MOMENTA PHARMACEUTICALS INC
Form 10-Q
August 04, 2017
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended June 30, 2017

or

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

For the Transition Period from to

Commission File Number 000-50797

Momenta Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	04-3561634
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

675 West Kendall Street, Cambridge, MA 02142
(Address of Principal Executive Offices) (Zip Code)

(617) 491-9700
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

As of July 26, 2017, there were 76,231,229 shares of the registrant’s common stock, par value $0.0001 per share, outstanding.

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MOMENTA PHARMACEUTICALS, INC.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Quarterly Report on Form 10-Q that are about future events or future results, or are otherwise not statements of historical fact, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management. In some cases, these statements can be identified by words such as “anticipate,” “approach,” “believe,” “can,” “considering,” “contemplate,” “continue,” “could,” “determine,” “ensure,” “estimate,” “expect,” “goal,” “guidance,” “intend,” “might,” “objective,” “opportunity,” “plan,” “possible,” “potential”, “predict,” “progress,” “project,” “pursue,” “seek,” “schedu “strategy,” “target,” “typically,” “will,” “working toward,” “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 and novel therapeutic programs; the timing of clinical trials and the availability and timing of reporting results; the timing of launch of products and product candidates, including GLATOPA® (glatiramer acetate injection) 40 mg/mL; market potential and product revenues of our products and product candidates, including GLATOPA and Enoxaparin Sodium Injection; the timing, merits, strategy, impact and outcome of, and decisions regarding, legal and regulatory proceedings; collaboration revenues and research and development revenues; manufacturing, including statements regarding Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; the FDA warning letter received by Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; timing of regulatory filings, reviews and approvals, including the timing of the regulatory review and approval of the GLATOPA 40 mg/mL ANDA; 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; 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, costs, and decision making 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, including Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; 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 collaboration and/or license arrangements; marketing plans; financing our planned operating and capital expenditure; the terms and conditions of our facility leases; materials used in our research and development; royalty rates; our collaborators' plans; 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.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$110,841	$ 150,738
Marketable securities	335,704	202,413
Collaboration receivable	24,806	70,242
Restricted cash	2,412	—
Prepaid expenses and other current assets	7,864	4,607
Total current assets	481,627	428,000
Marketable securities, long-term	10,279	—
Property and equipment, net	23,905	20,847
Restricted cash, long-term	19,349	21,761
Intangible assets, net	4,613	5,189
Other long-term assets	1,033	1,940
Total assets	$540,806	$ 477,737
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$12,053	$ 3,632
Accrued expenses	30,924	26,866
Collaboration advance	20,359	32,895
Deferred revenue	54,694	7,272
Other current liabilities	26	11
Total current liabilities	118,056	70,676
Deferred revenue, net of current portion	30,761	31,360
Other long-term liabilities	5,128	3,793
Total liabilities	153,945	105,829
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.0001 par value per share; 100,000 shares authorized, 76,447 shares issued and 76,218 shares outstanding at June 30, 2017 and 71,305 shares issued and 71,076 outstanding at December 31, 2016	8	7
Additional paid-in capital	932,797	848,304
Accumulated other comprehensive (loss) income	(5)	86
Accumulated deficit	(542,825)	(473,375)
Treasury stock, at cost, 229 shares	(3,114)	(3,114)
Total stockholders' equity	386,861	371,908

Total liabilities and stockholders' equity	$540,806	$ 477,737

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenues:				
Product revenue	$19,140	$20,692	$42,544	$35,492
Research and development revenue	4,430	5,738	7,640	10,788
Total collaboration revenue	23,570	26,430	50,184	46,280
Operating expenses:				
Research and development	39,063	33,173	75,164	61,930
General and administrative	22,572	14,896	45,677	30,543
Total operating expenses	61,635	48,069	120,841	92,473
Operating loss	(38,065)	(21,639)	(70,657)	(46,193)
Other income, net	1,157	653	1,990	1,195
Net loss	$(36,908)	$(20,986)	$(68,667)	$(44,998)
Basic and diluted net loss per share	$(0.50)	$(0.31)	$(0.96)	$(0.66)
Weighted average shares used in computing basic and diluted net loss per share	73,379	68,532	71,555	68,409
Comprehensive loss:				
Net loss	$(36,908)	$(20,986)	$(68,667)	$(44,998)
Net unrealized holding (losses) gains on available-for-sale marketable securities	(25)	149	(91)	282
Comprehensive loss	$(36,933)	$(20,837)	$(68,758)	$(44,716)

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

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

	Six Months Ended June 30,	
	2017	2016
Cash Flows from Operating Activities:		
Net loss	$(68,667)	$(44,998)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization of property and equipment	3,046	3,804
Share-based compensation expense	11,393	9,817
Amortization of premium on investments	111	429
Amortization of intangibles	576	898
Changes in operating assets and liabilities:		
Collaboration receivable	45,436	(14,677)
Prepaid expenses and other current assets	(2,220)	(606)
Other long-term assets	907	(688)
Accounts payable	8,988	8,086
Accrued expenses	3,106	(8,811)
Collaboration advance	(12,536)	—
Deferred revenue	46,823	37,350
Other current liabilities	15	(338)
Other long-term liabilities	1,335	895
Net cash provided by (used in) operating activities	38,313	(8,839)
Cash Flows from Investing Activities:		
Purchases of property and equipment	(5,719)	(3,704)
Purchases of marketable securities	(269,392)	(221,982)
Proceeds from maturities of marketable securities	125,620	261,726
Net cash (used in) provided by investing activities	(149,491)	36,040
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock under ATM facility	64,090	—
Proceeds from issuance of common stock under stock plans	7,191	627
Repurchase of common stock pursuant to share surrender	—	(1,065)
Net cash provided by (used in) financing activities	71,281	(438)
Net (decrease) increase in cash and cash equivalents	(39,897)	26,763
Cash and cash equivalents, beginning of period	150,738	61,461
Cash and cash equivalents, end of period	$110,841	$88,224
Non-Cash Investing/Financing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$1,320	$505
Common shares issued to Parivid to settle milestone payment	$—	$2,868

Receivable due from stock option exercises	$1,037	$—
Impact of adopting ASU 2016-09	$783	$—

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

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

1. The Company

Business
Momenta Pharmaceuticals, Inc., referred to as Momenta or the Company, 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 autoimmune diseases. 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, 2016, 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 24, 2017. The year-end condensed consolidated 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 subsidiaries, Momenta Pharmaceuticals Securities Corporation and Momenta Ireland Limited. 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, 2017, 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; Mylan Ireland Limited, a wholly-owned, indirect subsidiary of Mylan N.V., or Mylan; and CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited.

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The Company evaluates its arrangements pursuant to Accounting Standards Codification, or ASC, on Collaborative Arrangements, or ASC 808, and 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 either when the final deliverable is delivered to the customer or on a straight-line basis over the contracted or estimated period of performance if there are multiple deliverables that are satisfied over time. 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

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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.

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 on Sandoz' Sales of Enoxaparin Sodium Injection and GLATOPA® 20 mg/mL

Profit share revenue is reported as product revenue and is recognized based upon 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 and 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 Sandoz 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.

Collaboration Costs and Reimbursements

Under its collaborations, the Company incurs employee expenses as well as external costs for development and commercial activities, presented as operating expenses. Reimbursements of those costs under the Company's collaboration arrangements may be presented as revenue or a reduction of operating expenses, depending on the nature of responsibilities of each party under the collaboration.

Under the Company's collaboration with Mylan, because the collaboration arrangement is a cost sharing arrangement with shared responsibilities, reimbursement by Mylan for its share of the development effort is presented as a reduction of operating expense. Similarly, amounts owed to Mylan to reimburse them for the Company's share of their costs incurred are recorded as an operating expense.

Under the Company's collaborations with Sandoz, since the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for services the Company is obligated to provide to Sandoz, the reimbursements for such services are recorded as revenues on a gross basis. Revenues are recognized upon completion of the services.

Under the Company's collaboration with CSL, since the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for services the Company is obligated to provide to CSL, the reimbursements for such services are recorded as revenues on a gross basis. Revenues are recognized upon completion of the services performed. Under the arrangement, the Company incurs certain reimbursable materials costs on CSL's behalf, which are netted against research and development expense.

Collaboration Receivable

Collaboration receivable represents:

- Amounts due to the Company for its contractual profit share on Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL;

- Amounts due to the Company for reimbursement of research and development services and certain external costs under the collaborations with Sandoz and CSL, and, where applicable, the former collaboration with Baxalta;

- Amounts due from Mylan for its 50% share of certain collaboration expenses under the cost-sharing provisions of the Mylan Collaboration Agreement that are not funded through the continuation payments; and

- As of December 31, 2016, the $51.2 million asset return payment due from Baxalta, as discussed in Note 5, "Collaboration and License Agreements." In January 2017, the Company received the $51.2 million payment from Baxalta.

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

Collaboration Advance

Collaboration advance represents payments received from Mylan that will be applied to amounts due from Mylan in future periods for the funding of Mylan's 50% share of certain collaboration expenses under the cost-sharing provisions of the Mylan Collaboration Agreement.

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.

Adoption of ASU No. 2016-09

On January 1, 2017, the Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting and made an entity-wide accounting policy election to account for award forfeitures as they occur. As a result, the Company recorded a cumulative opening adjustment to accumulated deficit and additional paid-in capital of $0.8 million. The amended guidance also eliminates the requirement that excess tax benefits be realized as a reduction in current taxes payable before the associated tax benefit can be recognized in additional paid-in capital. This created approximately $5.3 million of deferred tax assets relating to federal and state net operating losses that are fully offset by a corresponding increase in the valuation allowance. As a result, there was no cumulative effect adjustment to accumulated deficit.

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 stock awards and units. 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 awards and units determined by applying the treasury stock method.

The following table presents anti-dilutive shares for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Weighted-average anti-dilutive shares related to:				
Outstanding stock options	4,784	7,156	4,273	6,908
Restricted stock awards	1,467	1,323	1,542	829

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, 2017 and 2016. 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, approximately 1.3 million of performance-based restricted common stock awards that were granted between April 2016 and June 30, 2017 had not vested as of June 30, 2017, and were excluded from diluted shares outstanding as the vesting conditions for the awards, discussed further in Note 6 “Share-Based Payments -- Restricted Stock and Restricted Stock Units,” had not been met as of June 30, 2017.

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, 2017 and December 31, 2016, and indicate the level within the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

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Description	Balance as of June 30, 2017	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	$98,090	$69,090	$29,000	$ —
Marketable securities:				
U.S. government-sponsored enterprise securities	2,187	—	2,187	—
Corporate debt securities	135,838	—	135,838	—
Commercial paper obligations	131,180	—	131,180	—
Asset-backed securities	76,778	—	76,778	—
Total	$444,073	$69,090	$374,983	$ —

Description	Balance as of December 31, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds and overnight repurchase agreements	$ 145,510	$121,510	$24,000	$ —
Marketable securities:				
Corporate debt securities	47,906	—	47,906	—
Commercial paper obligations	84,436	—	84,436	—
Asset-backed securities	70,071	—	70,071	—
Total	$ 347,923	$121,510	$226,413	$ —

The Company held $29.0 million and $24.0 million in overnight repurchase agreements as of June 30, 2017 and December 31, 2016, respectively. The instruments are classified as Level 2 due to the collateral including both U.S. government-sponsored enterprise securities and treasury instruments.

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, 2017 and 2016. 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, 2017. 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, 2016. The carrying amounts reflected in the Company's consolidated balance sheets for cash, collaboration receivable, 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 composed of money market funds and overnight repurchase agreements. Money market funds are carried at fair value, which approximate cost at June 30, 2017 and December 31, 2016. Overnight

repurchase agreement yields are comparable to money market funds where principal and interest on the instruments is due the next day.

The Company classifies corporate debt securities, commercial paper and asset-backed securities as short-term and long-term marketable securities in its consolidated financial statements. See Note 2 “Summary of Significant Accounting Policies --

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Cash, Cash Equivalents and Marketable Securities" to the Company's consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 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, 2017 and December 31, 2016 (in thousands):

As of June 30, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$110,841	$ —	$ —	$110,841
U.S. government-sponsored enterprise securities due in one year or less	2,188	—	(1)	2,187
Corporate debt securities due in one year or less	135,889	1	(52)	135,838
Commercial paper obligations due in one year or less	131,102	78	—	131,180
Asset-backed securities due in one year or less	66,519	—	(20)	66,499
Asset-backed securities due in two years or less	10,290	—	(11)	10,279
Total	$456,829	$ 79	$ (84)	$456,824
Reported as:				
Cash and cash equivalents	$110,841	$ —	$ —	$110,841
Marketable securities	345,988	79	(84)	345,983
Total	$456,829	$ 79	$ (84)	$456,824

As of December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$150,738	$ —	$ —	$150,738
Corporate debt securities due in one year or less	47,942	—	(36)	47,906
Commercial paper obligations due in one year or less	84,301	135	—	84,436
Asset-backed securities due in one year or less	70,084	1	(14)	70,071
Total	$353,065	$ 136	$ (50)	$353,151
Reported as:				
Cash and cash equivalents	$150,738	$ —	$ —	$150,738
Marketable securities	202,327	136	(50)	202,413
Total	$353,065	$ 136	$ (50)	$353,151

At June 30, 2017 and December 31, 2016, the Company held 59 and 31 marketable securities, respectively, that were in a continuous unrealized loss position for less than one year. As the unrealized losses on these securities were caused by fluctuations in interest rates, the Company concluded that no other-than-temporary impairment exists with respect to these securities. At June 30, 2017 and December 31, 2016, 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, 2017 and December 31, 2016 (in thousands):

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	As of June 30, 2017		As of December 31, 2016	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities due in one year or less	$123,068	$ (52)	$47,906	$ (36)
Asset-backed securities due in one year or less	$64,998	$ (20)	$60,787	$ (14)
Asset-backed securities due in two years or less	$10,279	$ (11)	$—	$ —
U.S. Government-sponsored enterprise due in one year or less	$2,187	$ (1)	$—	$ —

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

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB has subsequently issued the following amendments to ASU 2014-09, which have the same effective date and transition date of January 1, 2018:

- 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.

- In March 2016 the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations.

- In April 2016 the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance.

- In May 2016 the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other

similar taxes collected from customers.

- In December 2016 the FASB issued ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which amends certain narrow aspects of the guidance issued in ASU No. 2014-09 including guidance related to the disclosure of remaining performance obligations and prior-period performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples.

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The Company expects to adopt the new standard using the modified retrospective method as permissible under the transitional provisions of Topic 606 for all contracts not yet completed as of the effective date. The modified retrospective method applies the guidance retrospectively only to the most current period presented in the financial statements, recognizing the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings (or deficit) at the date of initial application. The Company continues to progress its analysis of its arrangements with Sandoz, Mylan and CSL under the new accounting standard. As of June 30, 2017, the Company is unable to estimate the expected financial statement impact of applying the new standard to these arrangements. During the second half of 2017, the Company plans to finalize its analysis to determine the impact this standard may have on its results of operations, financial position and disclosures.

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 August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230), which simplifies certain elements of cash flow classification. The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for annual periods beginning after December 15, 2017. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Restricted Cash, or ASU 2016-18. The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU 2016-18 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which amended guidance related to business combinations. The amended guidance clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new accounting guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company early adopted this new guidance as of January 1, 2017 and will apply this new guidance to any future acquisitions.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting or ASU 2017-09. The amendments in ASU 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU 2017-09 introduces guidance that an entity should account for the effects of a modification unless all the following are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified and if the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early

adoption permitted, applied prospectively to an award modified on or after the adoption date. The Company early adopted this new guidance as of July 1, 2017 and has applied this new guidance prospectively to any modifications to share-based payment awards.

3. Intangible Assets

Intangible assets consist solely of the core developed technology assets acquired from Parivid. See Note 6 “Intangible Assets” to the Company’s consolidated financial statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of the Parivid agreement.

The intangible assets are being amortized using the straight-line method over the estimated useful life of GLATOPA 20 mg/mL of approximately six years through June 2021. As of June 30, 2017 and December 31, 2016, intangible assets, net of accumulated amortization, were as follows (in thousands):

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	June 30, 2017			December 31, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Intangible assets	$13,617	$ (9,004)	$ 4,613	$13,617	$ (8,428)	$ 5,189

Amortization expense was approximately $0.3 million and $0.6 million for the three months ended June 30, 2017 and 2016, respectively. Amortization expense was approximately $0.6 million and $0.9 million for the six months ended June 30, 2017 and 2016, respectively.

The Company expects to incur amortization expense of approximately $1.2 million per year for the next four years.

4. Restricted Cash

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Amphastar and International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. Additional information regarding the litigation is discussed within Note 8 "Commitments and Contingencies." The $17.5 million is held in an escrow account by Hanover Insurance. The Company classified this restricted cash as long-term as the timing of a final decision in the Enoxaparin Sodium Injection patent litigation is not known.

The Company designated $2.4 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 is therefore classified as 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 is therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

The Company designated $1.1 million as collateral for a letter of credit related to the lease of office and laboratory space located on the fifth floor of 301 Binney Street in Cambridge, Massachusetts. This balance will remain restricted through June 2025 and is therefore 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, 2017, the Company had collaboration and license agreements with Sandoz, Sandoz AG, Mylan and CSL. M923, the Company's biosimilar HUMIRA® (adalimumab) candidate, was previously developed in collaboration with Baxalta under the Baxalta Collaboration Agreement, as defined below. The Baxalta Collaboration Agreement was terminated effective December 31, 2016.

The Company records product revenue based on Sandoz’ sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL.

Research and development revenue generally consists of amounts earned by the Company under its collaborations for technical development, regulatory and commercial milestones; reimbursement of research and development services and reimbursement of development costs under its collaborative arrangements; and recognition of the arrangement consideration.

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 Company is also reimbursed for certain costs under the arrangement with CSL, and such amounts are also recorded as revenue or reductions to research and development expense and general and administrative expense depending on the nature of the activities.

The following tables provide amounts by period indicated 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 FASB's Accounting Standards Codification Topic 808, Collaborative Arrangements.

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The amounts in operating expenses 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. The dollar amounts in the tables below are in thousands.

	For the Three Months Ended June 30, 2017				
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Mylan Collaboration Agreement (1)	CSL License Agreement (2)	Total Collaborations
Collaboration revenues:					
Product revenue	$—	$ 19,140	$ —	$ —	$ 19,140
Research and development revenue:					
Recognition of upfront payments	—	—	1,381	—	1,381
Research and development services and external costs	1,799	529	—	721	3,049
Total research and development revenue	1,799	529	1,381	721	4,430
Total collaboration revenues	$1,799	$ 19,669	$ 1,381	$ 721	$ 23,570
Operating expenses:					
Research and development expense	$411	$ 888	$ 17,070	$ 2,276	$ 20,645
General and administrative expense	5,080	213	962	41	6,296
Less: reimbursable costs	—	—	(7,214)	(3,496)	(10,710)
Total operating expenses	$5,491	$ 1,101	$ 10,818	$ (1,179)	$ 16,231

	For the Three Months Ended June 30, 2016				
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Mylan Collaboration Agreement (1)	Baxalta Collaboration Agreement (3)	Total Collaborations
Collaboration revenues:					
Product revenue	$—	$ 20,692	$ —	$ —	$ 20,692
Research and development revenue:					
Recognition of upfront payments	—	—	1,843	2,442	4,285
Research and development services and external costs	61	739	—	653	1,453
Total research and development revenue	61	739	1,843	3,095	5,738
Total collaboration revenues	$61	$ 21,431	$ 1,843	$ 3,095	$ 26,430
Operating expenses:					
Research and development expense	$—	$ 1,001	$ 16,816	$ 164	$ 17,981
General and administrative expense	469	180	904	42	1,595
Less: reimbursable costs	—	—	(8,860)	—	(8,860)
Total operating expenses	$469	$ 1,181	$ 8,860	$ 206	$ 10,716

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	For the Six Months Ended June 30, 2017				
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Mylan Collaboration Agreement (1)	CSL License Agreement (2)	Total Collaborations
Collaboration revenues:					
Product revenue	$—	$ 42,544	$ —	$ —	$ 42,544
Research and development revenue:					
Recognition of upfront payments	—	—	3,177	—	3,177
Research and development services and external costs	2,762	980	—	721	4,463
Total research and development revenue	2,762	980	3,177	721	7,640
Total collaboration revenues	$2,762	$ 43,524	$ 3,177	$ 721	$ 50,184
Operating expenses:					
Research and development expense	$1,937	$ 1,153	$ 29,672	$ 4,571	$ 37,333
General and administrative expense	9,630	237	1,492	62	11,421
Less: reimbursable costs	—	—	(12,936)	(3,496)	(16,432)
Total operating expenses	$11,567	$ 1,390	$ 18,228	$ 1,137	$ 32,322

	For the Six Months Ended June 30, 2016				
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Mylan Collaboration Agreement (1)	Baxalta Collaboration Agreement (3)	Total Collaborations
Collaboration revenues:					
Product revenue	$—	$ 35,492	$ —	$ —	$ 35,492
Research and development revenue:					
Recognition of upfront payments	—	—	2,765	4,884	7,649
Research and development services and external costs	138	1,384	—	1,617	3,139
Total research and development revenue	138	1,384	2,765	6,501	10,788
Total collaboration revenues	$138	$ 36,876	$ 2,765	$ 6,501	$ 46,280
Operating expenses:					
Research and development expense	$—	$ 1,294	$ 24,176	$ 478	$ 25,948
General and administrative expense	1,533	275	1,128	324	3,260
Less: reimbursable costs	—	—	(12,652)	—	(12,652)
Total operating expenses	$1,533	$ 1,569	$ 12,652	$ 802	$ 16,556

(1) The Mylan Collaboration Agreement, as defined below, became effective on February 9, 2016. As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, the Company offset approximately $6.8 million and $8.4 million, respectively, against research and development costs and $0.5 million and $0.5 million, respectively, against general and administrative expenses during the three months ended June 30, 2017 and June 30, 2016. During the six months ended June 30, 2017 and June 30, 2016, the Company offset approximately $12.3 million and $12.1 million, respectively, against research and development costs and $0.6 million and $0.6 million, respectively, against general and administrative expenses.

(2)

The CSL License Agreement, as defined below, became effective on February 17, 2017. Research and development expenses were reduced by $3.5 million of reimbursable M230 material costs incurred since February 17, 2017.

(3) The Baxalta Collaboration Agreement was terminated effective December 31, 2016.

2003 Sandoz Collaboration Agreement

In 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration Agreement, with Sandoz to jointly develop, manufacture and commercialize Enoxaparin Sodium Injection, a generic version of

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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. 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. Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three and six months ended June 30, 2017 and 2016, and therefore the Company recorded no product revenue for Enoxaparin Sodium Injection in those periods. The Company recognized research and development revenue from full-time equivalent, or FTE, services and external costs of $1.8 million and $0.1 million in the three months ended June 30, 2017 and 2016, respectively. The Company recognized research and development revenue from FTE services and external costs of $2.8 million and $0.1 million in the six months ended June 30, 2017 and 2016, respectively.

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. Under the 2006 Sandoz Collaboration Agreement, the Company and Sandoz AG agreed to exclusively collaborate on the development and commercialization of GLATOPA, 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, the Company is generally responsible for all of the development costs in the United States. For GLATOPA 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.

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 may terminate the 2006 Sandoz Collaboration Agreement with respect to GLATOPA 40 mg/mL, if clinical trials are required for regulatory approval of GLATOPA 40 mg/mL.

Sandoz commenced sales of GLATOPA 20 mg/mL 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 20 mg/mL. The Company is entitled to earn 50% of contractually defined profits on Sandoz' worldwide net sales of GLATOPA 40 mg/mL, if and when GLATOPA 40 mg/mL is commercialized. Profits on net sales of GLATOPA 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. With respect to GLATOPA, Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement, except for FTE costs with respect to certain legal activities for GLATOPA; 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, 2017, the Company recorded $19.1 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL. For the six months ended June 30, 2017, the Company recorded $42.5 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL. The Company recognized research and development revenue from FTE services and external costs of $0.5 million and $0.7 million in the three months ended June 30, 2017 and 2016, respectively. The Company recognized research and development revenue from FTE services and external costs of $1.0 million and $1.4 million in the six months ended June 30, 2017 and 2016, respectively. On July 1, 2017, the Company earned a $10 million milestone payment in connection with GLATOPA 20 mg/mL's continuing to be the sole FDA-approved generic of COPAXONE® (glatiramer acetate injection) and achieving a certain level of contractually defined profits in the United States The Company is eligible to receive in the aggregate up to $110 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA 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.

Baxalta Collaboration Agreement

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The Company and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (or collectively referred to as Baxter) entered into a global collaboration and license agreement, or the Baxter Collaboration Agreement, effective February 2012, to develop and commercialize biosimilars, including M923. In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned the Baxter Collaboration Agreement to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated, collectively referred to as Baxalta. Subsequent to the assignment, the Company refers to "Baxter" as "Baxalta" and the "Baxter Collaboration Agreement" as the "Baxalta Collaboration Agreement." 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, of which Baxalta US Inc. and Baxalta GmbH are wholly-owned subsidiaries, is a wholly-owned subsidiary of Shire. On September 27, 2016, Baxalta gave the Company twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement. On December 31, 2016, the Company and Baxalta entered into an asset return and termination agreement, or the Baxalta Termination Agreement, which amended certain termination provisions of the Baxalta Collaboration Agreement and made the termination of that agreement effective as of December 31, 2016. Baxalta was relieved of its obligations to continue to perform activities for M923 after December 31, 2016, except for certain on-going clinical and regulatory activities, the majority of which have been completed, and in January 2017, Baxalta paid the Company a one-time cash payment of $51.2 million representing the costs Baxalta would have incurred in performing the activities it would have performed under Baxalta Collaboration Agreement through the original termination date.

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 worldwide basis, to develop, manufacture and commercialize six of the Company's biosimilar candidates, including M834.

Under the terms of the Mylan Collaboration Agreement, Mylan paid the Company a non-refundable upfront payment of $45 million. In addition, the Company and Mylan equally share 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, two of which, totaling $60 million, the Company received in the year ended December 31, 2016.

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

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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 Topic 605, 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 associated with the upfront payment 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 five 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, 2017, $35.5 million was deferred under this agreement, of which $4.7 million was included in current liabilities and $30.8 million was included in non-current liabilities in the consolidated balance sheet.

The Company and Mylan share collaboration expenses under the Mylan Collaboration Agreement. 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. Mylan's share of collaboration expenses is recorded as a collaboration receivable or collaboration advance in the consolidated balance sheet and a reduction in research and development and/or general and administrative expenses in the consolidated statements of operations and comprehensive loss, in accordance with the Company’s policy, which is consistent with the nature of the cost reimbursement.

Mylan will initially fund a portion of its 50% share of collaboration expenses through contingent milestone payments of up to $200 million across the six product candidates and any unused portion of the contingent payment(s) will be available to offset Mylan’s 50% share of future collaboration costs. 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. During the year ended December 31, 2016, the Company received two milestone payments totaling $60 million, of which

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$20.4 million will be applied toward the funding of Mylan's 50% share of certain collaboration expenses to be incurred in 2017 and is included in collaboration advance in the Company's consolidated balance sheet. The Company is eligible to receive up to $140 million in additional contingent milestone payments from Mylan, of which the Company expects to receive $35 million in the next 12 months.

CSL License and Option Agreement

On January 5, 2017, the Company and CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited, entered into a License and Option Agreement, or the CSL License Agreement, which became effective on February 17, 2017, pursuant to which the Company granted CSL an exclusive worldwide license to research, develop, and commercialize the Company’s M230 pre-clinical product candidate, an Fc multimer protein that is a selective immunomodulator of the Fc receptor. The CSL License Agreement also provides, on an exclusive basis, for the Company and CSL to conduct research on other Fc multimer proteins, and provides CSL the right to develop and commercialize these additional research products globally.

Pursuant to the terms of the CSL License Agreement, CSL paid the Company a non-refundable upfront payment of $50 million. For the development and commercialization of M230, the Company is eligible to receive up to $550 million in contingent clinical, regulatory and sales milestone payments, and additional negotiated milestone payments for a named research stage product should that enter development. The Company is also entitled to sales-based royalty payments in percentages ranging from a mid-single digit to low-double digits for M230 and a named research stage product should that enter development and be commercialized, and royalties and development milestone payments to be negotiated for any other products developed under the CSL License Agreement. Sales milestones are based on aggregated sales across M230 and any other products developed under the CSL License Agreement. The Company also has the option to participate in a cost-and-profit sharing arrangement, under which the Company would fund 50% of global research and development costs and 50% of U.S. commercialization costs for all products developed pursuant to the CSL License Agreement, or the Co-Funded Products, in exchange for either a 50% share of U.S. profits or 30% share of U.S. profits, determined by the stage of development at which the Company makes such election. For Co-Funded Products, royalties remain payable for territories outside of the United States and milestone payments are reduced. The Company also has the right to opt-out of such arrangement at its sole discretion, which would result in milestone payments and royalties reverting to their pre-arrangement amounts. The Company also has the option to participate in the promotion of Co-Funded Products in the United States, subject to a co-promotion agreement to be negotiated with CSL.

Under the CSL License Agreement, the Company granted CSL an exclusive license under the Company’s intellectual property to research, develop, manufacture and commercialize product candidates for all therapeutic indications. CSL has granted the Company a non-exclusive, royalty-free license under CSL’s intellectual property for the Company’s research and development activities pursuant to the CSL License Agreement and its commercialization activities under any co-promotion agreement with CSL.

The Company and CSL formed a joint steering committee consisting of an equal number of members from the Company and CSL, to facilitate the research, development, and commercialization of product candidates.

Unless earlier terminated, the term of the CSL License Agreement commences on the Effective Date and continues until the later of (i) the expiration of all payment obligations with respect to products under the CSL License Agreement, (ii) the Company is no longer co-funding development or commercialization of any products and (iii) the Company and CSL are not otherwise collaborating on the development and commercialization of products or product candidates. CSL may terminate the CSL License Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. The Company may terminate the CSL License Agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the

CSL License Agreement. Either party may terminate the CSL License Agreement (i) on a product-by-product basis if certain patent challenges are made, (ii) on a product-by-product basis for material breaches, or (iii) due to the other party’s bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, the Company or CSL has the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

CSL's obligations under the CSL License Agreement are guaranteed by its parent company, CSL Limited.

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The Company identified the deliverables at the inception of the CSL License Agreement. The deliverables were determined to include (i) the M230 research, development, manufacturing and commercialization license, (ii) the research license for other Fc multimer proteins and (iii) the Company's responsibility to transfer the technology package relating to M230 to CSL. The best estimate of the selling price associated with the Company's participation on the joint steering committee was deemed to be de minimis, and therefore was not evaluated further. The Company determined that the M230 research, development, manufacturing and commercialization license does not have stand-alone value separate and apart from the Company's responsibility to transfer the M230 technology package to CSL because (1) there are no other vendors selling similar licenses on a stand-alone basis, (2) CSL does not have the contractual right to resell the license or the transferred technology, and (3) CSL is unable to use the license for its intended purpose without the technology transfer. In addition, the Company determined that the research license does not have stand-alone value. As such, the Company determined that there is one unit of accounting. The total arrangement consideration of $50 million was allocated to the single unit of accounting and will be recognized as revenue once the technology transfer is completed, which is the final item to be delivered in the unit of accounting. The technology transfer is expected to be completed by the end of 2017. As of June 30, 2017, $50 million was included in deferred revenue under the CSL License Agreement and was classified as a current liability in the consolidated balance sheet. The Company recognized research and development revenue from full-time equivalent, or FTE, services and external costs of $0.7 million in the three and six months ended June 30, 2017.

6. Share-Based Payments

Equity Award Plans

On March 14, 2017, the Company's Board of Directors approved the amendment and restatement of the Company’s 2013 Incentive Award Plan, or the Amended and Restated 2013 Plan, subject to and effective upon stockholder approval. At the Company’s 2017 Annual Meeting of Stockholders, held on June 20, 2017, stockholders approved the Amended and Restated 2013 Plan. The Amended and Restated 2013 Plan, among other things, increases the number of shares of common stock available for issuance under the plan by 4,300,000 shares.

On March 14, 2017, the Company's Board of Directors approved the amendment and restatement of the Company’s 2004 Employee Stock Purchase Plan, or the Amended and Restated ESPP, subject to and effective upon stockholder approval. Stockholders approved the Amended and Restated ESPP at the 2017 Annual Meeting. The Amended and Restated ESPP increases the number of shares of common stock available for issuance under the ESPP by 1,400,000 shares.

Equity Award Retirement Policy

In December 2016, the Company's board of directors adopted the Momenta Pharmaceuticals, Inc. Equity Award Retirement Policy, or the Retirement Policy, to provide for the treatment of time-based options and restricted stock units upon a participant’s qualifying retirement from the Company, allowing employees until January 11, 2017 to opt-out of a modification to certain of their outstanding grants of incentive stock options. Under the Retirement Policy, following the qualifying retirement of any employee of the Company or non-employee member of the board of directors, the participant’s then-outstanding time-based options and restricted stock units will continue to vest during the one year period following the retirement date. In addition, the participant will have until the first anniversary of the retirement date (or 90 days following the date an option becomes first exercisable if such date is within the 90 days preceding the first anniversary of the retirement date) to exercise any vested options, except that no option may be exercised following the date upon which it would have expired under the applicable option award agreement if the participant had remained in service with the Company.

For those employees who did not opt out, the Retirement Policy amended the terms of existing grants of time-based options effective January 11, 2017; therefore, in the consolidated statement of operations for the six months ended June 30, 2017, the Company recorded incremental compensation expense of $0.4 million related to the modification of those options, of which $0.3 million was included in the general administrative expense and $0.1 million was included in research and development expense.

Share-Based Compensation

The table below presents share-based compensation expense for research and development as well as general and administrative expense, both of which are included in operating expenses, in the three and six months ended June 30, 2017 and 2016 (in thousands):

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	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016
Research and development	$ 1,760	$ 2,319	$4,223	$ 4,384
General and administrative	2,830	2,670	7,170	5,433
Total share-based compensation expense	$ 4,590	$ 4,989	$11,393	$ 9,817

The following table summarizes share-based compensation expense by award category recorded in each of the three and six months ended June 30, 2017 and 2016 (in thousands):

	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016
Stock options	$ 2,719	$ 2,372	$5,325	$ 5,130
Restricted stock awards and units	1,754	2,514	5,831	4,472
Employee stock purchase plan	117	103	237	215
Total share-based compensation expense	$ 4,590	$ 4,989	$11,393	$ 9,817

During the six months ended June 30, 2017, the Company granted 1,321,630 options to its employees and board members. 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, 2017 and 2016 was $8.39 per option and $5.85 per option, respectively. The weighted average grant date fair value of option awards granted during the six months ended June 30, 2017 and 2016 was $9.23 per option and $5.82 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, 2017	For the Three Months Ended June 30, 2016	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016
Expected volatility	50 %	62 %	54 %	57 %
Expected dividends	—	—	—	—
Expected life (years)	6.1	5.8	0.5	0.5
Risk-free interest rate	2.0 %	1.5 %	0.7 %	0.5 %

	Weighted Average Assumptions	
	Stock Options	Employee Stock Purchase Plan

	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016
Expected volatility	53 %	58 %	57 %	56 %
Expected dividends	—	—	—	—
Expected life (years)	5.8	6.1	0.5	0.5
Risk-free interest rate	2.1 %	1.5 %	0.5 %	0.4 %

At June 30, 2017, the total remaining unrecognized compensation cost related to nonvested option awards amounted to $21.6 million, which will be recognized over the weighted average remaining requisite service period of 2.7 years.

During the six months ended June 30, 2017, the Company issued 57,007 shares of common stock to employees under the employee stock purchase plan, or ESPP, resulting in proceeds of approximately $0.5 million.

Restricted Stock and Restricted Stock Units

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The Company has granted time-based restricted stock and restricted stock units to its employees, officers and board members and performance-based restricted stock to its employees and officers.

Since April 2016, the Company awarded 1,728,495 shares of performance-based restricted stock to employees and officers. The vesting of the shares is subject to the Company achieving up to two of three possible performance milestones on or before April 13, 2019. Upon achieving each of the first and second milestones, 25% of the shares will vest on the later of the milestone achievement date and the first anniversary of the grant date, and an additional 25% of the shares will vest on the one year anniversary of such achievement date, subject to a requirement that recipients remain employees through each 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. As a result of discontinuing its necuparanib program in the third quarter of 2016, the Company determined that only two of the three performance milestones are possible to achieve prior to April 13, 2019. The Company has determined that attainment of the remaining performance conditions is probable and is expensing the fair value of the shares over the implicit service period using the accelerated attribution method. In the three and six months ended June 30, 2017, the Company recognized approximately $0.5 million and $3.5 million of stock compensation costs related to these awards, respectively.

In the six months ended June 30, 2017, the Company awarded 519,753 shares of time-based restricted stock units to its employees. The time-based restricted stock units 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. Time-based awards are generally forfeited if the employment relationship terminates with the Company prior to vesting, except as provided in the Retirement Policy.

As of June 30, 2017, the total remaining unrecognized compensation cost related to all nonvested time-based restricted stock and restricted stock units and performance-based restricted stock awards amounted to $18.4 million, which is expected to be recognized over the weighted average remaining requisite service period of approximately 2.5 years.

The following table summarizes restricted stock and restricted stock unit activity as of June 30, 2017 and the changes during the six months ended June 30, 2017 under the Company’s 2013 Incentive Award Plan, as amended and restated (in thousands, except per share amounts):

	Number of Shares or Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2017	1,992	$ 10.64
Granted	602	18.37
Vested	(196)	12.34
Forfeited	(237)	11.82
Nonvested at June 30, 2017	2,161	$ 12.51

Nonvested restricted stock awards and restricted stock units have vesting conditions as summarized below (in thousands):

Vesting Condition	Nonvested Shares or Units
Time-based	829
Performance-based and time-based	1,332

Nonvested at June 30, 2017	2,161

7. Equity Financings

In April 2015, the Company entered into an At-the-Market Equity Offering Sales Agreement, or the 2015 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 was 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. From April 2015 through December 2015, the Company sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement pursuant to an effective shelf registration statement on Form S-3 (Reg. No. 333-188227) previously filed with the SEC and a related prospectus supplement, and raised

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net proceeds of approximately $9.3 million. In the six months ended June 30, 2017, the Company sold approximately 4.5 million shares of common stock pursuant to an effective shelf registration statement (Reg. No. 333-209813) and a related prospectus supplement, raising net proceeds of $64.1 million, and concluded sales under the 2015 ATM Agreement.

8. Commitments and Contingencies

Operating Leases

The Company leases office space and equipment under various operating lease agreements. See Note 14 “Commitments and Contingencies” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of the Company’s operating lease agreements.

Total operating lease commitments as of June 30, 2017 are as follows (in thousands):

Operating lease commitments	Total
July 1 to December 31, 2017	$6,193
2018	15,369
2019	14,165
2020	14,581
2021	14,935
2022 and beyond	70,004
Total future minimum lease payments	$135,247

Legal Contingencies

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

GLATOPA 40 mg/mL-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 a suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and sought 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 that was 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. In December 2015, this suit was also consolidated with the initial suit that was filed in September 2014. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of the patents at issue. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017 decision to the Court of Appeals for the Federal Circuit.

On December 19, 2016, Teva and Yeda filed suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware again in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL, for alleged infringement of an Orange Book-listed patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,402,874. On May 1, 2017, the District Court entered the joint stipulation filed by the parties, dismissing the case pertaining to U.S. Patent No. 9,402,874.

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On January 31, 2017, Teva filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, which issued in October 2015 and expires in October 2035. The Company and Sandoz Inc. filed a motion to dismiss and a motion to transfer the suit to the United States District Court for the District of Delaware. On January 31, 2017, Teva voluntarily dismissed the Company from the New Jersey suit for U.S. Patent No. 9,155,775, maintaining the suit against Sandoz Inc. On May 23, 2017, the United States District Court for the District of New Jersey granted the motion to transfer the suit to the United States District Court for the District of Delaware.

On February 2, 2017, the Company filed a complaint in the United States District Court for the District of Delaware seeking a declaration that U.S. Patent No. 9,155,775 is invalid, not infringed or not enforceable against the Company. In March 2017, Teva filed a motion, which is currently pending, to stay further proceedings in the Delaware action.

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 patent infringement. 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 which was denied in June 2013.

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. On May 17, 2016, Amphastar filed a petition for writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied on October 3, 2016. In April 2017, the Company, Sandoz Inc. and Actavis, or the Settling Parties, settled and signed reciprocal releases of all claims, and filed a voluntary stipulation with the District Court, pursuant to which the Settling Parties stipulated and agreed to dismiss with prejudice all claims and counterclaims among the Settling Parties, without fees or costs to any party, and with the Settling Parties waiving any and all right of appeal. The District Court trial was held in July 2017, and the jury verdict found the Company's patent to be infringed, but invalid and unenforceable. The Company and Sandoz Inc. are considering all available legal options to overturn the portions of the verdict finding the Company's patent to be invalid and unenforceable, including post-trial motions and appeals. 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. The Company posted $17.5 million as collateral for the security bond and classified the collateral as restricted cash in its consolidated balance sheet. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz Inc. will prevail in this patent enforcement suit.

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 August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court of Appeals for the First Circuit reversed the District Court’s dismissal and remanded the case to the District Court

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for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, the Company and Sandoz Inc. filed their renewed motion to dismiss. Trial is scheduled for April 2019.

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 filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. On March 21, 2017, the United States District Court for the Middle District of Tennessee dismissed NGH’s claim for damages against the Company and Sandoz, but allowed the case to move forward, in part, for NGH’s claims for injunctive and declaratory relief. In the same opinion, the United States District Court for the Middle District of Tennessee denied our motion to transfer. On June 9, 2017, NGH filed a motion to amend its complaint to add a new named plaintiff, the American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan (“DC37”). NGH and DC 37 seek to assert claims for damages under the laws of more than 30 different states, on behalf of a putative class of indirect purchasers of Lovenox or generic enoxaparin. On June 30, 2017, the Company and Sandoz filed a brief opposing the motion to amend the complaint. The Court has not yet scheduled a hearing on the motion to amend. 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.

9. Subsequent Events

Milestone Payment

On July 1, 2017, the Company earned a $10 million milestone payment in connection with GLATOPA 20 mg/mL's continuing to be the sole FDA-approved generic of COPAXONE and achieving a certain level of contractually defined profits in the United States.

Lease Amendment

On July 24, 2017, the Company entered into the Fourth Amendment to the Lease, or the Fourth Amendment, with BMR-Rogers Street LLC, or BMR, which amends the Lease between Momenta and BMR, dated as of February 5, 2013, as amended. Pursuant to the Fourth Amendment, the Company will lease approximately 52,252 square feet of office space, or the Fourth Floor Binney Premises, on the fourth floor of 301 Binney Street, Cambridge, Massachusetts, or the Binney Building. The Fourth Amendment also amends certain of the terms and conditions of the Company's existing lease of office and laboratory space located in the basement and first and second floors of 320 Bent Street, Cambridge, Massachusetts, or the Bent Premises.

The term of the lease for the Fourth Floor Binney Premises will commence on or before October 1, 2017, or the Binney Commencement Date, and will end on the date that is 126 months from the Binney Commencement Date, unless earlier terminated or extended in accordance with the terms of the Fourth Amendment. The Company has an option, subject to certain terms and conditions, to extend the term of the lease for the Fourth Floor Binney Premises until June 30, 2035. BMR has agreed to make available an approximately $5.0 million allowance for certain tenant improvements the Company is planning to make to the Fourth Floor Binney Premises.

The Company is obligated to pay rent for the Fourth Floor Binney Premises beginning six months after the Binney Commencement Date, or the Rent Commencement Date. From the Rent Commencement Date until the first anniversary of the Rent Commencement Date, the Company is obligated to pay a monthly base rent for the Fourth Floor Binney Premises of $0.3 million, or $73.00 per square foot. On each subsequent anniversary of the Rent Commencement Date, the annual base rent will increase by 3% of the then-current annual base rent. The Company is also obligated to pay certain operating expenses and a property management fee beginning on the Rent

Commencement Date. Simultaneous with the execution of the Fourth Amendment, in July 2017, the Company delivered to BMR a security deposit in the form of a letter of credit in the amount of $1.3 million. This balance will remain restricted through September 2028. The Company will earn interest on the balance.

Pursuant to the Fourth Amendment, BMR also agreed to make available an additional $5.2 million allowance for certain tenant improvements the Company is planning to make to the Fourth Floor Binney Premises and the Bent Premises. The base rent for the Bent Premises will be correspondingly increased, effective September 1, 2017, to include the amount of the tenant improvement allowance as amortized over the term of the lease for the Bent Premises. From September 1, 2017 to August 31, 2018, the Company's monthly base rent obligation for the Bent Premises will be $0.7 million, or $77.52 per square foot. Each

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subsequent September 1 during the term of the lease for the Bent Premises, the Company's annual base rent for the Bent Premises will increase by approximately 2.7% of the then-current annual base rent. Subject to certain terms and conditions, the Company has an option to extend the term of the lease for the Bent Premises until June 30, 2035. In addition, under the terms of the Fourth Amendment, the Company has a right of first refusal on additional space on the fourth floor of the Binney Building, and a right of first offer on additional space on the fifth floor of the Binney Building.

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, 2016.

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 "Part II., Item 1A. Risk Factors" 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 autoimmune diseases.

To date, we have devoted substantially all of our capital resource expenditures to the research and development of our products and 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 development portfolio. As of June 30, 2017, we had an accumulated deficit of approximately $542.8 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 development portfolio.

Complex Generics

GLATOPA® 20 mg/mL—Generic Once-daily 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 20 mg/mL is the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. Sandoz commenced sales of GLATOPA 20 mg/mL on June 18, 2015. Under our collaboration agreement with Sandoz, we earn 50% of contractually defined profits on GLATOPA 20 mg/mL sales. For the three months ended June 30, 2017, we recorded $19.1 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting $19.7 million in profit share net of a deduction of $0.6 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz. On July 1, 2017, we earned a $10 million milestone payment in connection with GLATOPA 20 mg/mL's continuing to be the sole FDA-approved generic of COPAXONE and achieving a certain level of contractually defined profits in the United States.

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

An ANDA seeking approval for GLATOPA 40 mg/mL, our generic version of three-times-weekly COPAXONE 40 mg/mL, was filed by our partner, Sandoz, in February 2014 and remains under review by the FDA. Our GLATOPA 40 mg/mL formulation contains the same drug substance as GLATOPA 20 mg/mL, which we believe should help streamline the FDA review of the ANDA. To date, Sandoz is the only ANDA applicant for the three-times-weekly COPAXONE 40 mg/mL with an FDA-approved active pharmaceutical ingredient. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. Although the FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States, the FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. We are working with Sandoz to resolve this matter. We believe it continues to be possible for the GLATOPA 40 mg/mL ANDA to be approved in 2017.

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On January 30, 2017, the District Court for the District of Delaware found invalid four Orange Book-listed patents related to COPAXONE 40 mg/mL that we were alleged to have infringed. Three of these patents had previously been found invalid in August 2016 by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, in an Inter Partes Review, or IPR, filed by an unrelated third party. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017 decision to the Court of Appeals for the Federal Circuit. This and other legal proceedings related to GLATOPA 40 mg/mL are described under "Part II., Item 1. Legal Proceedings -- GLATOPA 40 mg/mL-Related Proceedings."

Enoxaparin Sodium Injection—Generic LOVENOX®

Under our amended collaboration agreement with Sandoz, Sandoz is obligated to pay us 50% of contractually defined profits on sales of Enoxaparin Sodium Injection.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended June 30, 2017, and therefore we recorded no product revenue for Enoxaparin Sodium Injection in the same period.

Legal proceedings related to Enoxaparin Sodium Injection are described under "Part II., Item 1. Legal Proceedings -- Enoxaparin Sodium Injection-Related Proceedings."

Biosimilars

M923—Biosimilar HUMIRA® (adalimumab) Candidate

In November 2016, following an interim analysis, we announced that the confirmatory, randomized, double-blind, multi-center, global study evaluating the efficacy, safety and immunogenicity of M923 in adult patients with moderate-to-severe chronic plaque psoriasis met its primary endpoint. Patients received up to 48 weeks treatment with M923, HUMIRA, or HUMIRA alternating with M923. The proportion of subjects who achieved the primary endpoint, at least 75% reduction in the Psoriasis Area and Severity Index, or PASI-75, following 16 weeks of treatment, was equivalent between M923 and HUMIRA. The estimated difference in responders was well within the pre-specified confidence interval, confirming equivalence. Equivalence was also achieved for all secondary efficacy endpoints, including the achievement of PASI-50, PASI-90, proportion achieving clear or near-clear skin, and change from baseline in absolute PASI score. Adverse events were comparable in terms of type, frequency, and severity, and were consistent with the published safety data for HUMIRA. Due to unexpectedly high enrollment rates, additional patients to those included in the interim analysis were enrolled in the study. These patients will be included in the regulatory submission.

We are working toward the first regulatory submission for marketing approval for M923 in the fourth quarter of 2017 and, subject to marketing approval and patent considerations, we believe the first commercial launch could be as early as the 2020 timeframe.

M923 was previously developed in collaboration with Baxalta. In June 2016, Baxalta became a wholly-owned subsidiary of Shire plc. In September 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience our collaboration agreement. On December 31, 2016, we and Baxalta entered into an asset return and termination agreement, or the Baxalta Termination Agreement, amending certain termination provisions of the Baxalta Collaboration Agreement and making the termination of the Baxalta Collaboration Agreement effective December 31, 2016. Baxalta was relieved of its obligations to continue to perform activities for M923 after December 31, 2016, except for certain clinical and regulatory activities, the majority of which have been completed. In January 2017, Baxalta paid us a one-time cash payment of $51.2 million, representing the costs Baxalta would have incurred in performing the activities it would have performed under the Baxalta Collaboration Agreement through the original termination effective date.

We continue to identify and evaluate potential collaboration opportunities to further develop and commercialize M923.

M834—Biosimilar ORENCIA® (abatacept) Candidate

On January 8, 2016, we entered into a collaboration agreement, which became effective on February 9, 2016, with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or Mylan, to develop and commercialize M834. In November 2016, we initiated a randomized, double-blind, three-arm, parallel group, single-dose Phase 1 clinical trial in normal healthy volunteers to compare the pharmacokinetics, safety and immunogenicity of M834 to U.S.-sourced and EU-sourced ORENCIA. We plan to report top-line data from the trial in the second half of 2017.

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We believe there is currently limited biosimilar competition for M834. Subject to development, marketing approval and patent considerations, we plan to be able to launch M834 in the 2020 timeframe to be able to be among the first biosimilars of ORENCIA on the market in the United States.
ORENCIA's composition of matter patents expire in the United States in 2019. In December 2016, the PTAB in an IPR we filed upheld the validity of Bristol-Myers Squibb's formulation patent U.S. Patent No. 8,476,239 on ORENCIA. This proceeding is further discussed below under "Part II., Item 1. Legal Proceedings -- M834-Related Proceedings."

Other Biosimilar Candidates

Our Mylan collaboration includes the development of five other biosimilar candidates from our portfolio in addition to M834, including our undisclosed biosimilar candidate, M710. We and Mylan are targeting the first regulatory submission for M710 clinical development in late 2017 or early 2018. We and Mylan will share equally costs and profits (losses) related to these earlier stage product candidates. We and Mylan will share development and manufacturing responsibilities across product candidates, and Mylan will lead commercialization of the products.

Novel Therapeutics

We believe our novel programs discussed below 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.

M281 - Anti-FcRn Candidate

M281 is a fully-human monoclonal antibody that blocks the neonatal Fc receptor, or FcRn. A Phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 was initiated in June 2016. In January 2017, we announced that we had successfully completed the single ascending dose, or SAD, portion of the Phase 1 study in healthy volunteers. In the SAD portion of the study, M281 was well-tolerated with no serious adverse events observed. The multiple ascending dose, or MAD, portion of the Phase 1 study was initiated in January 2017. We plan to report the data from both the SAD and MAD portions of the Phase 1 study in the second half of 2017.

M230 - Selective Immunomodulator of Fc receptors (SIF3) Candidate

M230, a selective immunomodulator of Fc receptors, or SIF3, is a novel homogenous recombinant Fc multimer containing three IgG Fc regions joined carefully to maximize activity. Nonclinical data have shown that M230 enhances the molecules' avidity and affinity for the Fc receptors matching the potency and efficacy of IVIg at significantly lower doses.

Pursuant to the License and Option Agreement with CSL, effective February 17, 2017, we have granted CSL an exclusive worldwide license to research, develop, manufacture and commercialize M230. CSL plans to advance this candidate with a goal of beginning clinical development in 2017.

M254 - hsIVIg Candidate

M254 is a hyper-sialylated version of IVIg, a therapeutic drug product that contains pooled, human immunoglobulin G, or IgG, antibodies purified from blood plasma. IVIg is used to treat several inflammatory diseases, including idiopathic thrombocytopenic purpura, Kawasaki disease, and chronic inflammatory demyelinating polyneuropathy. Our hsIVIg product is currently in nonclinical development and has the potential to be developed as a high-potency alternative to IVIg. We plan to initiate an investigational new drug application-enabling, or IND-enabling, toxicology study in 2017 and are targeting initiating a clinical trial in 2018. We continue to identify and explore potential collaboration opportunities to further develop and commercialize this product candidate.

Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2016

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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 earned on Sandoz' sales of GLATOPA 20 mg/mL.

GLATOPA® 20 mg/mL—Generic Once-daily COPAXONE® (glatiramer acetate injection) 20 mg/mL
Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. We earn 50% of contractually defined profits on Sandoz' sales of GLATOPA 20 mg/mL. A portion of certain legal expenses for GLATOPA, 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, 2017, we recorded $19.1 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting $19.7 million in profit share net of a deduction of $0.6 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz. For the three months ended June 30, 2016, we recorded $20.7 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL. The decrease in product revenues of $1.6 million, or 8%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 was primarily due to lower sales deductions in the second quarter of 2016 as well as reimbursement of legal expenses relating to GLATOPA in the second quarter of 2017. We estimate that the number of prescriptions for GLATOPA 20 mg/mL represents approximately 40% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

Although the market potential of GLATOPA 20 mg/mL is negatively impacted by the conversion of patients from once-daily COPAXONE to three-times-weekly COPAXONE, which accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed, we believe there remains a meaningful market opportunity for GLATOPA 20 mg/mL. The price for once-daily COPAXONE 20 mg/mL has increased over 190% since 2009, and there is no other generic for relapsing forms of multiple sclerosis currently available in the United States.

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 collaboration and, where applicable, our former collaboration with Baxalta;

- Reimbursement of research and development services and reimbursement of development costs under our Sandoz and CSL collaborations and, where applicable, our former collaboration with Baxalta; and

- Recognition of upfront arrangement consideration under our Mylan and CSL collaborations and, where applicable, our former collaboration with Baxalta.

Research and development revenue was $4.4 million and $5.7 million for the three months ended June 30, 2017 and 2016, respectively. The decrease in research and development revenue of $1.3 million, or 23%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 was primarily due to the termination of the Baxalta Collaboration Agreement, effective December 31, 2016, under which we were previously reimbursed for M923 FTE and external costs and for which we recognized a portion of Baxalta's initial upfront payment in the three months ended June 30, 2016, which were non-recurring in the same period in 2017.

We expect to continue to recognize revenue from Mylan's $45 million upfront payment on a quarterly basis. Finally, we expect to recognize the $10 million GLATOPA 20 mg/mL milestone payment as revenue in the third quarter of

2017 and the $50 million upfront payment from CSL as revenue in the fourth quarter of 2017.

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:

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- 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 are not tracked on a project-by-project basis. Internal costs 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.

We have a collaboration agreement with Mylan pursuant to which we share research and development expenses related to the biosimilar candidates under the collaboration. We record expenses incurred under this collaboration arrangement for such work as research and development expense, based on the nature of the cost reimbursement. Because the collaboration arrangement is a cost sharing arrangement, we concluded that when there is a period during the collaboration arrangement during which we are owed payment from Mylan, we record the reimbursement by Mylan for its share of the development effort as a reduction of research and development expense. Amounts owed to Mylan are recorded as incremental research and development expense.

Research and development expense for the three months ended June 30, 2017 was $39.1 million, compared with $33.2 million for the three months ended June 30, 2016. The increase of $5.9 million, or 18%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 was primarily due to $13.0 million in increased spending on M923, as the program was transitioned back to us effective December 31, 2016 in connection with the termination of the Baxalta Collaboration Agreement, partially offset by a $2.2 million reduction in spend on our necuparanib program, which we discontinued in August 2016, and a $3.5 million reduction in research and development expenses for reimbursable M230 materials costs incurred under the CSL License Agreement.

The lengthy process of securing FDA approval for generics, biosimilars 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 by product area for the three months ended June 30, 2017 and 2016, and from project inception to June 30, 2017. 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.

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	Phase of Development as of June 30, 2017	Three Months Ended June 30, 2017	2016	Project Inception to June 30, 2017
External Costs Incurred by Product Area:				
Complex Generics(1)	ANDAs filed(2)	$1,299	$1,001	$ 107,544
Biosimilars	Various(3)	17,717	1,762	140,230
Novel Therapeutics	Various(4)	666	9,498	99,376
Internal Costs		19,381	20,912	
Total Research and Development Expenses		$39,063	$33,173	

(1) Includes external costs for GLATOPA and Enoxaparin Sodium Injection.

(2) In July 2010, the first ANDA for Enoxaparin Sodium Injection was approved by the FDA, and Sandoz launched the product. In April 2015, the FDA approved the ANDA for once-daily GLATOPA 20 mg/mL. Sandoz launched GLATOPA 20 mg/mL in June 2015. The ANDA for GLATOPA 40 mg/mL is under FDA review. For more information on GLATOPA 40 mg/mL, see "—Overview—Complex Generics—GLATOPA® 40 mg/mL—Generic Three-times-weekly COPAXONE® (glatiramer acetate injection) 40 mg/mL."

(3) Biosimilars include M923, a biosimilar candidate of HUMIRA® (adalimumab), M834, a biosimilar candidate of ORENCIA® (abatacept), as well as five other biosimilar candidates, including our undisclosed biosimilar candidate, M710. In April 2016, enrollment in the pivotal clinical trial for M923 was completed and in November 2016, following an interim analysis, we announced top-line Phase III results including that M923 met its primary endpoint in the study. We initiated a Phase 1 clinical trial of M834 in November 2016. Our other biosimilar candidates are in discovery and process development. As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately $6.8 million and $8.4 million against research and development costs during the three months ended June 30, 2017 and 2016, respectively.

(4) Our novel therapeutic programs include M281, for which the multiple ascending dose portion of a Phase 1 study was initiated in January 2017; M230, which our licensee, CSL, plans to advance with a goal of beginning clinical development in 2017; M254, which is currently in preclinical development and for which we are planning to initiate an IND-enabling toxicology study in 2017; costs related to our necuparanib program, which was discontinued in August 2016; as well as other discovery and nonclinical stage programs.

External expenditures for complex generics increased by $0.3 million, or 30% from the three months ended June 30, 2016 to the three months ended June 30, 2017 as we continue to support our complex generics. External expenditures for our biosimilars programs increased by $16.0 million, or 906%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 driven primarily by our assuming responsibility for development and commercialization of M923 effective December 31, 2016. External costs of our novel therapeutic programs decreased by $8.8 million, or 93%, from the three months ended June 30, 2016 to the three months ended June 30, 2017, driven primarily by a $2.2 million decrease in costs related to our necuparanib program, which we discontinued in August 2016, and a $3.5 million reduction in research and development expenses for reimbursable M230 materials costs incurred under the CSL License Agreement. Finally, internal costs decreased by $1.5 million, or 7%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 primarily due to lower share-based compensation expense.

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 rent, facility and lab supplies, and depreciation expense.

We have a collaboration agreement with Mylan pursuant to which we share research and development expenses related to biosimilar candidates under the collaboration. We record expenses incurred under this collaboration arrangement for such work as general and administrative expense, based on the nature of the cost reimbursement. Because the collaboration

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arrangement is a cost sharing arrangement, we concluded that when there is a period during the collaboration arrangement during which we are owed payment from Mylan, we record the reimbursement by Mylan for its share of the development effort as a reduction of general and administrative expense. Amounts owed to Mylan are recorded as incremental general and administrative expense.

General and administrative expense for the three months ended June 30, 2017 was $22.6 million, compared with $14.9 million for the three months ended June 30, 2016. The increase of $7.7 million, or 52%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 was primarily driven by approximately $5.0 million in legal fees relating to our ongoing litigation and $1.3 million in personnel-related expenses driven by increased headcount and higher share-based compensation expense.

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

Other Income, Net

Other income, net, primarily includes interest income. Interest income was $1.1 million and $0.6 million for the three months ended June 30, 2017 and 2016, respectively. The increase of $0.5 million, or 83%, from the three months ended June 30, 2016 to the three months ended June 30, 2017 was caused by higher average investment balances due to funds raised under the 2015 ATM Agreement in 2017.

Comparison of Six Months Ended June 30, 2017 and 2016

Collaboration Revenue

GLATOPA® 20 mg/mL—Generic Once-daily COPAXONE® (glatiramer acetate injection) 20 mg/mL

For the six months ended June 30, 2017, we recorded $42.5 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting $43.4 million in profit share net of a deduction of $0.9 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz. For the six months ended June 30, 2016, we recorded $35.5 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL. The increase in product revenues of $7.0 million, or 20%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 was primarily due to a higher number of GLATOPA 20 mg/mL units sold in 2017.

Research and Development Revenue

Research and development revenue was $7.6 million and $10.8 million for the six months ended June 30, 2017 and 2016, respectively. The decrease in research and development revenue of $3.2 million, or 30%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 was primarily due to the termination of the Baxalta Collaboration Agreement, effective December 31, 2016, under which we were previously reimbursed for M923 FTE and external costs and for which we recognized a portion of Baxalta's initial upfront payment in the six months ended June 30, 2016, which were non-recurring in the same period in 2017.

Research and Development Expense

Research and development expense for the six months ended June 30, 2017 was $75.2 million, compared with $61.9 million for the six months ended June 30, 2016. The increase of $13.3 million, or 21%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 was primarily due to $20.5 million in increased spending on

M923, as the program was transitioned back to us effective December 31, 2016 in connection with the termination of the Baxalta Collaboration Agreement, partially offset by a $5.3 million reduction in spend on our necuparanib program, which we discontinued in August 2016.

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 by product area for the six months ended June 30, 2017 and 2016, and from project inception to June 30, 2017. 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

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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	Six Months Ended June 30,		Project Inception to
	June 30, 2017	2017	2016	June 30, 2017
External Costs Incurred by Product Area:				
Complex Generics(1)	ANDAs filed(2)	$3,090	$1,294	$ 107,544
Biosimilars	Various(3)	26,510	6,212	140,230
Novel Therapeutics	Various(4)	6,111	15,153	99,376
Internal Costs		39,453	39,271	
Total Research and Development Expenses		$75,164	$61,930	

(1) Includes external costs for GLATOPA and Enoxaparin Sodium Injection.

(2) In July 2010, the first ANDA for Enoxaparin Sodium Injection was approved by the FDA, and Sandoz launched the product. In April 2015, the FDA approved the ANDA for once-daily GLATOPA 20 mg/mL. Sandoz launched GLATOPA 20 mg/mL in June 2015. The ANDA for GLATOPA 40 mg/mL is under FDA review. For more information on GLATOPA 40 mg/mL, see "—Overview—Complex Generics—GLATOPA® 40 mg/mL—Generic Three-times-weekly COPAXONE® (glatiramer acetate injection) 40 mg/mL."

(3) Biosimilars include M923, a biosimilar candidate of HUMIRA® (adalimumab), M834, a biosimilar candidate of ORENCIA® (abatacept), as well as five other biosimilar candidates, including our undisclosed biosimilar candidate, M710. In April 2016, enrollment in the pivotal clinical trial for M923 was completed and in November 2016, following an interim analysis, we announced top-line Phase III results including that M923 met its primary endpoint in the study. We initiated a Phase 1 clinical trial of M834 in November 2016. Our other biosimilar candidates are in discovery and process development. As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately $12.3 million and $12.1 million against research and development costs during the six months ended June 30, 2017 and 2016, respectively.

(4) Our novel therapeutic programs include M281, for which the multiple ascending dose portion of a Phase 1 study was initiated in January 2017; M230, which our licensee, CSL, plans to advance with a goal of beginning clinical development in 2017; M254, which is currently in preclinical development and for which we are planning to initiate an IND-enabling toxicology study in 2017; costs related to our necuparanib program, which was discontinued in August 2016; as well as other discovery and nonclinical stage programs.

External expenditures for complex generics increased by $1.8 million, or 139%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 as we continue to support our complex generics. External expenditures for our biosimilars programs increased by $20.3 million, or 327%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 driven by our assuming responsibility for development and commercialization of M923 effective December 31, 2016. External costs of our novel therapeutic programs decreased by $9.0 million, or 60%, from the six months ended June 30, 2016 to the six months ended June 30, 2017, primarily driven by a $5.3 million decrease in costs related to our discontinued necuparanib program. Finally, internal costs for the six months ended June 30, 2016 and the six months ended June 30, 2017 were consistent period over period.

General and Administrative Expense

General and administrative expense for the six months ended June 30, 2017 was $45.7 million, compared with $30.5 million for the six months ended June 30, 2016. The increase of $15.2 million, or 50%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 was primarily driven by approximately $8.0 million of legal costs relating to our ongoing litigation and $3.3 million in personnel-related expenses driven by increased headcount and higher share-based compensation expense.

Other Income, Net

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Other income, net, primarily includes interest income. Interest income was $1.9 million and $1.1 million for the six months ended June 30, 2017 and 2016, respectively. The increase of $0.8 million, or 73%, from the six months ended June 30, 2016 to the six months ended June 30, 2017 was caused by higher average investment balances due to funds raised under the 2015 ATM Agreement in 2017.

Equity Financings

In April 2015, we entered into the 2015 ATM Agreement with Stifel, under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal. We were 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 net proceeds of approximately $9.3 million. In the six months ended June 30, 2017, we sold approximately 4.5 million shares of common stock pursuant to an effective shelf registration statement filed with the SEC (Reg. No. 333-209813) and a related prospectus supplement,raising net proceeds of $64.1 million, and concluded sales under the 2015 ATM Agreement.

Liquidity and Capital Resources

At June 30, 2017, we had $456.8 million in cash, cash equivalents and marketable securities and $24.8 million in collaboration receivables, which includes $19.1 million in profit share from Sandoz' sales of GLATOPA 20 mg/mL. In addition, we also held $21.8 million in restricted cash, of which $17.5 million serves as collateral for a $35 million security bond posted in the litigation against Amphastar.

We have funded our operations to date primarily through the sale of equity securities and payments received under our collaboration and license agreements, including contractual profits from Sandoz’ sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL, upfront and milestone payments, and reimbursement of research and development services and reimbursement of development costs. We expect to fund our planned operating and expenditure requirements through a combination of current cash, cash equivalents and marketable securities; equity financings; and milestone payments and contractual profits 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, projected milestone payments and contractual profits will be sufficient to meet our operating requirements through at least the end of 2018.

Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate precisely our future operating and expenditure requirements. For information regarding certain important factors that could impact our financial position or future results of operations, please see “Part II., Item IA. Risk Factors” of this Quarterly Report on Form 10-Q.

Cash, Cash Equivalents and Marketable Securities

Our funds at June 30, 2017 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, 2017.

Cash Flows

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash provided by (used in) operating activities	$38,313	$(8,839)
Net cash (used in) provided by investing activities	$(149,491)	$36,040
Net cash provided by (used in) financing activities	$71,281	$(438)
Net (decrease) increase in cash and cash equivalents	$(39,897)	$26,763

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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 provided by operating activities was $38.3 million for the six months ended June 30, 2017 reflecting a net loss of $68.7 million, which was partially offset by non-cash charges of $3.6 million for depreciation and amortization of property, equipment and intangible assets and $11.4 million in shared-based compensation. The net change in our operating assets and liabilities provided cash of $91.9 million and primarily resulted from the receipt of $50 million from CSL under the CSL License Agreement, which is included in deferred revenue at June 30, 2017, and a one-time cash payment of $51.2 million in connection with the termination of the Baxalta Collaboration Agreement, which was included in collaboration receivable at December 31, 2016, partially offset by the change in collaboration advance of $12.5 million, representing Mylan's 50% share of certain collaboration expenses under the cost-sharing provisions of the Mylan Collaboration Agreement.

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 primarily resulted from the receipt of $45 million from Mylan under the Mylan Collaboration Agreement, partially offset by amortization of collaboration upfront payments and a $12.7 million collaboration receivable from Mylan for its 50% share of collaboration expenses under the cost-sharing arrangement.

Cash (used in) provided by investing activities

Cash used in investing activities of $149.5 million for the six months ended June 30, 2017 includes cash outflows of $269.4 million for purchases of marketable securities and $5.7 million for capital equipment and leasehold improvements, partially offset by cash inflows of $125.6 million from maturities of marketable securities.

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, partially 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 (used in) financing activities

Cash provided by financing activities of $71.3 million for the six months ended June 30, 2017 includes $64.1 million of net proceeds from shares sold under the 2015 ATM Agreement and $7.2 million in proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

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.

Contractual Obligations

Our major outstanding contractual obligations primarily relate operating lease obligations and purchase obligations. As discussed in Note 9 "Subsequent Events", in July 2017, we amended our lease agreement with BMR-Rogers Street

LLC, and a result, rental payments for the Bent Premises will increase by $7.4 million over the remaining term of the lease, and rental payments for the Fourth Floor Binney Premises will be $43.7 million over the term of the lease. All other disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on February 24, 2017, 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

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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, 2016 filed with the SEC on February 24, 2017.

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 1. Financial Statements" 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.

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, 2017, 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, 2017. 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, 2017, 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, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

GLATOPA 40 mg/mL-Related Proceedings

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz Inc. in the United States District Court for the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and sought 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 that was 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. In December 2015, this suit was also consolidated with the initial suit that was filed in September 2014. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of the patents at issue. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017 decision to the U.S. Court of Appeals for the Federal Circuit.

On December 19, 2016, Teva and Yeda filed suit against us and Sandoz Inc. in the United States District Court for the District of Delaware again in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL, for alleged infringement of an Orange Book-listed patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,402,874. On May 1, 2017, the District Court entered the joint stipulation filed by the parties, dismissing the case pertaining to U.S. Patent No. 9,402,874.

On January 31, 2017, Teva filed a suit against us and Sandoz Inc. in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, which issued in October 2015 and expires in October 2035. We and Sandoz Inc. filed a motion to dismiss and a motion to transfer the suit to the United States District Court for the District of Delaware. On January 31, 2017, Teva voluntarily dismissed us from the New Jersey suit for U.S. Patent No. 9,155,775, maintaining the suit against Sandoz Inc. On May 23, 2017, the United States District Court for the District of New Jersey granted the motion to transfer the suit to the United States District Court for the District of Delaware.

On February 2, 2017, we filed a complaint in the United States District Court for the District of Delaware seeking a declaration that U.S. Patent No. 9,155,775 is invalid, not infringed or not enforceable against us. In March 2017, Teva filed a motion, which is currently pending, to stay further proceedings in the Delaware action.

M834-Related Proceedings

On July 2, 2015, we filed a petition for Inter Partes Review, or 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. Oral arguments took place in September 2016. On December 22, 2016, the PTAB issued a decision upholding the validity of the patent. We filed a notice of appeal in the United States Court of Appeals for the Federal Circuit, or the Federal Circuit, on February 22, 2017. BMS filed a motion to dismiss our appeal in the Federal Circuit on March 29, 2017, which the Federal Circuit denied on June 19, 2017, stating that the standing issue raised in BMS's motion to dismiss should be addressed in the parties' appeal briefs. On June 29, 2017, the Federal Circuit ordered an expedited briefing schedule

proposed by us, noting that oral argument will be scheduled once briefing is complete.

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 patent infringement. 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 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,

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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, which was denied in June 2013.

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. 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, which was denied on October 3, 2016. In April 2017, we, Sandoz Inc. and Actavis, or the Settling Parties, settled and signed reciprocal releases of all claims, and filed a voluntary stipulation with the District Court, pursuant to which the Settling Parties stipulated and agreed to dismiss with prejudice all claims and counterclaims among the Settling Parties, without fees or costs to any party, and with the Settling Parties waiving any and all right of appeal. The District Court trial was held in July 2017, and the jury verdict found our patent to be infringed, but invalid and unenforceable. We and Sandoz Inc. are considering all available legal options to overturn the portions of the verdict finding our patent to be invalid and unenforceable, including post-trial motions and appeals. 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. We posted $17.5 million as collateral for the security bond and classified the collateral as restricted cash in our consolidated balance sheet. 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 August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court of Appeals for the First Circuit reversed the District Court’s dismissal and remanded the case to the District Court for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, we and Sandoz Inc. filed our renewed motion to dismiss. Trial is scheduled for April 2019.

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 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. On March 21, 2017, the United States District Court for the Middle District of Tennessee dismissed NGH's claim for damages against us and Sandoz, but allowed the case to move forward, in part, for NGH's claims for injunctive and declaratory relief. In the same opinion, the United States District Court for the Middle District of Tennessee denied our motion to transfer. On June 9, 2017, NGH filed a motion to amend its complaint to add a new named plaintiff, the American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan ("DC37"). NGH and DC 37 seek to assert claims for damages under the laws of more than 30 different states, on behalf of a putative class of indirect purchasers of Lovenox or generic enoxaparin. On June 30, 2017, we and Sandoz filed a brief opposing the motion to amend the complaint. The Court has not yet scheduled a hearing on the motion to amend. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourselves in this litigation.

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Item 1A. RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks, 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 securities. The risks, uncertainties and other important factors described below are not the only ones we face. Additional risks, uncertainties and other important factors of which we are unaware, or that we currently believe are not material, may also affect us. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer.

Risks Relating to Our Business

If we or our collaborative partners encounter difficulties in our supply or manufacturing arrangements, including an inability by third party manufacturers to satisfy FDA quality standards and related regulatory requirements, 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, including sole source suppliers, 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. 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 scale-up 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 products 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. For example, on February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States; however, the FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. If the FDA delays an approval of the GLATOPA 40 mg/mL until satisfactory resolution of the compliance observations in the FDA warning letter, the greater the risk to us and Sandoz of prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL. Any prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

In addition, any change in manufacturers, including for GLATOPA, could be costly because the commercial terms of any new arrangement could be less favorable, and the expenses and development and commercial delays relating to the transfer of necessary technology and processes could be significant. For GLATOPA 40 mg/mL, the longer the period of time that it would take for Sandoz to transfer the necessary technology and processes to a new fill/finish manufacturer, the greater the risk to us and Sandoz of prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL. Any prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Moreover, in order to generate revenue from the sales of Enoxaparin Sodium Injection, GLATOPA 20 mg/mL, and if approved, GLATOPA 40 mg/mL, sufficient quantities of such product must also be produced in order to satisfy demand. If these contract manufacturers and suppliers, which include sole source suppliers, are unable to manufacture sufficient quantities of product or breach or terminate their manufacturing arrangements with us or Sandoz, as applicable, the development and commercialization of the affected products or product candidates could be delayed, which could have a material adverse effect on our business.

We have relied upon third parties, including sole source suppliers, 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 product candidates or market them.

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If GLATOPA 40 mg/mL is launched following any FDA approval and prior to final resolution of product-related patent infringement litigation in our favor, we may incur significant damages.

Sandoz has the sole right to decide the timing and scope of the launch of GLATOPA 40 mg/mL following FDA approval. If Sandoz markets and sells GLATOPA 40 mg/mL following any FDA approval and prior to a final judicial resolution of product-related patent infringement litigation in our and Sandoz' favor, we and Sandoz may be subject to claims for patent infringement damages. Damages for infringement may in some instances exceed the amount of revenue earned by the infringing product. If Sandoz launches GLATOPA 40 mg/mL prior to final resolution of any product-related patent infringement litigation and Teva subsequently succeeds in any such litigation, we and Sandoz may be liable for significant damages. Our collaboration with Sandoz provides that our fifty (50) percent share of such damages would be payable from any contractual profits due to us from sales of GLATOPA. Our payment of such damages could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Sandoz may delay or reduce the scope of a GLATOPA 40 mg/mL launch following any FDA approval until we and Sandoz prevail in product-related patent infringement litigation or until the relevant patents expire.

Since the damages associated with a GLATOPA 40 mg/mL launch prior to final resolution of any product-related patent infringement litigation in our and Sandoz' favor can be substantial, Sandoz may delay or reduce the scope of a GLATOPA 40 mg/mL launch following any FDA approval. A delayed launch could occur as late as final resolution of all GLATOPA 40 mg/mL-related patent infringement litigation in our and Sandoz' favor or, if we and Sandoz are unsuccessful in such litigation, the expiration of the GLATOPA 40 mg/mL-related patents. A launch that is delayed or reduced in scope could delay or reduce any future contractual profits due to us from sales of GLATOPA 40 mg/mL, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Sandoz may be prevented from marketing and selling GLATOPA 40 mg/mL following any FDA approval if Teva is successful in obtaining injunctive relief.

A court may issue a temporary or permanent injunction pending the outcome of any GLATOPA 40 mg/mL-related patent infringement litigation or as a remedy if Teva prevails in any GLATOPA 40 mg/mL-related patent infringement litigation. An injunction would prevent us and Sandoz from manufacturing and selling GLATOPA 40 mg/mL and/or prohibit the use of previously manufactured GLATOPA 40 mg/mL for commercial sale until we and Sandoz prevail in litigation or the relevant patents expire. If Teva is successful in obtaining injunctive relief for any GLATOPA 40 mg/mL-related patents, Sandoz' ability to successfully commercialize GLATOPA 40 mg/mL would be significantly impaired, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We may incur significant expenses and damages in the future in connection with allegations by Teva that we and Sandoz are infringing COPAXONE-related patents other than those at issue in the current GLATOPA 40 mg/mL-related patent infringement suits.

We and Sandoz are currently parties in patent infringement litigation in respect of all Orange Book-listed patents for COPAXONE 40 mg/mL as well as an additional COPAXONE 40 mg/mL-related patent. Teva may allege in the future that our and Sandoz' manufacturing and sale of GLATOPA infringes COPAXONE-related patents other than those at issue in the currently pending litigation, including patents that may issue in the future. We would incur significant expenses under the terms of our collaboration with Sandoz to respond to and litigate any such claims, the outcomes of which would be uncertain. Furthermore, we may be liable for significant damages from the contractual profits of GLATOPA 20 mg/mL and, if approved and launched, GLATOPA 40 mg/mL if we and Sandoz are found to have infringed any such patents, which could have a material adverse effect on our business, financial position and

results of operations and could cause the market value of our common stock to decline. Moreover, litigation concerning intellectual property and proprietary technologies can be protracted and expensive and can distract management and 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 20 mg/mL, GLATOPA 40 mg/mL, 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,

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respectively. Accordingly, revenue and profits from GLATOPA 20 mg/mL 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 20 mg/mL 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 and several other companies have 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 20 mg/mL and, if approved and launched, GLATOPA 40 mg/mL. The longer the period of time that it takes us and Sandoz to receive approval of the GLATOPA 40 mg/mL ANDA, the greater the risk of prior or contemporaneous competition from other generic versions of COPAXONE. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

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, ORENCIA or another of the reference products for which we have a biosimilar product candidate prior to approval of M923, M834 or our other applicable biosimilar product candidates may therefore delay any 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 reference product, such as COPAXONE, HUMIRA or ORENCIA, 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 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 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 product market and significantly reduce the market for the original reference 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 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed. As a result, the market potential for GLATOPA 20 mg/mL 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 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. Reference 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 product to our generic products and product candidates and our biosimilar product candidates, respectively, sales of reference products and biosimilar and generics may be significantly and adversely impacted and may render the reference products obsolete.

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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 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.

Our future GLATOPA product revenue is dependent on the continued successful commercialization of GLATOPA 20 mg/mL and successful commercialization of GLATOPA 40 mg/mL, if approved.

Our near-term ability to generate GLATOPA product revenue depends, in large part, on Sandoz' ability to continue to manufacture and commercialize GLATOPA 20 mg/mL, and manufacture and commercialize GLATOPA 40 mg/mL, if approved. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States; however, the FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

Our near-term ability to generate GLATOPA product revenue also depends in large part on Sandoz' ability to maintain market share and the pricing levels for GLATOPA 20 mg/mL and, if approved, GLATOPA 40 mg/mL, as Sandoz competes with Teva's three-times-weekly COPAXONE 40 mg/mL, which currently accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed. Because GLATOPA 20 mg/mL is only a substitutable generic version of the once-daily 20 mg/mL formulation of COPAXONE, the market potential of GLATOPA 20 mg/mL is negatively impacted by the conversion of patients from once-daily COPAXONE 20 mg/mL to three-times-weekly COPAXONE 40 mg/mL prior to the approval and launch of the GLATOPA 40 mg/mL product, which is currently pending FDA approval. Following any such approval and launch of the GLATOPA 40 mg/mL product, our near-term ability to generate GLATOPA product revenue will continue to depend on Sandoz' ability to compete with Teva's three-times-weekly COPAXONE 40 mg/mL product. In addition, other competitors may in the future receive approval to market generic versions of the 20 mg/mL or 40 mg/mL formulations 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 Sodium Injection product revenue is dependent on the successful manufacture and commercialization of Enoxaparin Sodium Injection.

Our near-term ability to generate Enoxaparin Sodium Injection product revenue depends, in large part, on Sandoz' ability to manufacture and commercialize Enoxaparin Sodium Injection 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. Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the six months ended June 30, 2017, and therefore we recorded no product revenue for Enoxaparin Sodium Injection in the same period. Accordingly, we do not anticipate significant Enoxaparin Sodium Injection revenue in the near term.

If our patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful or third parties are successful in antitrust litigation against us relating to Enoxaparin Sodium Injection, we may be liable for damages and our business may be materially harmed.

The District Court trial in our patent litigation against Amphastar related to Enoxaparin Sodium Injection was held in July 2017, and the jury verdict found our patent to be infringed by Amphastar, but invalid and unenforceable. We and Sandoz Inc. are considering all available legal options to overturn the portions of the verdict that found our patent to be invalid and unenforceable, including post-trial motions and appeals. 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, we could be liable for up to $35 million of the security

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bond for such damages. Moreover, if third parties are successful in antitrust 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 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 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 by litigation or legislative action 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 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 20 mg/mL, 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

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generic or biosimilar products. Teva may seek to file additional Citizen Petitions pertaining to the GLATOPA 40 mg/mL ANDA or file other forms of comments to the FDA, and seek to delay or prevent the FDA approval of the GLATOPA 40 mg/mL 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 and biosimilar products, if approved, which could have a material adverse effect on our sales and profitability.

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, biosimilars and novel therapeutics, 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 and biologics 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, or PBMs, such as Express Scripts or CVS. These GPOs and PBMs rely on competitive bidding, discounts and rebates

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across their purchasing arrangements. We 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 relationships with GPOs and PBMs. The GPOs, PBMs 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, PBMs, 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 PBMs, 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 GLATOPA 40 mg/mL, our opportunity to capture market share would be significantly restricted for the term of these contracts even after a launch of GLATOPA 40 mg/mL. 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 testing of our complex generic products and biosimilarity or interchangeability testing of our 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

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the intrinsic value of equity awards, including stock options. Stock options granted to our executives and employees may be under pressure given the volatility of our stock performance and at such times may not always provide a retentive effect. 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 operations rely on the secure processing, storage and transmission of confidential and other information in our and our third party contractors' computer systems and networks. Our internal computer systems are vulnerable to breakdown or breach, including as a result of computer viruses, security breaches by individuals with authorized access, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The increased use of mobile and cloud technologies can heighten these and other operational risks. Moreover, systems breaches are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Any breakdown or 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, we could suffer reputational harm, we could be subject to regulatory action, and the trading price of our common stock could be adversely affected. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to breakdown or breach of our computer systems and other related breaches.

As we continue to evolve from a company primarily involved in discovery and development of pharmaceutical products 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 manage additional relationships with various collaborative partners, suppliers and other organizations.

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 can 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,

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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 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, as amended, 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

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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, as amended. 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 Our Financial Position and Need for Additional Capital

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, 2017, our accumulated deficit was $543 million. We may incur annual operating losses over the next several years as we expand our product development, commercialization and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our product candidates, and effectively manufacture, market and sell any products 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 products 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 enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other therapeutic candidates or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

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 and license agreements, we may breach those agreements and our collaboration partners could terminate those agreements.

As of June 30, 2017, we had cash, cash equivalents and marketable securities totaling approximately $456.8 million. For the quarter ended June 30, 2017, we had a net loss of $36.9 million and our operations provided cash of $38.3 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 product 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 20 mg/mL;

- the successful commercialization of GLATOPA 40 mg/mL 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, obtaining reference product for nonclinical and clinical studies, manufacturing nonclinical and clinical supply material, and obtaining regulatory approvals;

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

- the receipt of milestone payments under our CSL License Agreement;

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- the continuation without disruption of development and manufacturing activities of M923 following Baxalta's termination of the Baxalta Collaboration Agreement, which was effective on December 31, 2016;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar relating to Enoxaparin Sodium Injection, that is not otherwise covered by our collaboration agreements, or potential patent litigation with others, as well as any damages, including possibly treble damages, that may be owed to third parties should we be unsuccessful in such litigation;
- the ability to enter into additional strategic alliances for our non-partnered programs, such as M923, as well as the terms and timing of any milestone, royalty or profit share payments thereunder;
- whether we opt in to a cost-and-profit sharing arrangement under the CSL License Agreement;
- 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 and license agreements and equity financings, continuation and milestone payments and product revenues under existing collaboration and license 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. Additional funds may not be available to us on acceptable terms or at all. 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 and license 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.

Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may seek to raise the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaboration and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect our stockholders' rights or, in the case of debt securities, require us to pay interest that would reduce our cash flows from operations or comply with certain covenants that could restrict our operations. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Risks Relating to Development and Regulatory Approval

The future success of our business is significantly dependent on the success of our GLATOPA 40 mg/mL product candidate. If we are not able to obtain regulatory approval for the commercial sale of our GLATOPA 40 mg/mL

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 GLATOPA 40 mg/mL. Our application for GLATOPA 40 mg/mL 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 GLATOPA 40 mg/mL:

- 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

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- 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 GLATOPA 40 mg/mL to COPAXONE 40 mg/mL will be based, in part, on our demonstration of the chemical equivalence of our version to its respective reference listed drugs. The FDA may not agree that we have adequately characterized GLATOPA 40 mg/mL or that GLATOPA 40 mg/mL 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 GLATOPA 40 mg/mL 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 GLATOPA 40 mg/mL could be delayed or prevented or become more expensive. Regulatory approval of this or any other product may also be significantly delayed where manufacturing inspections are pending or have unresolved pending compliance issues. Delays in any part of the process or our inability to obtain regulatory approval for GLATOPA 40 mg/mL could adversely affect our operating results by restricting or significantly delaying our introduction of GLATOPA 40 mg/mL.

Moreover, on February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

Although the BPCI Act establishes a regulatory pathway for the approval by the FDA of biosimilars, the standards for determining biosimilarity and interchangeability for biosimilars are only just being implemented by the FDA under recently developed and developing guidance. 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 biosimilar versions of biologic and complex protein products remains uncertain, even following the 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 a series of draft and final guidance documents on certain matters concerning approval of biosimilars, interchangeable biologics, non-proprietary naming and labeling, as well as quality and scientific considerations. Experience will develop as the number of products and applications increase. The pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing reference product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the reference 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 reference 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 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.

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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 reference product company's and patent owner's counsel;
- the inclusion of multiple potential patent rights in the patent clearance process; and
- a grant to each reference product company of 12 years of marketing exclusivity following the reference product approval.

Furthermore, the regulatory pathway creates the risk that the reference product 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 reference product 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 hiring and 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 2017 or future years. In addition, from time to time, the federal government implements hiring and regulatory freezes, such as the hiring and regulatory freezes implemented in early 2017, and other regulatory reform initiatives that have the potential to impact the future implementation of the biosimilar regulatory pathway. While proposals to repeal the Affordable Care Act do not appear to include proposals to repeal the BPCI Act, there is still some uncertainty about that possibility. 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

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the pharmacy level for the corresponding reference product. If our generic or biosimilar products are not substitutable at the pharmacy level for the corresponding 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 reference 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 drugs and product candidates therapeutically equivalent, physicians will be required to specifically prescribe a generic product alternative rather than have a routine substitution at the pharmacy level for the prescribed reference product. Should this occur with respect to one of our generic drugs or 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, reference product pharmaceutical companies are lobbying state legislatures and the FDA to enact physician prescription requirements, or in the absence of a prescription, physician and patient notification requirements, special labeling requirements and unique naming requirements for biosimilars which if enacted could create barriers to substitution and adoption rates of interchangeable biologics as well as non-interchangeable biosimilars. Should this occur with respect to one of our biosimilars or interchangeable biologic product candidates in a discriminatory manner, it could materially reduce sales in those states which would substantially harm our business. To date, the FDA has adopted, but not implemented, a non-discriminatory policy that would apply the same non-proprietary naming requirements to reference products.

If nonclinical studies and clinical trials are required for regulatory approval of our product candidates and are delayed or are not successful, we may incur additional costs, experience delays in obtaining, or ultimately be unable 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 product candidates are safe and effective. Nonclinical studies and clinical trials of novel product candidates are lengthy and expensive and there is a high probability of significant delays to or failure of novel product candidates during nonclinical studies or clinical trials.

To obtain regulatory approval for the commercial sale of our biosimilar product candidates, the BPCI Act requires nonclinical studies and clinical trials to demonstrate biosimilarity, unless the FDA in its discretion determines such studies and trials are not necessary.

A delay or failure of one of our product candidates during nonclinical studies or clinical trials, if required, can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, nonclinical studies and clinical trials, if required, that could delay or prevent our ability to receive regulatory approval or commercialize our product 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;

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- the effects of our product 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 product candidate and in initial human clinical studies of a product candidate may not predict the results that will be obtained in subsequent human clinical trials, if required. If we are required by regulatory authorities to conduct additional clinical trials or other testing of our 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 product 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 product candidates. 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 pharmaceutical products we develop will be subject to ongoing regulatory review, including the review of clinical results that 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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs, and to

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spur innovation, but its ultimate implementation remains unclear. 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 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. In the 2016 Physician Fee Schedule Final Rule, CMS made it clear that the payment amount for a biosimilar is based on the average sales price of all products included within the same billing and payment code. In general, this means that CMS will group biosimilar products that rely on a common reference product's biologics license application into the same payment calculation, and these products will share a common payment limit and billing code. Separate codes could reduce or significantly impair the value of interchangeability of the biosimilar. However, it is unclear what effect this will have on private payers. 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.

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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 MMA changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for pharmaceutical products that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for pharmaceutical product purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered pharmaceutical products, and provides authority for limiting the number of pharmaceutical products that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered pharmaceutical products. As a result of the MMA and the expansion of federal coverage of pharmaceutical 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 pharmaceutical product 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, healthcare reform legislation known as the Affordable Care Act that was enacted in 2010 significantly changed 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 pharmaceutical products sold into the Medicaid program, an extension of the rebate requirement to pharmaceutical products used in risk-based Medicaid managed care plans, an extension of mandatory discounts for pharmaceutical products sold to certain critical access hospitals, cancer hospitals and other covered entities, and discounts and fees applicable to brand-name pharmaceutical products. 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. In 2017, members of Congress and the President have sought to repeal and replace the Affordable Care Act. It is uncertain whether such repeal and replace legislation will be enacted into law, and if enacted, what the impact might be on our business.

Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs or introduce price controls or price negotiation may cause the government or other organizations to limit both coverage and level of reimbursement for approved products and, as a result, they may not cover or provide adequate payment for our products and product candidates. We expect to experience pricing pressures in connection with the sale of any of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, the BPCI Act establishes an abbreviated regulatory pathway for the approval of biosimilars and provides that reference 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 reference 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 full effects of the Affordable Care Act or its repeal and replacement, if enacted, 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 or new legislation is enacted. 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. In 2017 and beyond, we may face additional uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Affordable Care Act. There is no assurance that the Affordable Care Act, as amended in the future, will not

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adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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 application for GLATOPA 40 mg/mL 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 application for GLATOPA 40 mg/mL and any supplements may be subject to significant delays during their review cycles, which may adversely affect our business and financial condition. In addition, from time to time the federal government implements hiring freezes, such as the one implemented in early 2017, which could also impact the review and potential approval of our application for GLATOPA 40 mg/mL and, as a result, may adversely affect our business and financial condition.

Risks Relating to Intellectual Property

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

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the

first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patent applications. As a result, we may be required to obtain licenses under third-party patents to market our proposed products. If licenses are not available to us on acceptable terms, or at all, we will not be able to market the affected products.

Assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or 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.

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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.

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.

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If we remain involved in patent litigation or other proceedings to determine or enforce our intellectual property rights, we could incur substantial costs or experience delays that could have a material adverse effect on 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, or any delays to the development of our product candidates resulting from such litigation or other proceeding, even if the litigation or proceeding is 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 and resulting development delays 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 and could ultimately lead to a decision to discontinue a program. 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 20 mg/mL and GLATOPA 40 mg/mL, 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 20 mg/mL and are significantly dependent on Sandoz AG to successfully commercialize GLATOPA 40 mg/mL. 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 and product candidates differently than we do or it may fail to allocate sufficient

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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 development and commercialization of our lead biosimilar product candidate, M923, could be delayed or terminated as a result of the termination of the Baxalta Collaboration Agreement, and our business may be adversely affected.

On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement, or the Baxalta Termination. On December 31, 2016, we and Baxalta entered into an Asset Return and Termination Agreement pursuant to which the effective date of the Baxalta Termination was December 31, 2016. Following the effective date of the Baxalta Termination, Baxalta is not obligated to continue to perform development, manufacturing or commercialization activities for M923 except for certain transitional clinical and regulatory activities, the majority of which have been completed. There could be changes or delays in the timing of the M923 program in connection with the return of the M923 program to us.

In addition, following the effective date of the Baxalta Termination, we have the right to research, develop, manufacture and commercialize M923 or license a third party to do so. In the event we elect to research, develop, manufacture and commercialize M923 by ourselves, we would need to expand our internal capabilities, in connection with which there could be significant delays in the M923 program. In the event we elect to license M923 to a third party, the terms of such a license and collaboration could be less favorable than those under the Baxalta Collaboration Agreement, and finding and negotiating a new collaboration could cause significant delays in the M923 program. Any of the delays described above could prevent us from commercializing M923. In addition, we may need to seek additional financing to support the research, development and commercialization of M923, or alternatively we may decide to discontinue M923, which could have a material adverse effect on our business.

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 Mylan Collaboration 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 were 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 were 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 and product candidates 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.

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The CSL License Agreement is important to our business. If we or CSL fail to adequately perform under the Agreement, or if we or CSL terminate the Agreement, the development and commercialization of our novel therapeutic, M230, could be delayed or terminated and our business would be adversely affected.

CSL may terminate the CSL License Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. We may terminate the CSL License Agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the CSL License Agreement. Either party may terminate the Agreement on a product-by-product basis if certain patent challenges are made, on a product-by-product for material breaches, or due to the other party's bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, we or CSL have the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

If the CSL License Agreement were terminated and we had the right to continue the research, 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 research, 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 CSL License Agreement were terminated and CSL 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 CSL License Agreement, we are dependent upon CSL to successfully perform its responsibilities and activities, including the research, development and commercialization of M230 and research on other Fc multimer proteins. We do not control CSL's execution of its responsibilities or the resources it allocates to our products and product candidates. Our interests and CSL's interests may differ or conflict from time to time, or we may disagree wi