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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended March 31, 2018

or

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

For the Transition Period from to

Commission File Number 000-50797

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(617) 491-9700

(Registrant's Telephone Number, Including Area Code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒	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 ☒

As of May 2, 2018, there were 77,588,904 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

MOMENTA PHARMACEUTICALS, INC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Quarterly Report on Form 10-Q that are about future events or future results, or are otherwise not statements of historical fact, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management. In some cases, these statements can be identified by words such as "anticipate," "approach," "believe," "can," "contemplate," "continue," "could," "ensure," "estimate," "expect," "goal," "intend," "likely," "may," "might," "objective," "opportunity," "plan," "potential", "predict," "project," "pursue," "seek," "schedule," "should," "strategy," "target," "typically," "will," "would," and other similar words or expressions, or the negative of these words or similar words or expressions. These statements include, but are not limited to, statements regarding our expectations regarding the development and utility of our products and product candidates; development timelines for our products, including next steps for our M834 program; 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 of results; the timing of launch of products and product candidates; market share 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 proceedings; timing of biosimilar market formation; collaboration revenues and research and development revenues; manufacturing; timing of regulatory filings, reviews and approvals; the sufficiency of our current capital resources and projected milestone payments and product revenues for future operations; our future financial position, including but not limited to our future operating losses, our potential future profitability, our future expenses, our strategic review, 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 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; 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; dilution; royalty rates; and vesting of equity awards.

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

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.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 88,226	$ 73,651
Marketable securities	235,674	269,017
Collaboration receivable	4,753	15,048
Prepaid expenses and other current assets	7,236	6,798
Restricted cash	2,412	2,412
Total current assets	338,301	366,926
Marketable securities, long-term	22,108	37,222
Property and equipment, net	31,506	29,916
Restricted cash, long-term	20,620	20,620
Intangible assets, net	3,748	4,036
Other long-term assets	661	711
Total assets	$ 416,944	$ 459,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,969	$ 11,456
Accrued expenses	16,543	20,528
Collaboration liabilities	7,888	9,258
Deferred revenue	3,490	2,866
Other current liabilities	622	379
Total current liabilities	34,512	44,487
Deferred revenue, net of current portion	34,890	30,751
Other long-term liabilities	13,125	10,039
Total liabilities	82,527	85,277
Commitments and contingencies (Note 6)		
Stockholders' Equity:		
Common stock, $0.0001 par value per share; 100,000 shares authorized, 77,329 shares issued and 77,100 shares outstanding at March 31, 2018 and 76,584 shares issued and 76,355 shares outstanding at December 31, 2017	8	8
Additional paid-in capital	953,494	939,654
Accumulated other comprehensive loss	(575)	(140)
Accumulated deficit	(615,396)	(562,254)
Treasury stock, at cost, 229 shares	(3,114)	(3,114)
Total stockholders' equity	334,417	374,154
Total liabilities and stockholders' equity	$ 416,944	$ 459,431

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

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

	Three Months Ended March 31,	
	2018	**2017**
Collaboration revenue:		
Product revenue	$ 3,521	$ 23,404
Research and development revenue	1,331	3,210
Total collaboration revenue	4,852	26,614
Operating expenses:		
Research and development	33,242	36,101
General and administrative	20,612	23,105
Total operating expenses	53,854	59,206
Operating loss	(49,002)	(32,592)
Other income, net	1,371	833
Net loss	$ (47,631)	$ (31,759)
Basic and diluted net loss per share	$ (0.63)	$ (0.46)
Weighted average shares used in computing basic and diluted net loss per share	75,454	69,711
Comprehensive loss:		
Net loss	$ (47,631)	$ (31,759)
Net unrealized holding losses on available-for-sale marketable securities	(435)	(66)
Comprehensive loss	$ (48,066)	$ (31,825)

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

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

	Three Months Ended March 31,	
	2018	**2017**
Cash Flows from Operating Activities:		
Net loss	$ (47,631)	$ (31,759)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization of property and equipment	1,786	1,266
Share-based compensation expense	4,874	6,803
Amortization of premium on investments	74	37
Amortization of intangibles	288	288
Loss on disposal of assets	76	—
Changes in operating assets and liabilities:		
Collaboration receivable	10,295	43,698
Prepaid expenses and other current assets	205	(506)
Other long-term assets	50	63
Accounts payable	(5,635)	3,438
Accrued expenses	(3,746)	(3,953)
Collaboration liabilities	(1,370)	(5,692)
Deferred revenue	(748)	48,205
Lease incentive	2,196	—
Other current liabilities	—	(11)
Other long-term liabilities	1,133	1,167
Net cash (used in) provided by operating activities	(38,153)	63,044
Cash Flows from Investing Activities:		
Purchases of property and equipment	(3,555)	(1,700)
Proceeds from disposal of equipment	12	—
Purchases of marketable securities	(43,434)	(47,384)
Proceeds from maturities of marketable securities	91,382	76,432
Net cash provided by investing activities	44,405	27,348
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock under ATM facility	—	14,441
Proceeds from issuance of common stock under stock plans	8,323	4,916
Net cash provided by financing activities	8,323	19,357
Net increase in cash, cash equivalents and restricted cash	14,575	109,749
Cash, cash equivalents and restricted cash, beginning of period	96,683	172,499
Cash, cash equivalents and restricted cash, end of period	$ 111,258	$ 282,248
Non-Cash Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 1,228	$ 1,051
Receivable due from broker for issuance of common stock under ATM facility	$ —	$ 4,072
Receivable due from stock option exercises	$ 643	$ (38)
Impact of adopting ASU 2016-09	$ —	$ 783
Impact of adopting ASC 606	$ 5,511	$ —

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

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

1. The Company

Business Overview

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

In the opinion of management, the accompanying unaudited, condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's financial statements for interim periods in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The information included in this quarterly report on Form 10-Q should be read in conjunction with the Company's audited consolidated financial statements and the accompanying notes included in its Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission, or SEC, on February 26, 2018. The Company's accounting policies are described in the “Notes to Consolidated Financial Statements” in its Annual Report on Form 10-K for the year ended December 31, 2017 and updated, as necessary, in this Form 10-Q. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from the Company's audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2018, are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

Consolidation

The accompanying unaudited, 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. Intercompany balances and transactions are eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that may 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 may differ from these estimates.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, using the modified retrospective transition method as permissible for all contracts not yet completed as of January 1, 2018. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

License Agreements

The Company has entered into license arrangements with pharmaceutical companies for the development and commercialization of product candidates. The terms of these agreements may include (i) transfer of intellectual property rights (licenses) and (ii) providing research and development services. Payments made by the customers may include non-refundable upfront license fees, payments for research and development activities, payments based upon the achievement of defined collaboration objectives and a share of profits on net sales of licensed products.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. The Company evaluates all other promised goods or services in the license agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services that reflect their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations. If optional future services reflect a significant or incremental discount, they are material rights, and are accounted for as performance obligations.

The Company utilizes judgment to determine the transaction price. The Company evaluates contingent milestones to estimate the amount which is not probable of a material reversal to include in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development milestone payments which may not be subject to a material reversal, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect research and development revenue and earnings in the period of adjustment.

The Company then determines whether the performance obligations or combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company may earn a contractual percentage of a licensor's revenues or profits after the successful development and commercialization of a licensed product. A sales or usage-based royalty on a license of intellectual property where the license is the predominant item to which the royalty relates is eligible for an exception to the standard revenue recognition model under Topic 606. Under this exception, an entity is permitted to (i) exclude such amounts from the initial determination of the transaction price (hence no amounts to allocate amongst the performance obligations) and (ii) defer recognition until underlying sales occur. The amount of net sales and contractual profit is determined based on information provided by the licensor and involves 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. Net sales and contractual profit may also include or exclude other amounts as defined in an agreement. The Company is highly dependent on the licensor for timely and accurate information regarding any net revenues realized from sales of the licensed products in order to accurately report its results of operations. Sales-based milestones and profit share revenues are recognized as revenue when sales thresholds are met under the sales or usage-based royalty exception under Topic 606.

Collaborative Arrangements

The Company considers the nature and contractual terms of the arrangement and assesses whether the arrangement involves a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement, the Company accounts for the arrangement as a collaboration under Topic 808, *Collaborative Arrangements*. Topic 808 describes arrangements within its scope and considerations surrounding presentation and disclosure, with recognition matters subjected to other authoritative guidance, in certain cases by analogy.

With respect to consideration other than cost sharing payments received from a collaboration partner, the Company has applied an accounting policy to analogize to other accounting guidance concerning revenue recognition, specifically Topic 606. Payments received from a collaboration partner to which this policy applies may include upfront payments in respect of a license of intellectual property, development milestones, profit share payments, and sales-based milestones.

The Company classifies the payments received or made under the cost sharing provisions of the arrangement as a component of research and development or general and administrative expense, respectively, to reflect the joint risk sharing nature of the payment received or made.

Impact of Adoption

Under the modified retrospective transition method, the Company applied Topic 606 to all contracts within its scope as of January 1, 2018. Under the practical expedient concerning contract modifications contained in the transitional provisions of Topic 606, the Company has not retrospectively restated its contracts for modifications prior to the earliest period presented, and instead has reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price. Qualitatively, the effect of applying this practical expedient is not material to the periods presented in the consolidated financial statements.

As more fully discussed in Note 4, "*License Agreements and Collaborative Agreements*", only the arrangement with Mylan was determined to have unsatisfied performance obligations as of the adoption date for which the pattern of revenue recognition would change. All other agreements were unaffected by the adoption of Topic 606 in all periods presented in the consolidated financial statements through application of the modified retrospective transition method. As a result of adopting Topic 606, the Company recorded a $5.5 million cumulative transition adjustment to the opening balance of accumulated deficit on January 1, 2018 to reflect the use of a proportional performance method using costs incurred as an input measure of progress in satisfying performance obligations under the Mylan collaboration. The Company previously applied a straight-line method of recognition through the expected date of the Food and Drug Administration's, or FDA, approval for each product candidate.

The tables below include the amount by which each financial statement line item was affected as a result of applying or analogizing (with respect to the Company's collaboration agreements) to Topic 606 as compared to the previous accounting policy. The amounts in the tables below are in thousands.

Condensed Consolidated Statement of Operations and Comprehensive Loss

	For the Three Months Ended March 31, 2018		
	Topic 606	Topic 605	Change
Research and development revenue	$ 1,331	$ 1,299	$ 32
Loss from operations	$ 49,002	$ 49,034	$ (32)
Net loss	$ 47,631	$ 47,663	$ (32)
Comprehensive loss	$ 48,066	$ 48,098	$ (32)

Condensed Consolidated Balance Sheet

	For the Three Months Ended March 31, 2018		
	Topic 606	Topic 605	Change
Deferred revenue, current	$ 3,490	$ 2,866	$ 624
Deferred revenue, non-current	$ 34,890	$ 30,035	$ 4,855
Accumulated deficit	$ 615,396	$ 609,917	$ 5,479

Condensed Consolidated Statement of Cash Flows

	For the Three Months Ended March 31, 2018		
	Topic 606	Topic 605	Change
Net loss	$ 47,631	$ 47,663	$ (32)
Adjustments to reconcile net loss to net cash used in operating activities:			
Deferred revenue	$ 748	$ 716	$ 32

Collaboration Receivable

Collaboration receivable includes:

- Amounts due to the Company for its contractual profit share on Sandoz Inc.'s, or Sandoz's, sales of Enoxaparin Sodium Injection and GLATOPA;
- Amounts due to the Company for reimbursement of research and development services and certain external costs under the collaborations with Sandoz and CSL Behring Recombinant Facility AG, or CSL; and
- Amounts due from Mylan for its 50% share of certain collaboration expenses under the cost-sharing provisions of the agreement with Mylan, as described in Note 4, "*License Agreements and Collaborative Agreements*", that are not funded through the continuation payments.

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 Liability

Collaboration liability includes:

- Advance 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 agreement with Mylan; and
- Net payable to CSL for the Company's 50% share of collaboration expenses under the cost-sharing provisions of the agreement with CSL.

Deferred Revenue

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

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period, which includes common stock issued and outstanding and excludes unvested shares of restricted stock awards and units. Diluted net loss per common share is calculated 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 months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Weighted-average anti-dilutive shares related to:		
Outstanding stock options	3,635	3,761
Restricted stock awards and units	701	1,615

Fair Value Measurements

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

Description	Balance as of March 31, 2018	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	$ 49,712	$ 49,712	$ —	$ —
Overnight repurchase agreements	8,500	—	8,500	—
Marketable securities:				
U.S. government-sponsored enterprise securities	15,519	—	15,519	—
Corporate debt securities	150,210	—	150,210	—
Certificates of deposit	16,521	—	16,521	—
Commercial paper obligations	50,527	—	50,527	—
Asset-backed securities	25,005	—	25,005	—
Total	$ 315,994	$ 49,712	$ 266,282	$ —

Description	Balance as of December 31, 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	$ 49,204	$ 49,204	$ —	$ —
Overnight repurchase agreements	11,250	—	11,250	—
Marketable securities:				
U.S. government-sponsored enterprise securities	18,181	—	18,181	—
Corporate debt securities	148,874	—	148,874	—
Certificates of deposit	7,794	—	7,794	—
Commercial paper obligations	108,630	—	108,630	—
Asset-backed securities	22,760	—	22,760	—
Total	$ 366,693	$ 49,204	$ 317,489	$ —

The Company held $8.5 million and $11.3 million in overnight repurchase agreements as of March 31, 2018 and December 31, 2017, 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 months ended March 31, 2018 and 2017. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three months ended March 31, 2018. 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, 2017. 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 March 31, 2018 and December 31, 2017. 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: Cash, Cash Equivalents and Marketable Securities*", in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 for a discussion of the Company's accounting policies.

The following tables summarize the Company's cash, cash equivalents and marketable securities as of March 31, 2018 and December 31, 2017 (in thousands):

As of March 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$ 88,226	$ —	$ —	$ 88,226
U.S. government-sponsored enterprise securities due in one year or less	15,524	—	(5)	15,519
Corporate debt securities due in one year or less	132,802	—	(366)	132,436
Corporate debt securities due in more than one year	17,894	—	(120)	17,774
Certificates of deposit due in one year or less	16,536	—	(15)	16,521
Commercial paper obligations due in one year or less	50,510	20	(3)	50,527
Asset-backed securities due in one year or less	20,744	—	(73)	20,671
Asset-backed securities due in more than one year	4,347	—	(13)	4,334
Total	$ 346,583	$ 20	$ (595)	$ 346,008
Reported as:				
Cash and cash equivalents	$ 88,226	$ —	$ —	$ 88,226
Marketable securities	258,357	20	(595)	257,782
Total	$ 346,583	$ 20	$ (595)	$ 346,008

As of December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$ 73,651	$ —	$ —	$ 73,651
U.S. government-sponsored enterprise securities due in one year or less	18,186	—	(5)	18,181
Corporate debt securities due in one year or less	118,541	3	(115)	118,429
Corporate debt securities due in more than one year	30,487	1	(43)	30,445
Certificates of deposit due in one year or less	6,501	—	—	6,501
Certificates of deposit due in more than one year	1,297	—	(4)	1,293
Commercial paper obligations due in one year or less	108,573	65	(8)	108,630
Asset-backed securities due in one year or less	17,307	—	(30)	17,277
Asset-backed securities due in more than one year	5,487	—	(4)	5,483
Total	$ 380,030	$ 69	$ (209)	$ 379,890
Reported as:				
Cash and cash equivalents	$ 73,651	$ —	$ —	$ 73,651
Marketable securities	306,379	69	(209)	306,239
Total	$ 380,030	$ 69	$ (209)	$ 379,890

Cash, Cash Equivalents, and Restricted Cash

The following tables summarize the Company's cash, cash equivalents and restricted cash as of March 31, 2018 and March 31, 2017 (in thousands):

	As of March 31, 2018	As of March 31, 2017
Cash and cash equivalents	$ 88,226	$ 260,487
Restricted cash, current portion	2,412	—
Restricted cash, long-term	20,620	21,761
Total	$ 111,258	$ 282,248

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 Loss

Comprehensive 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 loss includes net loss and the change in accumulated other comprehensive loss for the period. Accumulated other comprehensive 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 Financial Accounting Standards Board, or FASB, or other standard setting bodies that the Company adopts as of the specified effective date.

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 new guidance is effective for annual periods beginning after December 15, 2017. The adoption of this ASU on January 1, 2018 did not have a material impact on the Company's 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 those years, beginning after December 15, 2017. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The retrospective adoption of ASU 2016-18 in the first quarter of 2018 resulted in $21.8 million of restricted cash being included in cash, cash equivalents and restricted cash balances on the statement of cash flows for the period ended March 31, 2017. The Company included the necessary reconciliation above.

3. 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 14, "*Commitments and Contingencies"* in the Company's Annual Report on Form 10-K for the year ended December 31, 2017. 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 following table summarizes the amounts designated as collateral for letters of credit related to the lease of office and laboratory space in Cambridge, Massachusetts (collateral amounts are presented in thousands).

Property Location	Approximate Square Footage	Lease Expiration Date	Letter of Credit Amount	Balance Sheet Classification
675 West Kendall Street	78,500	4/30/2018	2,412	Current Asset
320 Bent Street	105,000	2/28/2027	748	Non-Current Asset
301 Binney Street, Fifth Floor	80,000	6/29/2025	1,101	Non-Current Asset
301 Binney Street, Fourth Floor	52,000	3/31/2028	1,271	Non-Current Asset
Total			$ 5,532	

4. License Agreements and Collaborative Agreements

Contracts with Customers

2003 Sandoz Agreement

In 2003, the Company entered into a license agreement with Sandoz, or the 2003 Sandoz Agreement, to jointly develop, manufacture and commercialize enoxaparin sodium injection, a generic version of LOVENOX® (enoxaparin), in the United States, the licensed product. The Company and Sandoz agreed to exclusively work with each other to develop and commercialize the 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.

The term of the agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party. Either party may terminate the agreement if the other party breaches the agreement or files for bankruptcy. Additionally, Sandoz may terminate the agreement for commercial viability reasons.

Sandoz 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.

Sandoz began selling the licensed product in July 2010. In June 2015, the Company and Sandoz amended the agreement 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 the licensed product, Sandoz did not record any profit on sales of the licensed product in the three months ended March 31, 2018 and 2017, and therefore the Company did not record product revenue for the licensed product in those periods. The Company is no longer eligible to receive milestones under the agreement.

The Company concluded that the license agreement is within the scope of Topic 606. As of January 1, 2018, the Company has completed its performance obligations under the contract. The Company continues to be eligible to receive contractual profit share on Sandoz' sales of the licensed product, which is recorded as product revenue. The Company recognizes revenue for profit share in the period the related sales occur. The Company recognizes research and development revenue related to on-going commercial services under the contract as those services are delivered, as they represent customer options for future services that reflect their standalone selling price. The adoption of Topic 606 had no impact on the accounting for this license agreement.

2006 Sandoz Agreement

In 2006 and 2007, the Company entered into a series of agreements with Sandoz, or the 2006 Sandoz Agreement, where the Company and Sandoz agreed to exclusively collaborate on the development and commercialization of GLATOPA 20 mg/mL and 40 mg/mL, collectively GLATOPA, a generic version of COPAXONE, among other potential 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 for personnel costs and external costs incurred in the development of products to the extent development costs are borne by Sandoz, as described above. All commercialization costs are borne by Sandoz. With respect to GLATOPA, Sandoz is responsible for funding legal expenses, except for personnel costs with respect to certain legal activities for GLATOPA; however 50% of legal expenses, including any patent infringement damages, can be offset against the profit-sharing amounts. Development costs, commercialization costs and legal costs have defined meanings under the agreement.

The term of the agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party. The agreement may be terminated if either party breaches the agreement or files for bankruptcy, or, on a region-by-region basis, in the event clinical studies are needed in order to obtain marketing approval. Sandoz 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.

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States in June 2015 and of GLATOPA 40 mg/mL in the United States in February 2018. Under the agreement, the Company earns 50% of contractually defined profits on Sandoz' worldwide net sales of GLATOPA. 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 GLATOPA net sales, and post-launch commercial milestones achieved.

Following FDA approval of Mylan N.V.'s generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL, which Mylan N.V. announced in October 2017, the Company is no longer eligible to earn $80 million in future post-launch commercial milestones; however, the Company is still eligible to receive up to $30 million in 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.

On October 4, 2017, the Company and Sandoz entered into a letter agreement, pursuant to which the Company agreed to reduce its 50% share of contractually defined profits on worldwide net sales of GLATOPA by up to an aggregate of approximately $9.8 million, commencing in the first quarter of 2018, representing 50% of GLATOPA 40 mg/mL pre-launch inventory costs. In the first quarter of 2018, the Company's product revenue was reduced by $9.8 million for the Company's 50% share of GLATOPA 40 mg/mL inventory written off by Sandoz, consistent with the timing agreed to in the letter agreement.

The Company concluded that the license agreement is within the scope of Topic 606. As of January 1, 2018, the Company has completed its performance obligations under the contract. The Company continues to be eligible to receive contractual profit share on Sandoz' sales of GLATOPA, which is recorded as product revenue. The Company recognizes revenue for profit

share in the period the related sales occur. The Company recognizes research and development revenue related to on-going commercial services under the agreement as those services are delivered, as they represent customer options for future services that reflect their standalone selling price. The adoption of Topic 606 had no impact on the accounting for this license agreement.

Collaborative Arrangements

Mylan Collaboration Agreement

The Company and Mylan entered into a collaboration agreement, or the Mylan Collaboration Agreement, effective 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.

Under the 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.

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 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.

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

The 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.

The Mylan agreement is accounted for as a collaboration arrangement pursuant to Topic 808. The Company's accounting policy for collaborations analogizes to Topic 606, primarily in determining the appropriate recognition for the upfront license fee and other consideration.

Upfront Payments for License of Intellectual Property

The Company identified the following material promises under the contract: (i) licenses to develop, manufacture and commercialize the named product candidates (six product candidates in total) and (ii) research and development services through FDA approval for each of the six product candidates. The Company's participation in the joint steering committee was assessed as immaterial in the context of the contract. As the licenses for each of the products and the related research and development services for each of the product candidates are not capable of being distinct and are not distinct within the context of the contract, the Company concluded that each of the six bundles of a product license and the related research and development services through FDA approval should be combined as performance obligations. The Company next assessed whether each of the six bundles of a particular product license and the related research and development services is distinct from each other. The Company concluded that each of the six license and research and development services bundles is capable of being distinct, as Mylan can obtain benefit from each separately, and each is distinct within the context of the contract. Therefore, each of the six license and service bundles individually represent distinct performance obligations.

The Company determined that the upfront payment constituted the entirety of the consideration to be included in the transaction price to be allocated to the performance obligations at contract inception based on the stand-alone selling prices for each of the six license and service performance obligations. For the licenses, the relative stand-alone selling prices were based on an analysis of its existing license arrangements and other available data, with consideration given to the products' stage of development at the time the licenses were delivered. The stand-alone selling prices of the research and development services were based on the nature and extent of the research and development services to be performed. Changes in the key assumptions used to determine the relative stand-alone selling prices would not have a significant effect on the allocation of the transaction price to the performance obligations. Of the $45 million upfront payment, $8.2 million was allocated to M834, $7.1 million was allocated to M710, and between $5.7 million and $9.0 million was allocated to the four additional performance obligations.

The Company considered both input and output methods to determine a method that depicts its performance in transferring control of the goods and services promised. The Company concluded that costs incurred over the total estimated costs to be incurred during the period the services are delivered reflects the relative level of effort towards FDA approval, being the ultimate objective of each performance obligation, was the most appropriate measure. As of March 31, 2018, $38.4 million of the transaction price remains allocated to unsatisfied performance obligations. The license and related research and development services performance obligations are expected to be delivered over a period through estimated FDA approval of each product candidate. The pattern of recognition differs from the Company's previous accounting policy. Refer to Note 2, *"Summary of Significant Accounting Policies"*, for disclosure of the quantification and impact of this change as a result of adopting Topic 606.

Development milestones, sales-based milestones, and profit share related to the license of intellectual property will be recognized by analogy to the Company's revenue accounting policies.

Collaboration Costs and Reimbursements

Collaboration costs incurred by the parties are subject to quarterly reconciliation such that the final amount of expense included in the Company's statement of operations is equal to its 50% share of the total collaboration costs. The Company classifies the payments received or made under the cost sharing provisions of the arrangement as a component of research and development or general and administrative expense accordingly to reflect the joint risk sharing nature of the arrangement. Mylan funds its 50% share of development-related collaboration costs through contingent milestone payments of up to $200 million across the six product candidates, while other shared collaboration costs are reconciled by the parties with the owing party reimbursing the other party by making quarterly payments. The Company records a contract asset to reflect a receivable due from Mylan for Mylan's 50% share of other shared collaboration costs and a contract liability to reflect the balance of any advance payment from Mylan to be applied towards Mylan's 50% share of future development-related collaboration costs.

CSL License and Option Agreement

The Company and CSL a wholly owned indirect subsidiary of CSL Limited, entered into a License and Option Agreement, or the CSL License Agreement, effective February 17, 2017, pursuant to which the Company granted CSL an exclusive worldwide license to research, develop, manufacture and commercialize the M230 pre-clinical product candidate, an Fc multimer protein that is a selective immunomodulator of the Fc receptor. The 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, manufacture and commercialize these additional research products globally. CSL's obligations under the agreement are guaranteed by its parent company, CSL Limited.

Pursuant to the terms of the 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 development, 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 agreement. Sales milestones are based on aggregated sales across M230 and any other products developed under the agreement. The Company also had the option to participate in a cost-and-profit sharing arrangement, or a co-funding option, 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 agreement 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. The Company also has the option to participate in the promotion of products under the agreement in the United States, subject to a co-promotion agreement to be negotiated with CSL. On August 28, 2017, the Company exercised its co-funding option for a 50% share of U.S. profits. As a result, royalties remain payable for territories outside of the United States, and the milestone payments for which the Company is eligible are reduced from up to $550 million to up to $297.5 million. 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-co-funded arrangement amounts.

Under the agreement, the Company granted CSL an exclusive license under its intellectual property to research, develop, manufacture and commercialize product candidates for all therapeutic indications. CSL 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 agreement and the Company's 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 agreement commences on the Effective Date, as defined in the agreement, and continues until the later of (i) the expiration of all payment obligations with respect to products under the 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 agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. The Company may terminate the agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the agreement. Either party may terminate the 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 agreement, subject to certain exceptions, the licenses granted under the agreement terminate. In addition, dependent upon the circumstances under which the 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.

After the Company exercised its co-funding option for a 50% share of U.S. profits, the company has accounted for the CSL agreement as a collaboration arrangement pursuant to Topic 808. The Company’s accounting policy for collaborations analogizes to Topic 606, primarily in determining the appropriate recognition for the upfront license fee and other consideration.

Upfront Payments for License of Intellectual Property

The Company identified the following material promises under the contract: (i) license to research, develop, manufacture and commercialize M230 and (ii) to perform a technology transfer to CSL. The Company’s participation in the joint steering committee and other promises were assessed as immaterial in the context of the contract. As the licenses and technology transfer are not capable of being distinct and are not distinct within the context of the contract, the Company concluded that the bundle of the licenses and technology transfer should be combined as one performance obligation. The combined performance obligation was delivered in 2017. As the $50 million upfront payment reflected the transaction price at contract inception, all revenue related to the single performance obligation was recognized prior to the date of adoption of Topic 606. Development

milestones, sales-based milestones, and profit share related to the license of intellectual property will be recognized by analogy to the Company's revenue accounting policies. No transition adjustment was recognized as a result of adopting Topic 606.

Co-funding Costs and Reimbursements

The co-funding arrangement with CSL is a cost-sharing arrangement. Reimbursement by CSL for its share of the development effort is presented as a reduction of operating expenses, and reimbursement by the Company for its share of the development effort is recorded as an incremental operating expense, consistent with the Company's accounting policy for collaboration arrangements. Such amounts are settled quarterly amongst the parties.

License Agreement Summary

The following tables provide amounts by year indicated and by line item included in the Company's accompanying consolidated financial statements attributable to transactions arising from its license arrangements. The dollar amounts in the tables below are in thousands.

	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	CSL Collaboration Agreement	Total
Contract assets					
Collaboration receivables					
Opening - January 1, 2018	$ 406	$ 14,219	$ 423	$ —	$ 15,048
Revenue / cost recovery	4	4,099	160	—	4,263
Receipts	(406)	(13,729)	(423)	—	(14,558)
Ending - March 31, 2018	$ 4	$ 4,589	$ 160	$ —	$ 4,753
Contract liabilities					
Deferred revenue:					
Opening - January 1, 2018	$ —	$ —	$ 39,128	$ —	$ 39,128
Amortization of deferred revenue	—	—	(748)	—	(748)
Ending - March 31, 2018	—	—	38,380	—	38,380
Less: current portion	—	—	(3,490)	—	(3,490)
Deferred revenue, net of current portion - March 31, 2018	$ —	$ —	$ 34,890	$ —	$ 34,890
Collaboration liabilities:					
Opening - January 1, 2018	$ —	$ —	$ 8,245	$ 1,013	$ 9,258
Payments	—	—	—	(1,013)	(1,013)
Net collaboration costs incurred in the period	—	—	(2,222)	1,865	(357)
Ending - March 31, 2018	$ —	$ —	$ 6,023	$ 1,865	$ 7,888
For the Three Months Ended March 31, 2018					
Product revenue	$ —	$ 3,521	$ —	$ —	$ 3,521
Research and development revenue	4	579	748	—	1,331
Total collaboration revenue	$ 4	$ 4,100	$ 748	$ —	$ 4,852
Operating expenses:					
Research and development expense	—	117	9,372	303	9,792
General and administrative expense	2,479	16	586	11	3,092
Net amount (recovered from) / payable to collaborators	—	—	(2,382)	1,865	(517)

Total operating expenses	$ 2,479	$ 133	$ 7,576	$ 2,179	$ 12,367

For the Three Months Ended March 31, 2017					
Product revenue	$ —	$ 23,404	$ —	$ —	$ 23,404
Research and development revenue	963	451	1,796	—	3,210
Total collaboration revenue	$ 963	$ 23,855	$ 1,796	$ —	$ 26,614
Operating expenses:					
Research and development expense	$ 1,526	$ 265	$ 12,602	$ —	$ 14,393
General and administrative expense	4,550	24	530	—	5,104
Net amount (recovered from) / payable to collaborators	—	—	(5,722)	—	(5,722)
Total operating expenses	$ 6,076	$ 289	$ 7,410	$ —	$ 13,775

5. Share-Based Payments

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 months ended March 31, 2018 and 2017 (in thousands):

	For the Three Months Ended March 31, 2018	For the Three Months Ended March 31, 2017
Research and development	$ 1,925	$ 2,463
General and administrative	2,949	4,340
Total share-based compensation expense	$ 4,874	$ 6,803

The following table summarizes share-based compensation expense recorded in each of the three months ended March 31, 2018 and 2017 (in thousands):

	For the Three Months Ended March 31, 2018	For the Three Months Ended March 31, 2017
Stock options	$ 2,076	$ 2,606
Restricted stock awards and restricted stock units	2,700	4,077
Employee stock purchase plan	98	120
Total share-based compensation expense	$ 4,874	$ 6,803

During the three months ended March 31, 2018, the Company granted 197,500 options to an employee. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions are noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended March 31, 2018 and 2017 was $8.05 per option and $9.49 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 March 31, 2018	For the Three Months Ended March 31, 2017	For the Three Months Ended March 31, 2018	For the Three Months Ended March 31, 2017
Expected volatility	48%	54%	49%	57%
Expected dividends	—	—	—	—
Expected life (years)	6.1	5.7	0.5	0.5
Risk-free interest rate	2.7%	2.1%	1.4%	0.5%

Since April 13, 2016, the Company has awarded 1,785,600 shares of performance-based restricted stock to its employees. 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 2016, the Company determined that only two of the three performance milestones are possible to achieve prior to April 13, 2019. In the first quarter of 2018, one of the two available performance milestones was met and 25% of the awards vested. The Company is expensing the fair value of the shares expected to vest over the implicit service period using the accelerated attribution method. For the three months ended March 31, 2018, the Company recognized approximately $0.6 million of stock-based compensation costs related to these awards.

In the three months ended March 31, 2018, the Company awarded 998,657 shares of time-based restricted stock units to its employees. The time-based restricted stock units vest as to 50% on the one year anniversary of the grant date and as to 50% on the second anniversary of 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 Company's Equity Award Retirement Policy.

6. 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, 2017 for a discussion of the Company's operating lease agreements.

Total operating lease commitments as of March 31, 2018 are as follows (in thousands):

April 1 to December 31, 2018	$	14,189
2019		18,848
2020		19,380
2021		19,856
2022		20,319
2023 and beyond		82,541
Total future minimum lease payments	$	175,133

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 in the United States District Court for the District of Delaware in response to the filing by Sandoz of the Abbreviated New Drug Application, or 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 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 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. In February 2017, Teva and Yeda appealed the District Court's January 30, 2017, decision to the U.S. Court of Appeals for the Federal Circuit, or CAFC. Briefing was completed in the third quarter of 2017. Oral argument was held on May 1, 2018, at the CAFC. A decision is pending.

On January 31, 2017, Teva filed a suit against the Company and Sandoz 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 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. 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. A claim construction hearing was held on November 2, 2017, and a claim construction opinion issued on December 1, 2017. A seven day trial is scheduled to commence before the United States District Court for the District of Delaware on October 9, 2018.

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 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 to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the 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 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. In February 2018, the District Court confirmed the jury's opinion that the patent was infringed but invalid, and narrowed the jury's recommendation on unenforceability by finding the patent to be unenforceable against only one of the two infringing methods used by Amphastar. On March 20, 2018, the District Court entered its final judgment affirming its February 2018 rulings. On March 27, 2018, the Company and Sandoz filed a notice of appeal of the final judgment with the CAFC. The appeal has been docketed and opening briefs are due May 29, 2018. In the event that the Company is not successful in further appeal or 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. On March 23, 2018, Amphastar filed a motion to enforce liability on the security bond with the District Court. On April 3, 2018, the Company and Sandoz filed an emergency motion to defer consideration of Amphastar's motion to enforce liability on the security bond pending exhaustion of appeals. On April 17, 2018, Amphastar filed an opposition to the Company's emergency motion and on April 23, 2018, the Company and Sandoz filed a reply to Amphastar's opposition. All motions are pending. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against the Company and Sandoz 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 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 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' 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, the Company and Sandoz filed a renewed motion to dismiss which was denied by the District Court on March 20, 2018. On April 27, 2018, the Company and Sandoz filed with the District Court a motion for certification of an interlocutory appeal and motion for reconsideration of the District Court's denial of the Company's motion to dismiss. Amphastar has filed an opposition to the motion and the motion is pending. A trial is scheduled for September 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 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 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 the Company's 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, or DC37. NGH and DC37 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. On December 14, 2017, the Court granted NGH's motion to amend. In January 2018, the Company and Sandoz filed three motions to dismiss the amended complaint. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and intend to vigorously defend itself in this litigation.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

Overview

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

To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. Although we were profitable in fiscal years 2010 and 2011, since that time we have been incurring operating losses and we expect to incur annual operating losses over the next several years as we advance our drug development portfolio. As of March 31, 2018, we had an accumulated deficit of approximately $615.4 million. We will need to generate significant revenue to return to profitability. We expect that our return to profitability, if at all, will most likely come from the commercialization of the products in our drug development portfolio.

Complex Generics

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

In April 2015, the Food and Drug Administration, or the FDA, approved the Abbreviated New Drug Application, or ANDA, for GLATOPA 20 mg/mL, a generic equivalent of once-daily COPAXONE 20 mg/mL. GLATOPA 20 mg/mL was the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. Sandoz commenced sales of GLATOPA 20 mg/mL in June 2015. Under our 2006 collaboration agreement with Sandoz, or the 2006 Sandoz Agreement, we earn 50% of contractually defined profits on GLATOPA 20 mg/mL sales.

In October 2017, Mylan N.V. announced the launch of its generic equivalents of once-daily COPAXONE 20 mg/mL and three-times-weekly COPAXONE 40 mg/mL. Following Mylan N.V.'s entry into the market, Sandoz has defended GLATOPA's share of the 20 mg/mL glatiramer acetate injection market by using one or more contracting strategies, including but not limited to, lowering its GLATOPA 20 mg/mL price or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue. Additionally, as a result of Mylan N.V.'s and our launches of generic equivalents of COPAXONE 40 mg/mL, the market and contractual profit share revenue of GLATOPA 20 mg/mL may be reduced by an accelerated conversion of patients from once-daily 20 mg/mL glatiramer acetate injection to three-times-weekly 40 mg/mL glatiramer acetate injection due to lower pricing in that market. As of the end of the first quarter of 2018, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 83% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed.

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

On February 13, 2018, we announced that GLATOPA 40 mg/mL, a generic version of three-times-weekly COPAXONE 40 mg/mL, was approved by the FDA and launched by our collaborator, Sandoz.

As a result of Mylan N.V.'s launch of its generic equivalent of three-times-weekly COPAXONE 40 mg/mL in October, 2017 we expect the potential market share, price and contractual profit share revenue available for GLATOPA 40 mg/mL to be reduced.

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 filed by an unrelated third party. In February 2017, Teva and Yeda appealed the District Court's January 30, 2017 decision to the U.S. Court of Appeals for the Federal Circuit. Briefing was completed in the third quarter of 2017 and a decision is pending oral argument. 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."*

GLATOPA refers to GLATOPA 20 mg/mL and GLATOPA 40 mg/mL, collectively.

Enoxaparin Sodium Injection—Generic LOVENOX®

Under our amended 2003 collaboration agreement with Sandoz, or the 2003 Sandoz Agreement, 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, we expect any future revenues from Sandoz's sales of Enoxaparin Sodium Injection will be minimal.

Biosimilars

M923—Biosimilar HUMIRA® (adalimumab) Candidate

In November 2016, 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.

The timing of the first regulatory submission for marketing approval for M923 in the United States is dependent on the outcome of our ongoing strategic review. We expect that U.S. market formation for biosimilar versions of HUMIRA will likely be in the 2022-2023 time frame, subject to marketing approval, patent considerations and litigation timelines.

M834—Biosimilar ORENCIA® (abatacept) Candidate

M834 is being developed in collaboration with Mylan. In the fourth quarter of 2017, we completed 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. On November 1, 2017, we announced that M834 did not meet its primary pharmacokinetic endpoints in the Phase 1 clinical trial. We and Mylan continue to gather and analyze the data from the Phase 1 clinical trial to better understand the results and evaluate the next steps for M834 which will delay any future development and cause us to incur additional costs.

ORENCIA's composition of matter patents expire in the United States in 2019. We are currently involved in legal proceedings aimed at invalidating Bristol-Myers Squibb's formulation patent on ORENCIA. This proceeding is further discussed below under "*Part II. Item 1. Legal Proceedings -- M834-Related Proceedings*."

M710—Biosimilar EYLEA® (aflibercept) Candidate

M710 is being developed in collaboration with Mylan. On January 3, 2018, we announced the development strategy for M710. We and Mylan plan to start up the pivotal clinical trial in patients in the first half of 2018. This trial is randomized, double-blind, active-control, multi-center study in patients with diabetic macular edema to compare the safety, efficacy and immunogenicity of M710 with EYLEA. Subject to development, marketing approval and patent considerations, we expect U.S. market formation for biosimilar versions of EYLEA will likely be in the 2023 time frame.

Other Biosimilar Candidates

The Mylan collaboration also includes four other biosimilar candidates from our portfolio, in addition to M834 and M710. Under our collaboration agreement with Mylan, or the Mylan Collaboration Agreement, 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, if approved.

In January 2018, we announced that we have begun a strategic review to address funding challenges and revenue uncertainty related to our biosimilar programs. Potential management actions include establishing new collaborations across the portfolio, implementing additional cost reduction strategies, slowing the pace of future biosimilar program development and the potential sale of certain biosimilar assets. Pending a decision to undertake any strategic alternatives, we are continuing development and collaboration activities for our biosimilar programs in accordance with our current strategy while focusing on managing our cash position. We expect to complete this strategic review by the end of the second quarter of 2018. We can provide no assurance that any strategic alternative we pursue will have a positive impact on our results of operations or financial condition.

Novel Therapeutics

We believe our novel product candidates could be capable of treating a large number of immune-mediated disorders driven by autoantibodies, immune complexes, and Fc receptor biology.

M281 - Anti-FcRn Candidate

M281 is a fully-human anti-neonatal Fc receptor (FcRn), aglycosylated immunoglobulin G, or IgG1, monoclonal antibody, engineered to reduce circulating pathogenic IgG antibodies, in excess of that achieved by any current treatments, by completely blocking endogenous IgG recycling via FcRn.

A Phase 1 randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 in normal healthy volunteers was initiated in June 2016. In January 2018, we announced the full results of the Phase 1 study. The single ascending dose, or SAD, portion of the study enrolled five cohorts with a total of 34 healthy adult volunteers and showed that a single dose of M281 achieved up to an 80% reduction of circulating IgG antibodies. The multiple ascending dose, or MAD, portion of the study assessed M281 in two cohorts, administered in four weekly doses to 16 healthy adult volunteers and showed predictable pharmacokinetics, and commensurate, controllable and reproducible reductions in circulating IgG. The data showed greater than 80% reduction in circulating IgG antibodies with a mean reduction of 84%. M281 was well tolerated at all dose levels and no serious adverse events or unexpected safety findings were observed in either portion of the study. We are targeting two proof of concept clinical trials in the second half of 2018.

M230 (CSL730) - Recombinant Fc Multimer Candidate

M230 is a novel recombinant trivalent human IgG1 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 collaboration agreement with CSL Behring Recombinant Facility AG (CSL), or the CSL Collaboration Agreement, effective February 17, 2017, we granted CSL an exclusive worldwide license to research, develop, manufacture and commercialize M230. On August 28, 2017, we exercised our 50% co-funding option, which is discussed further in Note 4, "*License Agreements and Collaborative Agreements - CSL Collaboration Agreement*". CSL initiated a Phase I study for M230 in normal healthy volunteers in January 2018.

M254 - hsIVIg Candidate

M254 is a hyper-sialylated immunoglobulin designed as a high potency alternative for intravenous immunoglobulin (IVIg), a therapeutic drug product that is manufactured using pooled, human immunoglobulin G, or IgG, antibodies purified from blood plasma. IVIg is used to treat several inflammatory diseases, including idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. If approved, M254 has the potential to remediate the limitations of IVIg because sialylation of the Fc region of IgG has been seen to augment the anti-inflammatory attributes of IVIg. We expect to complete the IND-enabling toxicology study and to initiate a clinical study in the second half of 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 March 31, 2018 and 2017

Product revenue includes our contractually defined profits earned on Sandoz' sales of GLATOPA and Enoxaparin Sodium Injection. Research and development revenue generally consists of amounts earned by us under our collaborations for

development, regulatory and commercial milestones; reimbursement of research and development services and reimbursement of development costs; and recognition of upfront payments.

The following data summarizes our collaboration revenues for the periods indicated.

	Three Months Ended March 31,	
	2018	2017
Collaboration revenue:	(in thousands)	(in thousands)
Product revenue	$ 3,521	$ 23,404
Research and development revenue	1,331	3,210
Total collaboration revenue	$ 4,852	$ 26,614

Product Revenue

GLATOPA

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States in June 2015 and GLATOPA 40 mg/mL in February 2018. We earn 50% of contractually defined profits on Sandoz' sales of GLATOPA. Pursuant to the letter agreement dated October 4, 2017 between Sandoz and us, we agreed to reduce our 50% contractual profit share, commencing in the first quarter of 2018, by up to an aggregate of approximately $9.8 million, representing 50% of potential GLATOPA 40 mg/mL pre-launch inventory costs. The following table presents GLATOPA product revenue by period.

	Three Months Ended March 31,		Change period over period	
	2018	2017	2018 compared to 2017	
	(in thousands)	(in thousands)	(in thousands)	(%)
GLATOPA	$ 3,521	$ 23,404	$ (19,883)	(85)%

The decrease in GLATOPA product revenue of $19.9 million, or 85%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 was primarily due to lower net sales of GLATOPA 20 mg/mL driven by Mylan N.V.'s entry into the COPAXONE market and a $9.8 million deduction in the first quarter of 2018 for our 50% share of GLATOPA 40 mg/mL inventory written off by Sandoz, consistent with the timing agreed to in the letter agreement.

We estimate that the number of prescriptions for GLATOPA 20 mg/mL currently represents approximately 40% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

In October 2017, Mylan N.V. announced the launch of its generic equivalents of once-daily COPAXONE 20 mg/mL and three-times-weekly COPAXONE 40 mg/mL. Following Mylan N.V.'s entry into the market, Sandoz has defended GLATOPA's share of the 20 mg/mL glatiramer acetate injection market by using one or more contracting strategies, including but not limited to, lowering its GLATOPA 20 mg/mL price or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue. Additionally, as a result of Mylan N.V.'s and our launches of generic equivalents of COPAXONE 40 mg/mL, the market and contractual profit share revenue of GLATOPA 20 mg/mL may be reduced by an accelerated conversion of patients from once-daily 20 mg/mL glatiramer acetate injection to three-times-weekly 40 mg/mL glatiramer acetate injection due to lower pricing in that market. As a result of Mylan N.V.'s launch of its generic equivalent of three-times-weekly COPAXONE 40 mg/mL in October, 2017 we expect the potential market share, price and contractual profit share revenue available for GLATOPA 40 mg/mL to be reduced. As of the end of the first quarter of 2018, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 83% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed.

Enoxaparin Sodium Injection—Generic LOVENOX®

Effective April 1, 2015, we began to earn 50% of contractually defined profits on Sandoz' sales of Enoxaparin Sodium Injection. A portion of Enoxaparin Sodium Injection development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, are offset against profit-sharing amounts, royalties and milestone payments.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, Sandoz did not record a profit on sales of Enoxaparin Sodium Injection in the periods presented and we do not anticipate significant Enoxaparin Sodium Injection product revenue in the future.

Research and Development Revenue

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

Research and development revenue was $1.3 million and $3.2 million for the three months ended March 31, 2018 and 2017, respectively. The decrease in research and development revenue of $1.9 million, or 59%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 was driven by lower revenue recognized from the Mylan upfront payment as compared to the amount recognized in the 2017 period and lower reimbursable expenses for our complex generic programs. Prior to January 1, 2018, we applied a straight-line method to recognize the Mylan upfront payment as revenue through the expected date of FDA approval for each product candidate. Effective January 1, 2018, we use a proportional performance method to recognize the upfront payment using costs incurred over total costs expected to be incurred during the period the services are delivered.

Operating Expenses

The following table summarizes our operating expenses for the periods indicated, together with the changes period over period.

	Three Months Ended March 31,				Change period over period	
	2018	% of Total Operating Expenses	2017	% of Total Operating Expenses	2018 compared to 2017	
	(in thousands)	(%)	(in thousands)	(%)	(in thousands)	(%)
Operating expenses:						
Research and development	$ 33,242	62%	$ 36,101	61%	$ (2,859)	(8)%
General and administrative	20,612	38%	23,105	39%	(2,493)	(11)%
Total operating expenses	$ 53,854	100%	$ 59,206	100%	$ (5,352)	(9)%

Research and Development Expense

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

- expenses incurred under agreements with consultants, third-party contract research organizations, or CROs, and investigative sites where all of our nonclinical studies and clinical trials are conducted;
- costs of acquiring reference comparator materials and manufacturing nonclinical study and clinical trial supplies and other materials from contract manufacturing organizations, or CMOs, and related costs associated with release and stability testing; and
- costs associated with process development activities.

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

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

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

For our collaboration arrangements in which the parties share in collaboration expenses for products under the arrangement (cost sharing arrangements), we record the reimbursement by the collaborator for its share of the development effort as a reduction of research and development expense. Our share of costs incurred by collaborators are recorded as research and development expense.

Research and development expense for the three months ended March 31, 2018 was $33.2 million, compared with $36.1 million for the three months ended March 31, 2017. The decrease of $2.9 million, or 8%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 was primarily due to a decrease in external R&D expense for CRO and CMO spend of $10.9 million partially offset by increases of $5.3 million in cost sharing payments under our collaborations and $2.7 million in facility and related expenses.

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

The following table sets forth research and development costs for our principal programs by product area for the three months ended March 31, 2018 and 2017. The figures in the table include GLATOPA and Enoxaparin Sodium Injection research and development costs incurred by us and reimbursed by Sandoz. For our cost sharing arrangements with Mylan and CSL, we have also included our share of costs incurred by Mylan and CSL, including costs for full-time equivalents. Although we track and accumulate personnel effort by percentage of time spent on our programs, a significant portion of our internal research and development costs, including salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies are not directly charged to programs. Therefore, our methods for accounting for internal research and development costs preclude us from reporting these costs on a project-by-project basis.

	Phase of Development as of March 31, 2018	Three Months Ended March 31,	
		2018	2017
		(in thousands)	(in thousands)
External Costs Incurred by Product Area:			
Complex Generics(1)	(1)	$ 117	$ 1,791
Biosimilars	Various(2)	3,919	8,793
Novel Therapeutics	Various(3)	6,493	5,445
Internal Costs		22,713	20,072
Total Research and Development Expenses		$ 33,242	$ 36,101

(1) Includes external costs for GLATOPA and Enoxaparin Sodium Injection. 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. In February 2018, the FDA approved the ANDA for three-times-weekly GLATOPA 40 mg/mL, and Sandoz launched the product. 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."

(2) Biosimilars include M923, a biosimilar candidate of HUMIRA® (adalimumab), M834, a biosimilar candidate of ORENCIA® (abatacept), M710, a biosimilar candidate of EYLEA® (aflibercept), as well as four other biosimilar candidates. In January 2018, we announced that the Biologics License Application for M923 is prepared to be filed with the FDA. We completed a Phase 1 clinical trial of M834 and in November 2017 we announced that M834 did not meet its primary pharmacokinetic endpoints in its trial. For M710, we plan to start up the pivotal clinical trial in patients in the first half of 2018. Our other biosimilar candidates are in the discovery and process development phase.

(3) Our novel therapeutic programs include M281, for which we completed a Phase 1 study; M230, which our licensee, CSL initiated a Phase I study in normal healthy volunteers in January 2018; M254, for which we expect to complete the IND-enabling toxicology study, commenced in 2017, and to initiate a clinical study in the second half of 2018; as well as other discovery and nonclinical stage programs.

External expenditures for complex generics decreased by $1.7 million, or 93% from the three months ended March 31, 2017 to the three months ended March 31, 2018 as we had incurred non-recurring costs in the 2017 period. External expenditures for our biosimilars programs decreased by $4.9 million, or 55%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 due to a decrease in activities for M923 and M834 partially offset by increase in development of M710 and other biosimilar candidates. External costs of our novel therapeutic programs increased by $1.0 million, or 19%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 driven by activities to support advancing M281 towards Phase 2 clinical trials. Finally, internal costs grew by $2.6 million, or 13%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 primarily due to increased rent and other facility-related expenses.

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, share-based compensation and other related costs for personnel in general and administrative functions, professional fees for legal and accounting services, royalty and license fees, insurance costs, allocated rent, facility and lab supplies, and depreciation expense.

For our collaboration arrangements in which the parties share in collaboration expenses for products under the arrangement (cost sharing arrangements), we record the reimbursement by the collaborator for its share of the development effort as a reduction of general and administrative expense. Our share of costs incurred by collaborators are recorded as general and administrative expense.

General and administrative expense for the three months ended March 31, 2018 was $20.6 million, compared with $23.1 million for the three months ended March 31, 2017. The decrease of $2.5 million, or 11%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 was primarily driven by lower legal expenses related to our litigation.

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 includes other items of non-operating income and expense. Other income, net was $1.4 million and $0.8 million for the three months ended March 31, 2018 and 2017, respectively. The increase of $0.6 million or 75%, from the three months ended March 31, 2017 to the three months ended March 31, 2018 was caused by higher interest income due to higher average investment balances from funds raised in 2017 under the 2015 At-the-Market Agreement, or the 2015 ATM Agreement, and higher market yields on our investments.

Liquidity and Capital Resources

At March 31, 2018, we had $346.0 million in cash, cash equivalents and marketable securities and $4.8 million in collaboration receivables, which includes $3.5 million in profit share from Sandoz' sales of GLATOPA. In addition, we also held $23.0 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, 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 2019.

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 March 31, 2018 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 March 31, 2018.

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Net cash (used in) provided by operating activities	$ (38,153)	$ 63,044
Net cash provided by investing activities	$ 44,405	$ 27,348
Net cash provided by financing activities	$ 8,323	$ 19,357
Net increase in cash, cash equivalents, and restricted cash	$ 14,575	$ 109,749

Cash provided by operating activities

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

Cash used in operating activities was $38.2 million for the three months ended March 31, 2018 reflecting a net loss of $47.6 million, which was partially offset by non-cash charges of $2.1 million for depreciation and amortization of property, equipment and intangible assets and $4.9 million in shared-based compensation. The net change in our operating assets and liabilities provided cash of $2.4 million and resulted from the receipt of $13.4 million for Sandoz' sales of GLATOPA 20 mg/mL and Enoxaparin, partially offset by decrease in accounts payable and accrued expenses of $9.4 million and a decrease in our collaboration liabilities of $1.4 million in connection with our collaboration agreements with CSL and Mylan.

Cash provided by operating activities was $63.0 million for the three months ended March 31, 2017 reflecting a net loss of $31.8 million, which was partially offset by non-cash charges of $1.6 million for depreciation and amortization of property, equipment and intangible assets and $6.8 million in shared-based compensation. The net change in our operating assets and liabilities provided cash of $86.4 million and primarily resulted from the receipt of $50 million from CSL under the collaboration agreement and a one-time cash payment of $51.2 million in connection with the termination of our agreement with Baxalta, partially offset by the change in profit share receivable from Sandoz' sales of GLATOPA 20 mg/mL of $7.6 million, which was included in collaboration receivable.

Cash provided by investing activities

Cash provided by investing activities of $44.4 million for the three months ended March 31, 2018 includes cash inflows of $91.4 million from maturities of marketable securities partially offset by cash outflows of $43.4 million for purchases of marketable securities and $3.6 million for capital equipment and leasehold improvements.

Cash provided by investing activities of $27.3 million for the three months ended March 31, 2017 included cash inflows of $76.4 million from maturities of marketable securities partially offset by cash outflows of $47.4 million for purchases of marketable securities and $1.7 million for capital equipment and leasehold improvements.

Cash provided by financing activities

Cash provided by financing activities of $8.3 million for the three months ended March 31, 2018 consists solely of proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Cash provided by financing activities of $19.4 million for the three months ended March 31, 2017 included $14.4 million of net proceeds from shares sold under the 2015 ATM Agreement and $4.9 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 relate to license maintenance obligations including royalties payable to third parties as well as operating lease obligations. The disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on February 26, 2018, have not materially changed since we filed that report.

Critical Accounting Policies and Estimates

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

Please refer to the significant accounting policies described in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 26, 2018.

Please refer to Revenue Recognition within Note 2 "*Summary of Significant Accounting Policies*" to our condensed consolidated financial statements contained in Part I, Item I of this Quarterly Report on Form 10-Q for a discussion of our accounting policies for license and collaboration agreements as well as the impact of adopting Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, on January 1, 2018.

New Accounting Standards

Please refer to Note 2 "*Summary of Significant Accounting Policies*" to our condensed consolidated financial statements contained in Part I, Item I of this Quarterly Report on Form 10-Q 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 March 31, 2018, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

Item 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of March 31, 2018. Our management recognizes that any controls and procedures, no

matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

There was no change in our internal control over financial reporting during the quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

GLATOPA 40 mg/mL-Related Proceedings

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz in the United States District Court for the District of Delaware in response to the filing by Sandoz 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 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 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. In February 2017, Teva and Yeda appealed the District Court's January 30, 2017 decision to the U.S. Court of Appeals for the Federal Circuit, or CAFC. Briefing was completed in the third quarter of 2017.Oral argument was held on May 1, 2018, at the CAFC. A decision is pending.

On January 31, 2017, Teva filed a suit against us and Sandoz 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 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 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. A claim construction hearing was held on November 2, 2017, and a claim construction opinion issued on December 1, 2017. A seven day trial is scheduled to commence before the United States District Court for the District of Delaware on October 9, 2018.

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 Patent Trial and Appeal Board, or 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 CAFC, 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. Oral argument before the Federal Circuit was held on December 5, 2017 and a decision is pending.

Enoxaparin Sodium Injection-Related Proceedings

On September 21, 2011, we and Sandoz 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 to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the CAFC and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded the case to the District Court. In September 2012, we filed a petition with the CAFC for rehearing by the full court *en banc*, which was denied. In February 2013, we filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, 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 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. In February 2018, the District Court confirmed the jury's opinion that the patent was infringed but invalid, but narrowed the jury's recommendation on unenforceability by finding our patent to be unenforceable against only one of the two infringing methods used by Amphastar. On March 20, 2018, the District Court entered its final judgment affirming its February 2018 rulings. On March 27, 2018, we and Sandoz filed a notice of appeal of the final judgment with the CAFC. The appeal has been docketed and opening briefs are due May 29, 2018. In the event that we are not successful in further appeal or 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. On March 23, 2018, Amphastar filed a motion to enforce liability on the security bond with the District Court. On April 3, 2018, we and Sandoz filed an emergency motion to defer consideration of Amphastar's motion to enforce liability on the security bond pending exhaustion of appeals. On April 17, 2018, Amphastar filed an opposition to our emergency motion and on April 23, 2018, we and Sandoz filed our reply to Amphastar's opposition. All motions are pending. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against us and Sandoz 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 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 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 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 filed our renewed motion to dismiss which was denied by the District Court on March 20, 2018. On April 27, 2018, we and Sandoz filed with the District Court a motion for certification of an interlocutory appeal and motion for reconsideration of the District Court's denial of our motion to dismiss. Amphastar has filed an opposition to the motion and the motion is pending. A trial is scheduled for September 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 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 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 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, or DC37. NGH and DC37 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. On December 14, 2017, the Court granted NGH's motion to amend. In January 2018, we and Sandoz filed three motions to dismiss the amended complaint. 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.

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 collaborators 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 collaborators 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 manufacturer for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA applied a compliance hold on the 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. On January 30, 2018, we announced that the FDA had changed the status of Pfizer's manufacturing facility to Voluntary Action Indicated, which lifted the compliance hold and was followed by a marketing approval in February 2018. The FDA delay in ability to approve GLATOPA 40 mg/mL until satisfactory resolution of the compliance observations in the FDA warning letter greatly increased the risk to us and Sandoz of prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL, limiting revenue potential. In October 2017, Mylan N.V. announced the launch of its generic equivalent of COPAXONE 40 mg/mL. As a result, we anticipate that any revenue and profits from GLATOPA 40 mg/mL will be reduced, perhaps significantly, which 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. Any additional prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL could have a further 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 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.

GLATOPA 40 mg/mL was launched prior to final resolution of product-related patent infringement litigation in our favor, which may cause us to incur significant damages.

Sandoz has the sole right to decide the timing and scope of the launch of GLATOPA 40 mg/mL and has commenced marketing the product prior to a final judicial resolution of product-related patent infringement litigation in our and Sandoz' favor. Accordingly, 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 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 be prevented from marketing and selling GLATOPA 40 mg/mL 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 four of the five 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 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, M710 and M834, are approved and successfully commercialized, our business would suffer.

Pricing and market share of generic and biosimilar products may decline, often dramatically, as other generics or biosimilars of the same brand name drug or reference product, respectively, enter the market. Competing generics include brand name manufacturers' "authorized generics" of their own brand name products. Generally, earlier-to-market generics and biosimilars are better able to gain significantly greater market share than later-to-market competing generics and biosimilars, respectively. Accordingly, revenue and profits from our generic products 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 our generic products and, if approved, certain of our generic and biosimilar product candidates may face intense and increasing competition from other generics and biosimilars. For example, in October 2017, Mylan N.V. announced the launch of its generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL. Following Mylan N.V.'s entry into the market, Sandoz has defended GLATOPA's share of the 20 mg/mL glatiramer acetate injection market by using one or more contracting strategies, including but not limited to, lowering its GLATOPA 20 mg/mL price or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue. Additionally, as a result of Mylan N.V.'s and our launches of generic equivalents of COPAXONE 40 mg/mL, the market and contractual profit share revenue of GLATOPA 20 mg/mL may be reduced by an accelerated conversion of patients from once-daily 20 mg/mL glatiramer acetate injection to

three-times weekly 40 mg/mL glatiramer acetate injection due to lower pricing in that market. As a result of Mylan N.V.'s launch of its generic equivalent of three-times-weekly COPAXONE 40 mg/mL in October, 2017 we expect the potential market share, price and contractual profit share revenue available for GLATOPA 40 mg/mL to be reduced. In addition, several other companies have submitted ANDAs to the FDA for generic versions of COPAXONE. A launch of one or more additional generic versions of COPAXONE could further reduce anticipated revenue from GLATOPA 20 mg/mL and GLATOPA 40 mg/mL.

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, EYLEA, ORENCIA or another of the reference products for which we have a biosimilar product candidate prior to approval of M923, M710, 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, EYLEA 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, as of the end of the first quarter of 2018, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 83% of the overall U.S. glatiramer acetate injection 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 or any generic equivalent to three-times-weekly COPAXONE or generic equivalent. 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, EYLEA 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.

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 current and near term product revenue is dependent on the continued successful commercialization of GLATOPA 20 mg/mL and successful commercialization of GLATOPA 40 mg/mL.

Our near-term ability to generate GLATOPA product revenue depends, in large part, on Sandoz' ability to continue to successfully manufacture and profitably commercialize GLATOPA 20 mg/mL, and successfully manufacture and profitably commercialize GLATOPA 40 mg/mL.

Our near-term ability to generate GLATOPA product revenue also depends in large part on Sandoz' ability to maintain market share and favorable pricing levels for GLATOPA 20 mg/mL and achieve profitable sales and market share for GLATOPA 40 mg/mL. In October 2017, Mylan N.V. announced the launch of its generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL. Following Mylan N.V.'s entry into the market, Sandoz has defended GLATOPA's share of the 20 mg/mL glatiramer acetate injection market by using one or more contracting strategies, including but not limited to, lowering its GLATOPA 20 mg/mL price or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue. Additionally, as a result of Mylan N.V.'s and our launches of generic equivalents of COPAXONE 40 mg/mL, the market and contractual profit share revenue of GLATOPA 20 mg/mL may be reduced by an accelerated conversion of patients from once-daily 20 mg/mL glatiramer acetate injection to three-times weekly 40 mg/mL glatiramer acetate injection due to lower pricing in that market. As a result of Mylan N.V.'s launch of its generic equivalent of three-times-weekly COPAXONE 40 mg/mL in October, 2017 we expect the potential market share, price and contractual profit share revenue available for GLATOPA 40 mg/mL to be reduced. Our near-term ability to generate GLATOPA 40 mg/mL product revenue will depend on Sandoz' ability to compete with Teva's three-times-weekly COPAXONE 40 mg/mL product and any generic equivalents. As of the end of the first quarter of 2018, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 83% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed. If other competitors receive approval to market generic versions of the 20 mg/mL or 40 mg/mL formulations of COPAXONE, our product revenue and profits would be further impacted, 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 strategic alternative we pursue may not be successful.

In January 2018, we announced that we have begun a strategic review to address funding challenges and revenue uncertainty related to our biosimilar programs. Potential management actions include establishing new collaborations across the portfolio, implementing additional cost reduction strategies, slowing the pace of future biosimilar program development and the potential sale of certain biosimilar assets. Pending a decision to undertake any strategic alternatives, we are continuing development and collaboration activities for our biosimilar programs in accordance with our current strategy while focusing on managing our cash position. We can provide no assurance that any strategic alternative we pursue will have a positive impact on our results of operations or financial condition.

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 three months ended March 31, 2018, 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 appeal in the 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. In February 2018, the District Court confirmed the jury's opinion that the patent was infringed but invalid, and narrowed the jury's recommendation on unenforceability by finding our patent to be unenforceable against only one of the two infringing methods used by Amphastar. We and Sandoz are considering all other available legal options to overturn the portions of the verdict that found our patent to be invalid and partially unenforceable, including a potential appeal to the CAFC. On March 20, 2018 the District Court entered its final judgment affirming its February 2018 rulings. On March 27, 2018 we and Sandoz filed a notice of appeal of the final judgment with the CAFC. The appeal has been docketed and opening briefs are due May 29, 2018.

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 bond for such damages. We posted $17.5 million as collateral for the security bond and classified the collateral as restricted cash in our consolidated balance sheet. On March 23, 2018, Amphastar filed a motion to enforce liability on the security bond with the District Court. On April 3, 2018, we and Sandoz filed an emergency motion to defer consideration of Amphastar's motion to enforce liability on the security bond pending exhaustion of appeals. On April 17, 2018 Amphastar filed an opposition to our emergency motion and on April 23, 2018, we and Sandoz filed our reply to Amphastar's opposition. All motions are pending. 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 generic or biosimilar products.

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 discounts, rebates and 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 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 contracted with Teva for net price discounts or rebates on COPAXONE 20 mg/mL and 40 mg/mL, or with Mylan N.V. for net price discounts or rebates on its generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL, in exchange for exclusivity or preferred status for COPAXONE prior to the February 2018 approval and launch of GLATOPA 40 mg/mL, our opportunity to capture market share would be significantly restricted for the term of these contracts.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 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, 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 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 March 31, 2018, our accumulated deficit was $615.4 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 product candidates, completing nonclinical testing and clinical trials of our 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 March 31, 2018, we had cash, cash equivalents and marketable securities totaling approximately $346.0 million. For the quarter ended March 31, 2018, we had a net loss of $47.6 million and our operations used cash of $38.2 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 and of GLATOPA 40 mg/mL;
- the successful commercialization of our other product candidates;
- the impact of prior or contemporaneous competition on our products and product candidates, such as Mylan N.V.'s generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL on GLATOPA 20 mg/mL and GLATOPA 40 mg/mL;
- 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;
- the continuation without disruption of development and manufacturing activities of M923;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation maintaining and enforcing our intellectual property rights and defending intellectual property related claims, 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;
- the scope, progress, results and costs of 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, contingent milestone payments, 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 2019. 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

Even if we complete necessary preclinical studies and clinical trials, provide evidence of therapeutic equivalence or provide evidence of biosimilarity or interchangeability, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import , are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and comparable regulatory authorities in other countries. With the exception of our generic Enoxaparin Sodium Injection, GLATOPA 20 mg/mL and GLATOPA 40 mg/mL, we and our collaborators have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate.

Securing marketing approval requires the submission of extensive preclinical and clinical data; strength, quality, purity, identity and therapeutic equivalence data; or biosimilarity or interchangeability data, as applicable, and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application we submit, or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

Accordingly, if we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

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. For example, we announced on November 1, 2017 that the results of the Phase I clinical trial for M834 indicated that it did not meet its primary pharmacokinetic endpoints, requiring an evaluation of next steps for the program,

which will delay any future development and cause us to incur additional costs. 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;
- 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.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or our collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

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.

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 2018 or future years. In addition, the hiring and regulatory freeze implemented by the federal government in 2017 and other potential regulatory reform initiatives could also 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 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 a non-discriminatory policy that would apply the same non-proprietary naming requirements to reference products.

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.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the EU requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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 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.

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

The Medicare Modernization Act, or MMA, changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for 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 and is now being implemented could significantly change the United States health care system and the reimbursement of products. A primary goal of the law is to reduce or limit the growth of health care costs, which could change the market for pharmaceuticals and biological products. The law contains provisions that will affect companies in the pharmaceutical industry and other healthcare-related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include an increase to the mandatory rebates for 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.

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.

In 2017, members of Congress and the President sought to repeal and replace the Affordable Care Act, and it is possible that similar efforts will be made in the future. It is uncertain whether any such repeal and replace legislation will be enacted into law, and if enacted, what the impact might be on our business. It is also uncertain whether regulatory changes to the implementation of the Affordable Care Act will restrict patient access to affordable insurance and impact their access to novel, biosimilar and complex generic products. The full effects of any repeal and replacement of the Affordable Care Act, or regulatory changes to its implementation cannot be known until a new law is implemented through regulations or guidance is issued by the CMS and other federal and state health care agencies. Any legislative or regulatory changes 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 2018 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 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.

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.

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.

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 adversely affect our business.

We may need to continue to resort to litigation to enforce a patent issued to us or to determine the scope and validity of a third-party patent or other proprietary rights such as trade secrets in jurisdictions where we intend to market our products, including the United States, the European Union, and many other foreign jurisdictions. The cost to us of any litigation or other proceeding relating to determining the validity of intellectual property rights, or any delays to the development of our product candidates resulting from such litigation or other proceeding, even if resolved in our favor, could be substantial and could divert our management's efforts. Some of our competitors may be able to sustain the costs and resulting development delays associated with 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 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 resources to effectively or optimally commercialize our products and alignment may only be achieved through dispute resolution. In the future, we and Sandoz may compete on other products outside of our collaboration, which could negatively impact our ability to work effectively with one another. 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 our inability to enter into an agreement with a collaboration partner, and our business may be adversely affected.

Our collaboration with Baxter terminated on December 31, 2016 and we have proceeded with the development program with the goal of entering into a new collaboration agreement to finance the launch and legal clearance of the product. There could be changes or delays in the timing of the M923 program should we fail to enter into a collaboration agreement with a suitable collaborative partner. 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 former collaboration agreement with Baxalta, 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 and M710, 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. Competition between us and Mylan on other products outside of our collaboration, such as our respective generic equivalents of COPAXONE, could negatively impact our ability to work effectively with one another. If these events were to occur, our business would be adversely affected.

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 with CSL's level of effort or resource allocation. CSL 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.

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

Because we have limited internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we may need to enter into strategic alliances with other companies in addition to our current alliances with Sandoz, Mylan and CSL. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances as a result of many factors including the following:

- competition in seeking appropriate collaborators;

- restrictions on future strategic alliances in existing strategic alliance agreements;
- a reduced number of potential collaborators due to recent business combinations of large pharmaceutical companies;
- inability to negotiate strategic alliances on a timely basis; and
- inability to negotiate strategic alliances on acceptable terms.

Even if we do succeed in securing such alliances, we may not be able to maintain them or they may be unsuccessful. We may be unable to maintain a strategic alliance if the development or approval of a product candidate that is the subject of the alliance is delayed or sales of an approved product that is the subject of the alliance are disappointing. The success of our collaboration agreements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Any such alliance would entail numerous operational and financial risks, including significant integration and implementation challenges that could disrupt our business and divert our management's time and attention. If we are unable to secure or maintain such alliances or if such alliances are unsuccessful, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

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

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

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

A significant change in the business operations of, a change in the financial condition of, a change in senior executive management within, or a change in control of our third-party collaborators, or any future collaboration partners or third party manufacturers could have a negative impact on our business operations.

Since many of our product candidates are developed under collaborations or licenses with third parties, we do not have sole decision making authority with respect to commercialization or development of those product candidates. We have built relationships and work collaboratively with our third-party collaborators and manufacturers to ensure the success of our development and commercialization efforts. A significant change in the senior management team, a change in the financial condition or a change in the business operations, including a change in control or internal corporate restructuring, of any of our collaboration partners or third-party manufacturers, could result in delayed timelines on our products. In addition, we may have to re-establish working relationships and familiarize new counterparts with our products and business. Any such change may result in the collaboration partner or third party manufacturer internally re-prioritizing our programs or decreasing resources or funding allocated to support our programs. For example, in June 2016, Baxalta Incorporated and Shire announced the completion of a combination of Baxalta Incorporated and Shire, as a result of which Baxalta Incorporated became a wholly-owned subsidiary of Shire. On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the collaboration agreement with us, and on December 31, 2016, we and Baxalta entered into an Asset Return and Termination Agreement pursuant to which the effective date of the collaboration agreement was December 31, 2016. As a result, there could be changes or delays in the timing of the M923 program in connection with the

return of the M923 program to us. Similar changes with respect to any of our other collaborators may negatively impact our business operations.

General Company Related Risks

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

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

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

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

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

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

- delays in achievement of, or failure to achieve, program milestones that are associated with the valuation of our company or significant milestone revenue;
- failure of GLATOPA 20 mg/mL to sustain or GLATOPA 40 mg/mL to achieve profitable sales or market share that meet expectations of securities analysts;
- litigation involving our company or our general industry or both;
- a decision in favor of, or against, Amphastar in our patent litigation suits, a settlement related to any case; or a decision in favor of third parties in antitrust litigation filed against us;
- announcements by other companies regarding the status of their ANDAs for generic versions of COPAXONE;
- FDA approval of other companies' ANDAs for generic versions of COPAXONE;
- marketing and/or launch of other companies' generic versions of COPAXONE, such as Mylan N.V.'s October 2017 launch of its generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL;
- adverse FDA decisions regarding the development requirements for one of our biosimilar product candidates or failure of our other product applications to meet the requirements for regulatory review and/or approval;
- results or delays in our or our competitors' clinical trials or regulatory filings;

- enactment of legislation that repeals the law enacting the biosimilar regulatory approval pathway or amends the law in a manner that is adverse to our biosimilar development strategy;
- failure to demonstrate biosimilarity or interchangeability with respect to our biosimilar product candidates such as M923 or M834;
- demonstration of or failure to demonstrate the safety and efficacy for our novel product candidates;
- our inability to manufacture any products in conformance with cGMP or in sufficient quantities to meet the requirements for the commercial sale of the product or to meet market demand;
- failure of any of our product candidates, if approved, to achieve commercial success;
- the discovery of unexpected or increased incidence in patients' adverse reactions to the use of our products or product candidates or indications of other safety concerns;
- developments or disputes concerning our patents or other proprietary rights;
- changes in estimates of our financial results or recommendations by securities analysts;
- termination of any of our product development and commercialization collaborations;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- investors' general perception of our company, our products, the economy and general market conditions;
- rapid or disorderly sales of stock by holders of significant amounts of our stock; or
- significant fluctuations in the price of securities generally or biotechnology company securities specifically.

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

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

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

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Item 6. EXHIBITS

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Third Amended and Restated Certificate of Incorporation.	S-3	3.1	4/30/2013	333-188227
3.2	Fourth Amended and Restated By-Laws of the Registrant, adopted on March 14, 2017.	8-K	3.1	3/17/2017	000-50797
*31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
**32.1	Certification of Chief Executive Officer and Principal Executive, Financial and Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
*101.INS	XBRL Instance Document.				
*101.SCH	XBRL Taxonomy Extension Schema Document.				
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
*101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
*101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith.

** Furnished herewith.

The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at March 31, 2018 and December 31, 2017, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2018 and 2017, (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017, and (iv) Notes to Unaudited, Condensed Consolidated Financial Statements.

SIGNATURES

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

Momenta Pharmaceuticals, Inc.

Date: May 9, 2018

By: /s/ Craig A. Wheeler

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

Exhibit 31.1

CERTIFICATION

I, Craig A. Wheeler, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: May 9, 2018

/s/ Craig A. Wheeler

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

Dated: May 9, 2018

/s/ Craig A. Wheeler

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