS**, Sandoz and Momenta entered into a Collaboration and License Agreement effective as June 13, 2007, as amended by Amendment No. 1 dated April 25, 2008, a letter agreement dated December 22, 2008, Amendment No. 2 dated December 14, 2009 but made effective as of November 1, 2009 and Amendment No. 3 dated April 1, 2011; and

**WHEREAS**, Sandoz desires to transfer [\*\*\*] from [\*\*\*] to its [\*\*\*] in support of [\*\*\*], as further described below;

**WHEREAS**, the Agreement does not provide for the transfer of the [\*\*\*] and its [\*\*\*], except in the case of a transfer for [\*\*\*];

**WHEREAS**, the Parties desire to facilitate such transfer and to set forth the economic terms for such transfer under the Agreement; and

**WHEREAS**, the Parties now desire to amend the Agreement to reflect mutually agreed upon revised terms in accordance with the provisions of the Agreement; and

**NOW, THEREFORE**, in consideration of the foregoing recitals and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are mutually acknowledged, the Parties hereto, intending to be legally bound, do hereby agree that the Agreement shall be amended as follows:

1. Section 2.1.3 is hereby added to the Agreement as follows:

2.1.3. [\*\*\*], Transfer of [\*\*\*].

Subject to the terms and conditions of this Agreement,

(i) Sandoz and/or its [\*\*\*] may use or cross-reference the [\*\*\*] and any related [\*\*\*] solely in the following [\*\*\*] to support the development and/or commercialization of such [\*\*\*] a [\*\*\*] and [\*\*\*] to [\*\*\*] the [\*\*\*] and [\*\*\*] of [\*\*\*] and [\*\*\*] with [\*\*\*] in [\*\*\*] with [\*\*\*].

(ii) In support of such [\*\*\*], Sandoz or its designee intends to transfer [\*\*\*] of the [\*\*\*] (the “ [\*\*\*] ”), such transfer to be in [\*\*\*] installments. The transfer of the [\*\*\*] is [\*\*\*] from [\*\*\*] and any [\*\*\*] provided for in the Agreement, including but not limited to those set forth in [\*\*\*]. In consideration of such transfer of the [\*\*\*], Sandoz shall pay to Momenta [\*\*\*] (the “ [\*\*\*] ”), [\*\*\*] payments of [\*\*\*] per [\*\*\*]. Such payment to Momenta of the [\*\*\*] is [\*\*\*] the [\*\*\*] under the Collaboration for such [\*\*\*]. Sandoz or its designee shall notify Momenta within in [\*\*\*] of each shipment. Following notice of each shipment, Momenta shall [\*\*\*]. Sandoz shall render payment to Momenta within [\*\*\*] of receipt of invoice.

(iii) For the sake of clarity:

(A) No [\*\*\*] for [\*\*\*] made in [\*\*\*] as set forth in [\*\*\*] shall be made for such [\*\*\*];

(B) No [\*\*\*] by Momenta with respect to the transfer of the [\*\*\*] to the [\*\*\*].

2. All other terms of the Agreement not amended by this Amendment No. 4 shall remain in full force and effect.

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

Confidential Treatment Requested by Momenta Pharmaceuticals, Inc.

3. All capitalized terms used but not otherwise defined herein shall have the meaning set forth in the Agreement.

4. This Amendment No. 4 may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment No. 4 may be executed by facsimile or electronically transmitted signatures, such as by portable electronic document (PDF), and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

**IN WITNESS WHEREOF**, this Amendment No. 4 to the Agreement has been executed by the authorized representatives of each Party and shall be in full force and effect as of the Effective Date first above written.

**SANDOZ AG**

**MOMENTA PHARMACEUTICALS, INC.**

By: /s/ Georg Rieder

Name: Georg Rieder

Title: Chief Financial Officer, Sandoz AG

By: /s/ Craig A. Wheeler

Name: Craig A. Wheeler

Title: CEO

By: /s/ A. Eggmann

Name: Andreas Eggmann

Title: Head Sandoz AG

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

**MOMENTA PHARMACEUTICALS, INC.**  
**2013 INCENTIVE AWARD PLAN**  
**(as amended and restated, as approved by stockholders on June 22, 2016)**

**ARTICLE 1.**

**PURPOSE**

The purpose of the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan (as it may be amended or restated from time to time, the "*Plan*") is to promote the success and enhance the value of Momenta Pharmaceuticals, Inc. (the "*Company*") by linking the individual interests of the members of the Board, Employees, and Consultants to those of Company stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to Company stockholders. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of members of the Board, Employees, and Consultants upon whose judgment, interest, and special effort the successful conduct of the Company's operation is largely dependent.

**ARTICLE 2.**

**DEFINITIONS AND CONSTRUCTION**

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 "*Administrator*" shall mean the entity that conducts the general administration of the Plan as provided in Article 13. With reference to the duties of the Committee under the Plan which have been delegated to one or more persons pursuant to Section 13.6, or as to which the Board has assumed, the term "*Administrator*" shall refer to such person(s) unless the Committee or the Board has revoked such delegation or the Board has terminated the assumption of such duties.

2.2 "*Applicable Accounting Standards*" shall mean Generally Accepted Accounting Principles in the United States, International Financial Reporting Standards or such other accounting principles or standards as may apply to the Company's financial statements under United States federal securities laws from time to time.

2.3 "*Applicable Law*" shall mean any applicable law, including without limitation: (i) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (ii) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (iii) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.4 "*Award*" shall mean an Option, a Restricted Stock award, a Restricted Stock Unit award, a Performance Award, a Dividend Equivalents award, a Stock Payment award or a Stock Appreciation Right, which may be awarded or granted under the Plan (collectively, "*Awards*").

2.5 "*Award Agreement*" shall mean any written notice, agreement, terms and conditions, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine consistent with the Plan.

2.6 "*Award Limit*" shall mean with respect to Awards that shall be payable in Shares or in cash, as the case may be, the respective limit set forth in Section 3.3.

2.7 "*Board*" shall mean the Board of Directors of the Company.

2.8 "*Change in Control*" shall mean and includes each of the following:

- (a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires

beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.8(a) or 2.8(c)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the " *Successor Entity* ")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; *provided, however* , that no person or group shall be treated for purposes of this Section 2.8(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

(d) The liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any portion of an Award that provides for the deferral of compensation and is subject to Section 409A of the Code, the transaction or event described in subsection (a), (b), (c) or (d) with respect to such Award (or portion thereof) must also constitute a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Section 409A.

The Committee shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.9 " *Code* " shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder.

2.10 " *Committee* " shall mean the Compensation Committee of the Board, or another committee or subcommittee of the Board or the Compensation Committee, appointed as provided in Section 13.1.

2.11 " *Common Stock* " shall mean the common stock of the Company, par value \$0.0001 per share.

2.12 " *Company* " shall have the meaning set forth in Article 1.

2.13 " *Consultant* " shall mean any consultant or adviser engaged to provide services to the Company or any Subsidiary that qualifies as a consultant under the applicable rules of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement.

2.14 " *Covered Employee* " shall mean any Employee who is, or could be, a "covered employee" within the meaning of Section 162(m) of the Code.

2.15 " *Director* " shall mean a member of the Board, as constituted from time to time.

2.16 " *Disability* " shall mean that the Holder is either (a) unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve months, or (b) by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve months, receiving income replacement benefits for a period of not less than three months under an accident and health plan covering employees of the Company. For purposes of the Plan, a Holder shall be deemed to have incurred a Disability if the Holder is determined to be totally disabled by the Social Security Administration or in accordance with the applicable disability insurance program of the Company's, provided that the definition of "disability" applied under such disability insurance program complies with the requirements of this definition.

2.17 " *Dividend Equivalent* " shall mean a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 10.2.

2.18 " *DRO* " shall mean a domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder.

2.19 " *Effective Date* " shall mean March 5, 2013.

2.20 " *Eligible Individual* " shall mean any person who is an Employee, a Consultant or a Non-Employee Director, as determined by the Committee.

2.21 " *Employee* " shall mean any officer or other employee (as determined in accordance with Section 3401(c) of the Code and the Treasury Regulations thereunder) of the Company or of any Subsidiary.

2.22 " *Equity Restructuring* " shall mean a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other securities of the Company) or the share price of Common Stock (or other securities) and causes a change in the per-share value of the Common Stock underlying outstanding Awards.

2.23 " *Exchange Act* " shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.24 " *Expiration Date* " shall have the meaning given to such term in Section 14.1.

2.25 " *Fair Market Value* " shall mean, as of any given date, the value of a Share determined as follows:

(a) If the Common Stock is listed on any (i) established securities exchange (such as the New York Stock Exchange, the NASDAQ Global Market and the NASDAQ Global Select Market), (ii) national market system or (iii) automated quotation system on which the Shares are listed, quoted or traded, its Fair Market Value shall be the closing sales price for a Share as quoted on such exchange or system for such date or, if there is no closing sales price for a Share on the date in question, the closing sales price for a Share on the last preceding date for which such quotation exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or

(b) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system, its Fair Market Value shall be established by the Administrator in good faith.

2.26 " *Full Value Award* " shall mean any Award other than an Option or a Stock Appreciation Right and that is settled by the issuance of Shares.

2.27 " *Greater Than 10% Stockholder* " shall mean an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or any subsidiary corporation (as defined in Section 424(f) of the Code) or parent corporation thereof (as defined in Section 424(e) of the Code).

2.28 " *Holder* " shall mean a person who has been granted an Award.

2.29 " *Incentive Stock Option* " shall mean an Option that is intended to qualify as an incentive stock option and conforms to the applicable provisions of Section 422 of the Code.

2.30 " *Non-Employee Director* " shall mean a Director of the Company who is not an Employee.

2.31 " *Non-Employee Director Equity Compensation Policy* " shall have the meaning set forth in Section 4.6.

2.32 " *Non-Qualified Stock Option* " shall mean an Option that is not an Incentive Stock Option.

2.33 " *Option* " shall mean a right to purchase Shares at a specified exercise price, granted under Article 6. An Option shall be either a Non-Qualified Stock Option or an Incentive Stock Option; *provided, however*, that Options granted to Non-Employee Directors and Consultants shall only be Non-Qualified Stock Options.

2.34 " *Option Term* " shall have the meaning set forth in Section 6.4.

2.35 " *Parent* " shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities ending with the Company if each of the entities other than the Company beneficially owns, at the time of the determination, securities or interests representing at least fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.36 " *Performance Award* " shall mean a cash bonus award, stock bonus award, performance award or incentive award that is paid in cash, Shares or a combination of both, awarded under Section 10.1.

2.37 " *Performance-Based Compensation* " shall mean any compensation that is intended to qualify as "performance-based compensation" as described in Section 162(m)(4)(C) of the Code.

2.38 " *Performance Criteria* " shall mean the criteria (and adjustments) that the Committee selects for an Award for purposes of establishing the Performance Goal or Performance Goals for a Performance Period, determined as follows:

(a) The Performance Criteria that shall be used to establish Performance Goals are limited to the following: (i) net earnings (either before or after one or more of the following: (A) interest, (B) taxes, (C) depreciation and (D) amortization); (ii) gross or net sales or revenue; (iii) net income (either before or after taxes); (iv) adjusted net income; (v) operating earnings or profit; (vi) cash flow (including, but not limited to, operating cash flow and free cash flow); (vii) return on assets; (viii) return on capital; (ix) return on stockholders' equity; (x) total stockholder return; (xi) return on sales; (xii) gross or net profit or operating margin; (xiii) costs; (xiv) expenses; (xv) working capital; (xvi) earnings per share; (xvii) adjusted earnings per share; (xviii) price per share; (xix) regulatory body approval for commercialization of a product; (xx) implementation, completion or attainment of objectively determinable objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; (xxi) market share; and (xxii) economic value, any of which may be measured either in absolute terms or as compared to any incremental increase or decrease or as compared to results of a peer group or to market performance indicators or indices.

(b) The Administrator, in its sole discretion, may provide that one or more objectively determinable adjustments shall be made to one or more of the Performance Goals. Such adjustments may include one or more of the following: (i) items related to a change in accounting principle; (ii) items relating to financing activities; (iii) expenses for restructuring or productivity initiatives; (iv) other non-operating items; (v) items related to acquisitions; (vi) items attributable to the business operations of any entity acquired by the Company during the Performance Period; (vii) items related to the disposal of a business or segment of a business; (viii) items related to discontinued operations that do not qualify as a segment of a business under Applicable Accounting Standards; (ix) items attributable to any stock dividend, stock split, combination or exchange of stock occurring during the Performance Period; (x) any other items of significant income or expense which are determined to be appropriate adjustments; (xi) items relating to unusual or extraordinary corporate transactions, events or developments; (xii) items related to amortization of acquired intangible assets; (xiii) items that are outside the scope of the Company's core, on-going business activities; (xiv) items related to acquired in-process research and development; (xv) items relating to changes in tax laws; (xvi) items relating to major licensing or partnership arrangements; (xvii) items relating to asset impairment charges; (xviii) items relating to gains or losses for litigation, arbitration and contractual settlements; or (xix) items relating to any other unusual or nonrecurring events or changes in

Applicable Law, accounting principles or business conditions. For all Awards intended to qualify as Performance-Based Compensation, such determinations shall be made within the time prescribed by, and otherwise in compliance with, Section 162(m) of the Code.

2.39 " *Performance Goals* " shall mean, for a Performance Period, one or more goals established in writing by the Administrator for the Performance Period based upon one or more Performance Criteria. Depending on the Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of a Subsidiary, division, business unit, or an individual. The achievement of each Performance Goal shall be determined, to the extent applicable, with reference to Applicable Accounting Standards.

2.40 " *Performance Period* " shall mean one or more periods of time, which may be of varying and overlapping durations, as the Administrator may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Holder's right to, and the payment of, an Award.

2.41 " *Performance Stock Unit* " shall mean a Performance Award awarded under Section 10.1 which is denominated in units of value including dollar value of Shares.

2.42 " *Permitted Transferee* " shall mean, with respect to a Holder, any "family member" of the Holder, as defined in the instructions to Form S-8 under the Securities Act.

2.43 " *Plan* " shall have the meaning set forth in Article 1.

2.44 " *Prior Plans* " shall mean, collectively, the following plans of the Company: the Amended and Restated 2002 Stock Incentive Plan and the 2004 Stock Incentive Plan, in each case as such plan may be or may have been amended from time to time.

2.45 " *Program* " shall mean any program adopted by the Administrator pursuant to the Plan containing the terms and conditions intended to govern a specified type of Award granted under the Plan and pursuant to which such type of Award may be granted under the Plan.

2.46 " *Restricted Stock* " shall mean Common Stock awarded under Article 8 that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase.

2.47 " *Restricted Stock Units* " shall mean the right to receive Shares awarded under Article 9.

2.48 " *Securities Act* " shall mean the Securities Act of 1933, as amended.

2.49 " *Shares* " shall mean shares of Common Stock.

2.50 " *Stock Appreciation Right* " shall mean a stock appreciation right granted under Article 11.

2.51 " *Stock Appreciation Right Term* " shall have the meaning set forth in Section 11.4.

2.52 " *Stock Payment* " shall mean (a) a payment in the form of Shares, or (b) an option or other right to purchase Shares, as part of a bonus, deferred compensation or other arrangement, awarded under Section 10.3.

2.53 " *Subsidiary* " shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.54 " *Substitute Award* " shall mean an Award granted under the Plan upon the assumption of, or in substitution for, outstanding equity awards previously granted by a company or other entity in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock; *provided, however*, that in no event shall the term "Substitute Award" be construed to refer to an award made in connection with the cancellation and repricing of an Option or Stock Appreciation Right.

2.55 " *Termination of Service* " shall mean:

(a) As to a Consultant, the time when the engagement of a Holder as a Consultant to the Company or a Subsidiary is terminated for any reason, with or without cause, including, without limitation, by resignation, discharge, death or retirement, but excluding terminations where the Consultant simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(b) As to a Non-Employee Director, the time when a Holder who is a Non-Employee Director ceases to be a Director for any reason, including, without limitation, a termination by resignation, failure to be elected, death or retirement, but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(c) As to an Employee, the time when the employee-employer relationship between a Holder and the Company or any Subsidiary is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Subsidiary.

The Administrator, in its sole discretion, shall determine the effect of all matters and questions relating to any Termination of Service, including, without limitation, the question of whether a Termination of Service resulted from a discharge for cause and all questions of whether particular leaves of absence constitute a Termination of Service; *provided, however*, that, with respect to Incentive Stock Options, unless the Administrator otherwise provides in the terms of the Program, the Award Agreement or otherwise, or as otherwise required by Applicable Law, a leave of absence, change in status from an employee to an independent contractor or other change in the employee-employer relationship shall constitute a Termination of Service only if, and to the extent that, such leave of absence, change in status or other change interrupts employment for the purposes of Section 422(a)(2) of the Code and the then-applicable regulations and revenue rulings under said Section. For purposes of the Plan, a Holder's employee-employer relationship or consultancy relations shall be deemed to be terminated in the event that the Subsidiary employing or contracting with such Holder ceases to remain an Subsidiary following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off).

### ARTICLE 3.

#### SHARES SUBJECT TO THE PLAN

##### 3.1 *Number of Shares* .

(a) Subject to adjustment as provided in Section 3.1(b) and Section 14.2, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is the sum of (i) 11,900,000 Shares, plus (ii) the number of Shares subject to any option or stock appreciation right granted under a Prior Plan on or prior to December 31, 2012 to the extent such Shares become available for issuance under this Plan pursuant to Section 3.1(b) below thereafter, plus (iii) (A) 1.35 Shares multiplied by the number of Shares subject to any award granted under a Prior Plan on or prior to December 31, 2012 other than an option or stock appreciation right to the extent such Shares became available for issuance under this Plan pursuant to Section 3.1(b) below prior to June 9, 2015 and (B) 1.67 Shares multiplied by the number of Shares subject to any award granted under a Prior Plan on or prior to December 31, 2012 to the extent such Shares become available for issuance under this Plan pursuant to Section 3.1(b) below on or after June 9, 2015; *provided, however*, that in no event shall the number of Shares which shall become available for issuance or transfer pursuant to Awards under the Plan pursuant to clauses (ii) and (iii) above exceed an aggregate of 5,288,836 Shares. Any Shares that are subject to Awards of Options or Stock Appreciation Rights granted under the Plan shall be counted against this limit as one (1) Share for every one (1) Share granted. Any Shares that are subject to Awards granted under the Plan that are other than Options or Stock Appreciation Rights shall be counted against this limit as 1.35 Shares if the Award is granted prior to June 9, 2015 and as 1.67 Shares if the Award is granted on or after June 9, 2015 for every one (1) Share granted. After the date that the Plan is approved by the Company's shareholders, no awards may be granted under any Prior Plan, however, any awards under any Prior Plan that are outstanding as of the date that the Plan is approved by the Company's shareholders shall continue to be subject to the terms and conditions of such Prior Plan. Notwithstanding anything in this Section 3.1 to the contrary, the number of Shares that may be issued or transferred pursuant to Awards under the Plan (including Incentive Stock Options) shall not exceed an aggregate of 17,188,836 Shares, subject to adjustment pursuant to Section 14.2.

(b) If (i) any Shares subject to an Award are forfeited or expire or an Award is settled for cash (in whole or in part), or (ii) after the Effective Date any Shares subject to an award granted under any Prior Plan on or prior to December 31, 2012 are forfeited or expire or an award granted under any Prior Plan on

or prior to December 31, 2012 is settled for cash (in whole or in part), the Shares subject to such Award or award under the Prior Plan shall, to the extent of such forfeiture, expiration or cash settlement, again be available for Awards under the Plan, in accordance with Section 3.1(d) below. Notwithstanding anything to the contrary contained herein, the following Shares shall not be added to the Shares authorized for grant under Section 3.1(a) and shall not be available for future grants of Awards: (i) Shares tendered by a Holder or withheld by the Company in payment of the exercise price of an Option; (ii) Shares tendered by the Holder or withheld by the Company to satisfy any tax withholding obligation with respect to an Award; (iii) Shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the Stock Appreciation Right on exercise thereof; and (iv) Shares purchased on the open market with the cash proceeds from the exercise of Options. Any Shares repurchased by the Company under Section 8.4 at the same or lower price paid by the Holder so that such Shares are returned to the Company shall again be available for Awards. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan. Notwithstanding the provisions of this Section 3.1(b), no Shares may again be optioned, granted or awarded if such action would cause an Incentive Stock Option to fail to qualify as an incentive stock option under Section 422 of the Code.

(c) Substitute Awards shall not reduce the Shares authorized for grant under the Plan. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan; provided that Awards using such available Shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not employed by or providing services to the Company or its Subsidiaries immediately prior to such acquisition or combination.

(d) Any Shares that again become available for grant pursuant to this Section 3.1 shall be added back as: (i) one (1) Share if such Shares were subject to an Option or a Stock Appreciation Right granted under the Plan or an option or stock appreciation right granted under any Prior Plan, (ii) as 1.35 Shares if such Shares were subject to Awards other than Options or Stock Appreciation Rights granted under the Plan prior to June 9, 2015 or if such Shares became available for grant under the Plan pursuant to Section 3.1(b)(ii) prior to June 9, 2015, and (iii) as 1.67 Shares if such Shares were subject to Awards other than Options or Stock Appreciation Rights granted under the Plan on or after June 9, 2015 or if such Shares became available for grant under the Plan pursuant to Section 3.1(b)(ii) on or after June 9, 2015.

3.2 *Stock Distributed.* Any Shares distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Common Stock, treasury Common Stock or Common Stock purchased on the open market.

3.3 *Limitation on Number of Shares Subject to Awards.* Notwithstanding any provision in the Plan to the contrary, and subject to Section 14.2, the maximum aggregate number of Shares with respect to one or more Awards that may be granted to any one person other than a Non-Employee Director during any calendar year shall be 1,000,000, the maximum aggregate number of Shares with respect to one or more Awards that may be granted to a Non-Employee Director during any calendar year shall be 100,000 and the maximum aggregate amount of cash that may be paid in cash to any one person during any calendar year with respect to one or more Awards initially payable in cash shall be five million dollars.

## ARTICLE 4.

### GRANTING OF AWARDS

4.1 *Participation.* The Administrator may, from time to time, select from among all Eligible Individuals, those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not

be inconsistent with the requirements of the Plan. Except as provided in Section 4.6 regarding the grant of Awards pursuant to the Non-Employee Director Equity Compensation Policy, no Eligible Individual shall have any right to be granted an Award pursuant to the Plan.

4.2 *Award Agreement.* Each Award shall be evidenced by an Award Agreement that sets forth the terms, conditions and limitations for such Award, which may include the term of the Award, the provisions applicable in the event of the Holder's Termination of Service, and the Company's authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award. Award Agreements evidencing Awards intended to qualify as Performance-Based Compensation shall contain such terms and conditions as may be necessary to meet the applicable provisions of Section 162(m) of the Code. Award Agreements evidencing Incentive Stock Options shall contain such terms and conditions as may be necessary to meet the applicable provisions of Section 422 of the Code.

4.3 *Limitations Applicable to Section 16 Persons.* Notwithstanding any other provision of the Plan, the Plan, and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act, shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.4 *At-Will Employment; Voluntary Participation.* Nothing in the Plan or in any Program or Award Agreement hereunder shall confer upon any Holder any right to continue in the employ of, or as a Director or Consultant for, the Company or any Subsidiary, or shall interfere with or restrict in any way the rights of the Company and any Subsidiary, which rights are hereby expressly reserved, to discharge any Holder at any time for any reason whatsoever, with or without cause, and with or without notice, or to terminate or change all other terms and conditions of employment or engagement, except to the extent expressly provided otherwise in a written agreement between the Holder and the Company or any Subsidiary. Participation by each Holder in the Plan shall be voluntary and nothing in the Plan shall be construed as mandating that any Eligible Individual shall participate in the Plan.

4.5 *Foreign Holders.* Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in countries other than the United States in which the Company and its Subsidiaries operate or have Employees, Non-Employee Directors or Consultants, or in order to comply with the requirements of any foreign securities exchange, the Administrator, in its sole discretion, shall have the power and authority to: (a) determine which Subsidiaries shall be covered by the Plan; (b) determine which Eligible Individuals outside the United States are eligible to participate in the Plan; (c) modify the terms and conditions of any Award granted to Eligible Individuals outside the United States to comply with applicable foreign laws or listing requirements of any such foreign securities exchange; (d) establish subplans and modify exercise procedures and other terms and procedures, to the extent such actions may be necessary or advisable (any such subplans and/or modifications shall be attached to the Plan as appendices); *provided, however*, that no such subplans and/or modifications shall increase the share limitations contained in Sections 3.1 and 3.3; and (e) take any action, before or after an Award is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals or listing requirements of any such foreign securities exchange. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate Applicable Law. For purposes of the Plan, all references to foreign laws, rules, regulations or taxes shall be references to the laws, rules, regulations and taxes of any applicable jurisdiction other than the United States or a political subdivision thereof.

4.6 *Non-Employee Director Awards.* The Administrator, in its sole discretion, may provide that Awards granted to Non-Employee Directors shall be granted pursuant to a written nondiscretionary formula established by the Administrator (the "*Non-Employee Director Equity Compensation Policy*"), subject to the limitations of the Plan. The Non-Employee Director Equity Compensation Policy shall set forth the type of Award(s) to be granted to Non-Employee Directors, the number of Shares to be subject to Non-Employee Director Awards (subject to the limits of the Plan), the conditions on which such Awards shall be granted, become exercisable and/or payable and expire, and such other terms and conditions as the Administrator shall determine in its sole discretion. The Non-Employee Director Equity Compensation Policy may be modified by the Administrator from time to time in its sole discretion.

4.7 *Stand-Alone and Tandem Awards.* Awards granted pursuant to the Plan may, in the sole discretion of the Administrator, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the

Plan. Awards granted in addition to or in tandem with other Awards may be granted either at the same time as or at a different time from the grant of such other Awards.

## ARTICLE 5.

### PROVISIONS APPLICABLE TO AWARDS INTENDED TO QUALIFY AS PERFORMANCE-BASED COMPENSATION

5.1 *Purpose.* The Committee, in its sole discretion, may determine at the time an Award is granted or at any time thereafter whether such Award is intended to qualify as Performance-Based Compensation. If the Committee, in its sole discretion, decides to grant such an Award to an Eligible Individual that is intended to qualify as Performance-Based Compensation (other than an Option or Stock Appreciation Right), then the provisions of this Article 5 shall control over any contrary provision contained in the Plan. The Administrator, in its sole discretion, may grant Awards to other Eligible Individuals that are based on Performance Criteria or Performance Goals or any such other criteria and goals as the Administrator shall establish, but that do not satisfy the requirements of this Article 5 and that are not intended to qualify as Performance-Based Compensation. Unless otherwise specified by the Committee at the time of grant, the Performance Criteria with respect to an Award intended to be Performance-Based Compensation payable to a Covered Employee shall be determined on the basis of Applicable Accounting Standards.

5.2 *Applicability.* The grant of an Award to an Eligible Individual for a particular Performance Period shall not require the grant of an Award to such Eligible Individual in any subsequent Performance Period and the grant of an Award to any one Eligible Individual shall not require the grant of an Award to any other Eligible Individual in such period or in any other period.

5.3 *Types of Awards.* Notwithstanding anything in the Plan to the contrary, the Committee may grant any Award to an Eligible Individual intended to qualify as Performance-Based Compensation, including, without limitation, Restricted Stock the restrictions with respect to which lapse upon the attainment of specified Performance Goals, Restricted Stock Units that vest and become payable upon the attainment of specified Performance Goals and any Performance Awards described in Article 10 that vest or become exercisable or payable upon the attainment of one or more specified Performance Goals.

5.4 *Procedures with Respect to Performance-Based Awards.* To the extent necessary to comply with the requirements of Section 162(m)(4)(C) of the Code, with respect to any Award granted to one or more Eligible Individuals which is intended to qualify as Performance-Based Compensation, no later than 90 days following the commencement of any Performance Period or any designated fiscal period or period of service (or such earlier time as may be required under Section 162(m) of the Code), the Committee shall, in writing, (a) designate one or more Eligible Individuals, (b) select the Performance Criteria applicable to the Performance Period, (c) establish the Performance Goals, and amounts of such Awards, as applicable, which may be earned for such Performance Period based on the Performance Criteria, and (d) specify the relationship between Performance Criteria and the Performance Goals and the amounts of such Awards, as applicable, to be earned by each Covered Employee for such Performance Period. Following the completion of each Performance Period, the Committee shall certify in writing whether and the extent to which the applicable Performance Goals have been achieved for such Performance Period. In determining the amount earned under such Awards, the Committee shall have the right to reduce or eliminate (but not to increase) the amount payable at a given level of performance to take into account additional factors that the Committee may deem relevant, including the assessment of individual or corporate performance for the Performance Period.

5.5 *Payment of Performance-Based Awards.* Unless otherwise provided in the applicable Program or Award Agreement and only to the extent otherwise permitted by Section 162(m) of the Code, as to an Award that is intended to qualify as Performance-Based Compensation, the Holder must be employed by the Company or a Subsidiary throughout the Performance Period. Unless otherwise provided in the applicable Performance Goals, Program or Award Agreement, a Holder shall be eligible to receive payment pursuant to such Awards for a Performance Period only if and to the extent the Performance Goals for such period are achieved.

5.6 *Additional Limitations.* Notwithstanding any other provision of the Plan and except as otherwise determined by the Administrator, any Award which is granted to an Eligible Individual and is intended to qualify as

Performance-Based Compensation shall be subject to any additional limitations set forth in Section 162(m) of the Code or any regulations or rulings issued thereunder that are requirements for qualification as Performance-Based Compensation, and the Plan and the applicable Program and Award Agreement shall be deemed amended to the extent necessary to conform to such requirements.

## ARTICLE 6.

### GRANTING OF OPTIONS

6.1 *Granting of Options to Eligible Individuals.* The Administrator is authorized to grant Options to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan.

6.2 *Qualification of Incentive Stock Options.* No Incentive Stock Option shall be granted to any person who is not an Employee of the Company or any subsidiary corporation (as defined in Section 424(f) of the Code) of the Company. No person who qualifies as a Greater Than 10% Stockholder may be granted an Incentive Stock Option unless such Incentive Stock Option conforms to the applicable provisions of Section 422 of the Code. Any Incentive Stock Option granted under the Plan may be modified by the Administrator, with the consent of the Holder, to disqualify such Option from treatment as an "incentive stock option" under Section 422 of the Code. To the extent that the aggregate Fair Market Value of stock with respect to which "incentive stock options" (within the meaning of Section 422 of the Code, but without regard to Section 422(d) of the Code) are exercisable for the first time by a Holder during any calendar year under the Plan, and all other plans of the Company and any parent or subsidiary corporation thereof (each as defined in Section 424(e) and 424(f) of the Code, respectively), exceeds \$100,000, the Options shall be treated as Non-Qualified Stock Options to the extent required by Section 422 of the Code. The rule set forth in the immediately preceding sentence shall be applied by taking Options and other "incentive stock options" into account in the order in which they were granted and the Fair Market Value of stock shall be determined as of the time the respective options were granted.

6.3 *Option Exercise Price.* The exercise price per Share subject to each Option shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value of a Share on the date the Option is granted (or, as to Incentive Stock Options, on the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code). In addition, in the case of Incentive Stock Options granted to a Greater Than 10% Stockholder, such price shall not be less than 110% of the Fair Market Value of a Share on the date the Option is granted (or the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code).

6.4 *Option Term.* The term of each Option (the "*Option Term*") shall be set by the Administrator in its sole discretion; *provided, however*, that the Option Term shall not be more than ten (10) years from the date the Option is granted, or five (5) years from the date an Incentive Stock Option is granted to a Greater Than 10% Stockholder. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Options, which time period may not extend beyond the last day of the Option Term. Except as limited by the requirements of Section 409A, the Administrator may extend the Option Term of any outstanding Option, and may extend the time period during which vested Options may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 14.1, any other term or condition of such Option relating to such a Termination of Service.

6.5 *Option Vesting.*

(a) The period during which the right to exercise, in whole or in part, an Option vests in the Holder shall be set by the Administrator and the Administrator may determine that an Option may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Subsidiary, any of the Performance Criteria, or any other criteria selected by the Administrator, and, except as limited by the Plan, at any time after the grant of an Option, the Administrator, in its sole discretion and subject to whatever terms and conditions it selects, may accelerate the period during which an Option vests.

(b) No portion of an Option which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the

applicable Program, the Award Agreement evidencing the grant of an Option, or by action of the Administrator following the grant of the Option. Unless otherwise determined by the Administrator in the Award Agreement or by action of the Administrator following the grant of the Option, the portion of an Option that is unexercisable at a Holder's Termination of Service shall automatically expire thirty (30) days following such Termination of Service.

6.6 *Substitute Awards.* Notwithstanding the foregoing provisions of this Article 6 to the contrary, in the case of an Option that is a Substitute Award, the price per share of the Shares subject to such Option may be less than the Fair Market Value per share on the date of grant; *provided* that the excess of: (a) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the Shares subject to the Substitute Award, over (b) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

## ARTICLE 7.

### EXERCISE OF OPTIONS

7.1 *Partial Exercise.* An exercisable Option may be exercised in whole or in part. However, an Option shall not be exercisable with respect to fractional Shares and the Administrator may require that, by the terms of the Option, a partial exercise must be with respect to a minimum number of Shares.

7.2 *Manner of Exercise.* Unless otherwise indicated in an Award Agreement, all or a portion of an exercisable Option shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock administrator of the Company or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Option, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Option or such portion of the Option;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with Applicable Law. The Administrator, in its sole discretion, may also take whatever additional actions it deems appropriate to effect such compliance including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars;

(c) In the event that the Option shall be exercised pursuant to Section 12.3 by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Option, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes to the stock administrator of the Company for the Shares with respect to which the Option, or portion thereof, is exercised, in a manner permitted by Sections 12.1 and 12.2.

7.3 *Notification Regarding Disposition.* The Holder shall give the Company prompt written or electronic notice of any disposition of Shares acquired by exercise of an Incentive Stock Option which occurs within (a) two years from the date of granting (including the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code) such Option to such Holder, or (b) one year after the transfer of such Shares to such Holder.

## ARTICLE 8.

### AWARD OF RESTRICTED STOCK

8.1 *Award of Restricted Stock.*

(a) The Administrator is authorized to grant Restricted Stock to Eligible Individuals, and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock,

which terms and conditions shall not be inconsistent with the Plan, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate.

(b) The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock; *provided, however*, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock.

8.2 *Rights as Stockholders.* Subject to Section 8.4, upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all the rights of a stockholder with respect to said Shares, subject to the restrictions in the applicable Program or in each individual Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares; *provided, however*, that, in the sole discretion of the Administrator, any extraordinary distributions with respect to the Shares shall be subject to the restrictions set forth in Section 8.3. In addition, with respect to a share of Restricted Stock with performance-based vesting, dividends which are paid prior to vesting shall only be paid out to the Holder to the extent that the performance-based vesting conditions are subsequently satisfied and the share of Restricted Stock vests.

8.3 *Restrictions.* All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, in the terms of the applicable Program or in each individual Award Agreement, be subject to such restrictions and vesting requirements as the Administrator shall provide. Such restrictions may include, without limitation, restrictions concerning voting rights and transferability and such restrictions may lapse separately or in combination at such times and pursuant to such circumstances or based on such criteria as selected by the Administrator, including, without limitation, criteria based on the Holder's duration of employment, directorship or consultancy with the Company, the Performance Criteria, Company performance, individual performance or other criteria selected by the Administrator. By action taken after the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting of such Restricted Stock by removing any or all of the restrictions imposed by the terms of the applicable Program or Award Agreement. Restricted Stock may not be sold or encumbered until all restrictions are terminated or expire.

8.4 *Repurchase or Forfeiture of Restricted Stock.* Except as otherwise determined by the Administrator at the time of the grant of the Award or thereafter, if no price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Holder's rights in unvested Restricted Stock then subject to restrictions shall lapse, and such Restricted Stock shall be surrendered to the Company and cancelled without consideration. If a price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Company shall have the right to repurchase from the Holder the unvested Restricted Stock then subject to restrictions at a cash price per share equal to the price paid by the Holder for such Restricted Stock or such other amount as may be specified in the applicable Program or Award Agreement. Notwithstanding the foregoing, the Administrator, in its sole discretion, may provide that upon certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service or any other event, the Holder's rights in unvested Restricted Stock shall not lapse, such Restricted Stock shall vest and, if applicable, the Company shall not have a right of repurchase.

8.5 *Certificates for Restricted Stock.* Restricted Stock granted pursuant to the Plan may be evidenced in such manner as the Administrator shall determine. Certificates or book entries evidencing shares of Restricted Stock shall include an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock. The Company, in its sole discretion, may (a) retain physical possession of any stock certificate evidencing shares of Restricted Stock until the restrictions thereon shall have lapsed and/or (b) require that the stock certificates evidencing shares of Restricted Stock be held in custody by a designated escrow agent (which may but need not be the Company) until the restrictions thereon shall have lapsed, and that the Holder deliver a stock power, endorsed in blank, relating to such Restricted Stock.

8.6 *Section 83(b) Election.* If a Holder makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which the Holder would otherwise be taxable under Section 83(a) of the Code, the Holder shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service along with proof of the timely filing thereof with the Internal Revenue Service.

## ARTICLE 9.

### AWARD OF RESTRICTED STOCK UNITS

9.1 *Grant of Restricted Stock Units.* The Administrator is authorized to grant Awards of Restricted Stock Units to any Eligible Individual selected by the Administrator in such amounts and subject to such terms and conditions as determined by the Administrator.

9.2 *Term.* Except as otherwise provided herein, the term of a Restricted Stock Unit award shall be set by the Administrator in its sole discretion.

9.3 *Purchase Price.* The Administrator shall specify the purchase price, if any, to be paid by the Holder to the Company with respect to any Restricted Stock Unit award; *provided, however,* that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

9.4 *Vesting of Restricted Stock Units.* At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any Subsidiary, one or more Performance Criteria, Company performance, individual performance or other specific criteria, in each case on a specified date or dates or over any period or periods, as determined by the Administrator.

9.5 *Maturity and Payment.* At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units, which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted by the applicable Award Agreement); *provided* that, except as otherwise determined by the Administrator, set forth in any applicable Award Agreement, and subject to compliance with Section 409A of the Code, in no event shall the maturity date relating to each Restricted Stock Unit occur following the later of (a) the 15<sup>th</sup> day of the third month following the end of calendar year in which the applicable portion of the Restricted Stock Unit vests; or (b) the 15<sup>th</sup> day of the third month following the end of the Company's fiscal year in which the applicable portion of the Restricted Stock Unit vests. On the maturity date, the Company shall, subject to Section 12.4(e), transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously forfeited, or in the sole discretion of the Administrator, an amount in cash equal to the Fair Market Value of such Shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator.

9.6 *Payment upon Termination of Service.* An Award of Restricted Stock Units shall only be payable while the Holder is an Employee, a Consultant or a member of the Board, as applicable; *provided, however,* that the Administrator, in its sole discretion, may provide (in an Award Agreement or otherwise) that a Restricted Stock Unit award may be paid subsequent to a Termination of Service in certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service.

9.7 *No Rights as a Stockholder.* Unless otherwise determined by the Administrator, a Holder of Restricted Stock Units shall possess no incidents of ownership with respect to the Shares represented by such Restricted Stock Units, unless and until such Shares are transferred to the Holder pursuant to the terms of this Plan and the Award Agreement.

## ARTICLE 10.

### AWARD OF PERFORMANCE AWARDS, DIVIDEND EQUIVALENTS AND STOCK PAYMENTS

#### 10.1 *Performance Awards .*

(a) The Administrator is authorized to grant Performance Awards, including Awards of Performance Stock Units, to any Eligible Individual and to determine whether such Performance Awards shall be Performance-Based Compensation. The value of Performance Awards, including Performance Stock Units, may be linked to any one or more of the Performance Criteria or other specific criteria determined by the Administrator, in each case on a specified date or dates or over any period or periods and in such amounts as may be determined by the Administrator. Performance Awards, including Performance Stock Unit

awards may be paid in cash, Shares, or a combination of cash and Shares, as determined by the Administrator.

(b) Without limiting Section 10.1(a), the Administrator may grant Performance Awards to any Eligible Individual in the form of a cash bonus payable upon the attainment of objective Performance Goals, or such other criteria, whether or not objective, which are established by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator. Any such bonuses paid to a Holder which are intended to be Performance-Based Compensation shall be based upon objectively determinable bonus formulas established in accordance with the provisions of Article 5.

#### 10.2 *Dividend Equivalents.*

Dividend Equivalents may be granted by the Administrator based on dividends declared on the Common Stock, to be credited as of dividend payment dates with respect to dividends with record dates that occur during the period between the date an Award is granted to a Holder and the date such Award vests, is exercised, is distributed or expires, as determined by the Administrator. Such Dividend Equivalents shall be converted to cash or additional Shares by such formula and at such time and subject to such restrictions and limitations as may be determined by the Administrator. In addition, Dividend Equivalents with respect to an Award with performance-based vesting that are based on dividends paid prior to the vesting of such Award shall only be paid out to the Holder to the extent that the performance-based vesting conditions are subsequently satisfied and the Award vests.

10.3 *Stock Payments.* The Administrator is authorized to make Stock Payments to any Eligible Individual. The number or value of Shares of any Stock Payment shall be determined by the Administrator and may be based upon one or more Performance Criteria or any other specific criteria, including service to the Company or any Subsidiary, determined by the Administrator. Shares underlying a Stock Payment which is subject to a vesting schedule or other conditions or criteria set by the Administrator shall not be issued until those conditions have been satisfied. Unless otherwise provided by the Administrator, a Holder of a Stock Payment shall have no rights as a Company stockholder with respect to such Stock Payment until such time as the Stock Payment has vested and the Shares underlying the Award have been issued to the Holder. Stock Payments may, but are not required to, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to such Eligible Individual.

10.4 *Term.* The term of a Performance Award, Dividend Equivalent award and/or Stock Payment award shall be established by the Administrator in its sole discretion.

10.5 *Purchase Price.* The Administrator may establish the purchase price of a Performance Award or Shares distributed as a Stock Payment award; *provided, however*, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

10.6 *Termination of Service.* A Performance Award, Stock Payment award, and/or Dividend Equivalent award is distributable only while the Holder is an Employee, Director or Consultant, as applicable. The Administrator, however, in its sole discretion, may provide that the Performance Award, Dividend Equivalent award, and/or Stock Payment award may be distributed subsequent to a Termination of Service in certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service.

## ARTICLE 11.

### AWARD OF STOCK APPRECIATION RIGHTS

#### 11.1 *Grant of Stock Appreciation Rights.*

(a) The Administrator is authorized to grant Stock Appreciation Rights to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan.

(b) A Stock Appreciation Right shall entitle the Holder (or other person entitled to exercise the Stock Appreciation Right pursuant to the Plan) to exercise all or a specified portion of the Stock Appreciation Right (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying the difference obtained by subtracting the exercise price per share of the Stock Appreciation Right from the Fair Market Value on the date of exercise of the Stock Appreciation Right by

the number of Shares with respect to which the Stock Appreciation Right shall have been exercised, subject to any limitations the Administrator may impose. Except as described in (c) below, the exercise price per Share subject to each Stock Appreciation Right shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value on the date the Stock Appreciation Right is granted.

(c) Notwithstanding the foregoing provisions of Section 11.1(b) to the contrary, in the case of a Stock Appreciation Right that is a Substitute Award, the price per share of the Shares subject to such Stock Appreciation Right may be less than 100% of the Fair Market Value per share on the date of grant; *provided* that the excess of: (i) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the Shares subject to the Substitute Award, over (ii) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

#### 11.2 *Stock Appreciation Right Vesting.*

(a) The period during which the right to exercise, in whole or in part, a Stock Appreciation Right vests in the Holder shall be set by the Administrator and the Administrator may determine that a Stock Appreciation Right may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Subsidiary, any of the Performance Criteria, or any other criteria selected by the Administrator. Except as limited by the Plan, at any time after grant of a Stock Appreciation Right, the Administrator, in its sole discretion and subject to whatever terms and conditions it selects, may accelerate the period during which a Stock Appreciation Right vests.

(b) No portion of a Stock Appreciation Right which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator in the applicable Program, the Award Agreement evidencing the grant of a Stock Appreciation Right, or by action of the Administrator following the grant of the Stock Appreciation Right.

11.3 *Manner of Exercise.* All or a portion of an exercisable Stock Appreciation Right shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock administrator of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Stock Appreciation Right, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Stock Appreciation Right or such portion of the Stock Appreciation Right;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with Applicable Law. The Administrator, in its sole discretion, may also take whatever additional actions it deems appropriate to effect such compliance, including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars;

(c) In the event that the Stock Appreciation Right shall be exercised pursuant to this Section 11.3 by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Stock Appreciation Right, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes to the stock administrator of the Company for the Shares with respect to which the Stock Appreciation Right, or portion thereof, is exercised, in a manner permitted by Sections 12.1 and 12.2.

11.4 *Stock Appreciation Right Term.* The term of each Stock Appreciation Right (the "*Stock Appreciation Right Term*") shall be set by the Administrator in its sole discretion; *provided, however*, that the Stock Appreciation Right Term shall not be more than ten (10) years from the date the Stock Appreciation Right is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Stock Appreciation Rights, which time period may not extend beyond the last day of the Stock Appreciation Right Term applicable to such Stock Appreciation Right. Except as limited by the requirements of Section 409A of the Code and regulations and rulings thereunder or the first sentence of this Section 11.4, the Administrator may extend the Stock Appreciation Right Term of any outstanding Stock

Appreciation Right, and may extend the time period during which vested Stock Appreciation Rights may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 14.1, any other term or condition of such Stock Appreciation Right relating to such a Termination of Service.

11.5 *Payment.* Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 11 shall be in cash, Shares (based on its Fair Market Value as of the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

## ARTICLE 12.

### ADDITIONAL TERMS OF AWARDS

12.1 *Payment.* The Administrator shall determine the methods by which payments by any Holder with respect to any Awards granted under the Plan shall be made, including, without limitation: (a) cash or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) or Shares held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Holder has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; *provided* that payment of such proceeds is then made to the Company upon settlement of such sale, or (d) any other form of legal consideration acceptable to the Administrator in its sole discretion. The Administrator shall also determine the methods by which Shares shall be delivered or deemed to be delivered to Holders. Notwithstanding any other provision of the Plan to the contrary, no Holder who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

12.2 *Tax Withholding.* The Company or any Subsidiary shall have the authority and the right to deduct or withhold, or require a Holder to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Holder's FICA, employment tax or other social security contribution obligation) required by law to be withheld with respect to any taxable event concerning a Holder arising as a result of the Plan. The Administrator, in its sole discretion and in satisfaction of the foregoing requirement, may withhold, or allow a Holder to elect to have the Company withhold, Shares otherwise issuable under an Award (or allow the surrender of Shares). The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a fair market value on the date of withholding or repurchase equal to the aggregate amount of such liabilities based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income. The Administrator shall determine the fair market value of the Shares, consistent with applicable provisions of the Code, for tax withholding obligations due in connection with a broker-assisted cashless Option or Stock Appreciation Right exercise involving the sale of Shares to pay the Option or Stock Appreciation Right exercise price or any tax withholding obligation.

#### 12.3 *Transferability of Awards .*

(a) Except as otherwise provided in Section 12.3(b) and 12.3(c):

(i) No Award under the Plan may be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed;

(ii) No Award or interest or right therein shall be liable for the debts, contracts or engagements of the Holder or the Holder's successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment,

levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by Section 12.3(a)(i); and

(iii) During the lifetime of the Holder, only the Holder may exercise an Award (or any portion thereof) granted to such Holder under the Plan, unless it has been disposed of pursuant to a DRO; after the death of the Holder, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Program or Award Agreement, be exercised by the Holder's personal representative or by any person empowered to do so under the deceased Holder's will or under the then-applicable laws of descent and distribution.

(b) Notwithstanding Section 12.3(a), the Administrator, in its sole discretion, may determine to permit a Holder to transfer an Award other than an Incentive Stock Option to any one or more Permitted Transferees, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee other than by will or the laws of descent and distribution or pursuant to a DRO; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award); and (iii) the Holder and the Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer.

(c) Notwithstanding Section 12.3(a), a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Program or Award Agreement applicable to the Holder, except to the extent the Plan, the Program and the Award Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as the Holder's beneficiary with respect to more than 50% of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner. If no beneficiary has been designated or survives the Holder, payment shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; *provided* that the change or revocation is filed with the Administrator prior to the Holder's death.

#### 12.4 *Conditions to Issuance of Shares* .

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares pursuant to the exercise of any Award, unless and until the Board or the Committee has determined, with advice of counsel, that the issuance of such Shares is in compliance with Applicable Law and the Shares are covered by an effective registration statement or applicable exemption from registration. In addition to the terms and conditions provided herein, the Board or the Committee may require that a Holder make such reasonable covenants, agreements and representations as the Board or the Committee, in its sole discretion, deems advisable in order to comply with Applicable Law.

(b) All share certificates delivered pursuant to the Plan and all Shares issued pursuant to book entry procedures are subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with Applicable Law. The Administrator may place legends on any share certificate or book entry to reference restrictions applicable to the Shares.

(c) The Administrator shall have the right to require any Holder to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any Award, including a window-period limitation, as may be imposed in the sole discretion of the Administrator.

(d) No fractional Shares shall be issued and the Administrator, in its sole discretion, shall determine whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding down.

(e) Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by Applicable Law, the Company shall not deliver to any Holder certificates evidencing Shares issued in connection with any Award and instead such Shares shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

12.5 *Forfeiture and Claw-Back Provisions.* Pursuant to its general authority to determine the terms and conditions applicable to Awards under the Plan, the Administrator shall have the right to provide, in an Award Agreement or otherwise, or to require a Holder to agree by separate written or electronic instrument, that: (i) Any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of the Award, or upon the receipt or resale of any Shares underlying the Award, shall be paid to the Company, and (ii) the Award shall terminate and any unexercised portion of the Award (whether or not vested) shall be forfeited, if (x) a Termination of Service occurs prior to a specified date, or within a specified time period following receipt or exercise of the Award, or (y) the Holder at any time, or during a specified time period, engages in any activity in competition with the Company, or which is inimical, contrary or harmful to the interests of the Company, as further defined by the Administrator or (z) the Holder incurs a Termination of Service for "cause" (as such term is defined in the sole discretion of the Administrator, or as set forth in a written agreement relating to such Award between the Company and the Holder). All Awards (including any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of Applicable Law, including without limitation the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

12.6 *Prohibition on Repricing.* Subject to Section 14.2, the Administrator shall not, without the approval of the stockholders of the Company, (i) authorize the amendment of any outstanding Option or Stock Appreciation Right to reduce its price per share, or (ii) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares. Subject to Section 14.2, the Administrator shall have the authority, without the approval of the stockholders of the Company, to amend any outstanding Award to increase the price per share or to cancel and replace an Award with the grant of an Award having a price per share that is greater than or equal to the price per share of the original Award. Furthermore, for purposes of this Section 12.6, except in connection with a corporate transaction involving the Company (including, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination or exchange of shares), the terms of outstanding Awards may not be amended to reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights without the approval of the stockholders of the Company.

12.7 *Minimum Vesting Provision.* Notwithstanding any other provision of the Plan to the contrary, Awards (other than cash-settled Awards) made to Employees, Directors or Consultants shall not vest earlier than the date that is one year following the date the Award is approved by the Administrator; provided, however, that, notwithstanding the foregoing, Awards that result in the issuance of an aggregate of up to 5% of the Shares available pursuant to Section 3.1 may be granted to any one or more Employees, Directors or Consultants without respect to such minimum vesting provision.

## ARTICLE 13.

### ADMINISTRATION

13.1 *Administrator.* The Committee (or another committee or a subcommittee of the Board assuming the functions of the Committee under the Plan) shall administer the Plan (except as otherwise permitted herein). To the extent necessary to comply with Rule 16b-3 of the Exchange Act, and with respect to Awards that are intended to be Performance-Based Compensation, including Options and Stock Appreciation Rights, the Committee (or another committee or subcommittee of the Board assuming the functions of the Committee under the Plan) shall take all action with respect to such Awards, and the individuals taking such action shall consist solely of two or more Non-Employee Directors appointed by and holding office at the pleasure of the Board, each of whom is intended to qualify as both a "non-employee director" as defined by Rule 16b-3 of the Exchange Act or any successor rule and an "outside director" for purposes of Section 162(m) of the Code. Additionally, to the extent required by Applicable Law, each of the individuals constituting the Committee (or another committee or subcommittee of the Board assuming the functions of the Committee under the Plan) shall be an "independent director" under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded. Notwithstanding the foregoing, any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section 13.1 or otherwise provided in any charter of the Committee. Except as may otherwise be provided in any charter of the Committee, appointment of Committee members shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written or electronic notice to the Board. Vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the terms "Administrator" and "Committee" as used in the Plan shall be deemed to refer to the Board and (b) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 13.6.

13.2 *Duties and Powers of Committee.* It shall be the duty of the Committee to conduct the general administration of the Plan in accordance with its provisions. The Committee shall have the power to interpret the Plan, the Program and the Award Agreement, and to adopt such rules for the administration, interpretation and application of the Plan as are not inconsistent therewith, to interpret, amend or revoke any such rules and to amend any Program or Award Agreement; *provided* that the rights or obligations of the Holder of the Award that is the subject of any such Program or Award Agreement are not affected adversely by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 12.5 or Section 14.10. Any such grant or award under the Plan need not be the same with respect to each Holder. Any such interpretations and rules with respect to Incentive Stock Options shall be consistent with the provisions of Section 422 of the Code. In its sole discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee under the Plan except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or Section 162(m) of the Code, or any regulations or rules issued thereunder, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded are required to be determined in the sole discretion of the Committee.

13.3 *Action by the Committee.* Unless otherwise established by the Board or in any charter of the Committee, a majority of the Committee shall constitute a quorum and the acts of a majority of the members present at any meeting at which a quorum is present, and acts approved in writing by all members of the Committee in lieu of a meeting, shall be deemed the acts of the Committee. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Subsidiary, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

13.4 *Authority of Administrator.* Subject to the Company's Bylaws, the Committee's Charter and any specific designation in the Plan, the Administrator has the exclusive power, authority and sole discretion to:

- (a) Designate Eligible Individuals to receive Awards;
- (b) Determine the type or types of Awards to be granted to each Eligible Individual;
- (c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;
- (d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, purchase price, any Performance Criteria, any reload provision,

any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;

- (e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;
- (f) Prescribe the form of each Award Agreement, which need not be identical for each Holder;
- (g) Decide all other matters that must be determined in connection with an Award;
- (h) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;
- (i) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement;
- (j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan; and
- (k) Accelerate wholly or partially the vesting or lapse of restrictions of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects and Section 14.2.

13.5 *Decisions Binding.* The Administrator's interpretation of the Plan, any Awards granted pursuant to the Plan, any Program, any Award Agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding and conclusive on all parties.

13.6 *Delegation of Authority.* To the extent permitted by Applicable Law, the Board or Committee may from time to time delegate to a committee of one or more members of the Board or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to this Article 13; *provided, however*, that in no event shall an officer of the Company be delegated the authority to grant awards to, or amend awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act, (b) Covered Employees or (c) officers of the Company (or Directors) to whom authority to grant or amend Awards has been delegated hereunder; *provided, further*, that any delegation of administrative authority shall only be permitted to the extent it is permissible under Section 162(m) of the Code and other Applicable Law. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation, and the Board may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 13.6 shall serve in such capacity at the pleasure of the Board and the Committee.

## ARTICLE 14.

### MISCELLANEOUS PROVISIONS

14.1 *Amendment, Suspension or Termination of the Plan.* Except as otherwise provided in this Section 14.1, the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board or the Committee. However, without approval of the Company's stockholders given within twelve (12) months before or after the action by the Administrator, no action of the Administrator may, except as provided in Section 14.2, (a) increase the limits imposed in Section 3.1 on the maximum number of Shares which may be issued under the Plan, (b) reduce the price per share of any outstanding Option or Stock Appreciation Right granted under the Plan or take any action prohibited under Section 12.6, or (c) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares. Except as provided in Section 12.5 and Section 14.10, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, impair any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides. No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and notwithstanding anything herein to the contrary, in no event may any Award be granted under the Plan after

April 15, 2026 (the " *Expiration Date* "). Any Awards that are outstanding on the Expiration Date shall remain in force according to the terms of the Plan and the applicable Award Agreement.

14.2 *Changes in Common Stock or Assets of the Company, Acquisition or Liquidation of the Company and Other Corporate Events* .

(a) In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares of the Company's stock or the share price of the Company's stock other than an Equity Restructuring, the Administrator may make equitable adjustments, if any, to reflect such change with respect to: (i) the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Sections 3.1 and 3.3 on the maximum number and kind of Shares which may be issued under the Plan, and adjustments of the Award Limit, and adjustments of the manner in which shares subject to Full Value Awards will be counted); (ii) the number and kind of Shares (or other securities or property) subject to outstanding Awards; (iii) (iii) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (iv) the grant or exercise price per share for any outstanding Awards under the Plan. Any adjustment affecting an Award intended as Performance-Based Compensation shall be made consistent with the requirements of Section 162(m) of the Code.

(b) In the event of any transaction or event described in Section 14.2(a) or any unusual or nonrecurring transactions or events affecting the Company, any Subsidiary of the Company, or the financial statements of the Company or any Subsidiary, or of changes in Applicable Law or accounting principles, the Administrator, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Holder's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Holder's rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 14.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder's rights, then such Award may be terminated by the Company without payment) or (B) the replacement of such Award with other rights or property selected by the Administrator, in its sole discretion, having an aggregate value not exceeding the amount that could have been attained upon the exercise of such Award or realization of the Holder's rights had such Award been currently exercisable or payable or fully vested;

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(iii) To make adjustments in the number and type of Shares of the Company's stock (or other securities or property) subject to outstanding Awards, and in the number and kind of outstanding Restricted Stock and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards and Awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all Shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Program or Award Agreement; and

(v) To provide that the Award cannot vest, be exercised or become payable after such event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Section 14.2(a) and 14.2(b):

(i) The number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, shall be equitably adjusted; and/or

(ii) The Administrator shall make such equitable adjustments, if any, as the Administrator, in its sole discretion, may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Sections 3.1 and 3.3 on the maximum number and kind of Shares which may be issued under the Plan, adjustments of the Award Limit, and adjustments of the manner in which Shares subject to Full Value Awards will be counted). The adjustments provided under this Section 14.2(c) shall be nondiscretionary and shall be final and binding on the affected Holder and the Company.

(d) Notwithstanding any other provision of the Plan, in the event of a Change in Control, each outstanding Award shall continue in effect or be assumed or an equivalent Award substituted by the successor corporation or a parent or subsidiary of the successor corporation.

(e) In the event that the successor corporation in a Change in Control refuses to assume or substitute for the Award, the Administrator may cause any or all of such Awards to become fully exercisable immediately prior to the consummation of such transaction and all forfeiture restrictions on any or all of such Awards to lapse. If an Award is exercisable in lieu of assumption or substitution in the event of a Change in Control, the Administrator shall notify the Holder that the Award shall be fully exercisable for a period of fifteen (15) days from the date of such notice, contingent upon the occurrence of the Change in Control, and the Award shall terminate upon the expiration of such period.

(f) For the purposes of this Section 14.2, an Award shall be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); *provided, however*, that if such consideration received in the Change in Control was not solely common stock of the successor corporation or its parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Award, for each Share subject to an Award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per-share consideration received by holders of Common Stock in the Change in Control.

(g) The Administrator, in its sole discretion, may include such further provisions and limitations in any Award, agreement or certificate, as it may deem equitable and in the best interests of the Company that are not inconsistent with the provisions of the Plan.

(h) With respect to Awards which are granted to Covered Employees and are intended to qualify as Performance-Based Compensation, no adjustment or action described in this Section 14.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause such Award to fail to so qualify as Performance-Based Compensation, unless the Administrator determines that the Award should not so qualify. No adjustment or action described in this Section 14.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to violate Section 422(b)(1) of the Code. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 or violate the exemptive conditions of Rule 16b-3 unless the Administrator determines that the Award is not to comply with such exemptive conditions.

(i) The existence of the Plan, the Program, the Award Agreement and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock

or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(j) No action shall be taken under this Section 14.2 which shall cause an Award to fail to be exempt from or comply with Section 409A of the Code or the Treasury Regulations thereunder.

(k) In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares or the share price of the Common Stock including any Equity Restructuring, for reasons of administrative convenience, the Administrator, in its sole discretion, may refuse to permit the exercise of any Award during a period of up to thirty (30) days prior to the consummation of any such transaction.

14.3 *Approval of Plan by Stockholders.* The Plan shall be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the Board's initial adoption of the Plan. Awards may be granted or awarded prior to such stockholder approval; *provided* that such Awards shall not be exercisable, shall not vest and the restrictions thereon shall not lapse and no Shares shall be issued pursuant thereto prior to the time when the Plan is approved by the stockholders; and *provided, further*, that if such approval has not been obtained at the end of said twelve (12) month period, all Awards previously granted or awarded under the Plan shall thereupon be canceled and become null and void.

14.4 *No Stockholders Rights.* Except as otherwise provided herein, a Holder shall have none of the rights of a stockholder with respect to Shares covered by any Award until the Holder becomes the record owner of such Shares.

14.5 *Paperless Administration.* In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Holder may be permitted through the use of such an automated system.

14.6 *Effect of Plan upon Other Compensation Plans.* The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company or any Subsidiary. Nothing in the Plan shall be construed to limit the right of the Company or any Subsidiary: (a) to establish any other forms of incentives or compensation for Employees, Directors or Consultants of the Company or any Subsidiary, or (b) to grant or assume options or other rights or awards otherwise than under the Plan in connection with any proper corporate purpose including without limitation, the grant or assumption of options in connection with the acquisition by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, partnership, limited liability company, firm or association.

14.7 *Compliance with Laws.* The Plan, the granting and vesting of Awards under the Plan and the issuance and delivery of Shares and the payment of money under the Plan or under Awards granted or awarded hereunder are subject to compliance with all Applicable Law (including but not limited to state, federal and foreign securities law and margin requirements), and to such approvals by any listing, regulatory or governmental authority as may, in the opinion of counsel for the Company, be necessary or advisable in connection therewith. Any securities delivered under the Plan shall be subject to such restrictions, and the person acquiring such securities shall, if requested by the Company, provide such assurances and representations to the Company as the Company may deem necessary or desirable to assure compliance with all Applicable Law. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to Applicable Law.

14.8 *Titles and Headings, References to Sections of the Code or Exchange Act.* The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

14.9 *Governing Law.* The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

14.10 *Section 409A.* To the extent that the Administrator determines that any Award granted under the Plan is subject to Section 409A of the Code, the Program pursuant to which such Award is granted and the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A of the Code. To the extent applicable, the Plan, the Program and any Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Administrator determines that any Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Effective Date), the Administrator may adopt such amendments to the Plan and the applicable Program and Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (b) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance and thereby avoid the application of any penalty taxes under such Section.

14.11 *No Rights to Awards.* No Eligible Individual or other person shall have any claim to be granted any Award pursuant to the Plan, and neither the Company nor the Administrator is obligated to treat Eligible Individuals, Holders or any other persons uniformly.

14.12 *Unfunded Status of Awards.* The Plan is intended to be an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Holder pursuant to an Award, nothing contained in the Plan or any Program or Award Agreement shall give the Holder any rights that are greater than those of a general creditor of the Company or any Subsidiary.

14.13 *Indemnification.* To the extent allowable pursuant to Applicable Law, each member of the Committee or of the Board shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; *provided* he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

14.14 *Relationship to other Benefits.* No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

14.15 *Expenses.* The expenses of administering the Plan shall be borne by the Company and its Subsidiaries.

\* \* \* \* \*

## CERTIFICATION

I, Craig A. Wheeler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 5, 2016

/s/ Craig A. Wheeler

---

Craig A. Wheeler

President and Chief Executive Officer

## CERTIFICATION

I, Richard P. Shea, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 5, 2016

/s/ Richard P. Shea

---

Richard P. Shea

Senior Vice President and Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Richard P. Shea, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 5, 2016

/s/ Craig A. Wheeler

---

Craig A. Wheeler

President and Chief Executive Officer

Dated: August 5, 2016

/s/ Richard P. Shea

---

Richard P. Shea

Senior Vice President and Chief Financial Officer