MOMENTA PHARMACEUTICALS INC
Form 10-Q
May 03, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended March 31, 2019

or

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

For the Transition Period from to

Commission File Number 000-50797

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

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

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No ¨

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

Large accelerated filer x Accelerated filer ¨

Non-accelerated filer ¨ Smaller reporting company ¨

Emerging growth company ¨

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	MNTA	The Nasdaq Global Select Market

As of April 29, 2019, there were 98,611,523 shares of the registrant’s common stock, par value $0.0001 per share, outstanding.

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MOMENTA PHARMACEUTICALS, INC.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Quarterly Report on Form 10-Q that are about future events or future results, or are otherwise not statements of historical fact, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management. In some cases, these statements can be identified by words such as “anticipate,” “approach,” “believe,” “can,” “contemplate,” “continue,” “could,” “ensure,” “estimate,” “expect,” "goal," “intend,” “likely,” “may,” “might,” “objective,” “o “potential”, “predict,” “project,” “pursue,” “seek,” “schedule,” “should,” “strategy,” “target,” “typically,” “will,” “would,” and 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 priorities, goals and strategies, including our change in strategic focus toward the discovery and development of our novel drug candidates for rare immune-mediated diseases, including M281, M254 and M230, and the advancement of our late stage biosimilar candidates, M923 and M710; the use, efficacy, safety, potency, tolerability, dosing, convenience, differentiation and commercial potential of our products and product candidates; the design, timing and goals of clinical trials and the availability, timing and announcement of data and results; estimates of incidence of disease and patient populations; market potential and acceptance of our products and product candidates; the timing of regulatory filings, reviews and approvals; our expectations regarding the development and utility of our products and product candidates; development timelines for our product candidates; development, manufacture and commercialization of our products and product candidates; efforts to seek and manage relationships with collaboration partners, including without limitation for our novel therapeutic and biosimilar programs; 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; 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, including anticipated restructuring charges; 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; 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.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$131,228	$ 248,334
Marketable securities	204,043	174,076
Collaboration receivable	2,986	11,371
Prepaid expenses and other current assets	7,316	6,318
Assets held-for-sale	710	1,324
Total current assets	346,283	441,423
Marketable securities, long-term	81,182	27,001
Property and equipment, net	15,130	20,944
Restricted cash, long-term	37,898	37,898
Intangible assets, net	2,595	2,883
Other long-term assets	75,362	1,414
Total assets	$558,450	$ 531,563
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$9,319	$ 9,352
Accrued expenses	10,376	14,060
Accrued restructuring	1,556	3,235
Collaboration liabilities	2,770	4,721
Deferred revenue	3,606	3,916
Other current liabilities	23,953	16,227
Total current liabilities	51,580	51,511
Deferred revenue, net of current portion	743	1,774
Other long-term liabilities	83,569	17,270
Total liabilities	135,892	70,555
Commitments and contingencies (Note 8 and 13)		
Stockholders' Equity:		
Common stock, $0.0001 par value per share; 200,000 shares authorized, 99,176 shares issued and 98,947 shares outstanding at March 31, 2019 and 100,000 shares authorized, 98,695 shares issued and 98,466 shares outstanding at December 31, 2018	10	10
Additional paid-in capital	1,214,076	1,208,025
Accumulated other comprehensive income (loss)	255	(87)
Accumulated deficit	(788,669)	(743,826)
Treasury stock, at cost, 229 shares	(3,114)	(3,114)
Total stockholders' equity	422,558	461,008
Total liabilities and stockholders' equity	$558,450	$ 531,563

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

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

	Three Months Ended March 31,	
	2019	2018
Collaboration revenue:		
Product revenue	$2,352	$3,521
Research and development revenue	1,761	1,331
Total collaboration revenue	4,113	4,852
Operating expenses:		
Research and development	27,972	33,242
General and administrative	24,206	20,612
Restructuring	26	—
Total operating expenses	52,204	53,854
Operating loss	(48,091)	(49,002)
Other income, net	3,248	1,371
Net loss	$(44,843)	$(47,631)
Basic and diluted net loss per share	$(0.46)	$(0.63)
Weighted average shares used in computing basic and diluted net loss per share	98,195	75,454
Comprehensive loss:		
Net loss	$(44,843)	$(47,631)
Net unrealized holding gain (loss) on available-for-sale marketable securities	342	(435)
Comprehensive loss	$(44,501)	$(48,066)

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

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

	Three Months Ended March 31,	
	2019	2018
Cash Flows from Operating Activities:		
Net loss	$(44,843)	$(47,631)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	5,859	1,786
Share-based compensation expense	3,474	4,874
Amortization of premium on investments	(581)	74
Amortization of intangibles	288	288
(Gain) loss on disposal of assets	(440)	76
Changes in operating assets and liabilities:		
Collaboration receivable	8,385	10,295
Prepaid expenses and other current assets	(1,508)	205
Other long-term assets	2,722	50
Accounts payable	10	(5,635)
Accrued expenses	(3,962)	(3,746)
Accrued restructuring	(1,679)	—
Collaboration liabilities	(1,951)	(1,370)
Deferred revenue	(1,341)	(748)
Other liabilities	(2,025)	3,329
Net cash used in operating activities	(37,592)	(38,153)
Cash Flows from Investing Activities:		
Purchases of property and equipment	(137)	(3,555)
Proceeds from disposal of equipment	1,285	12
Purchases of marketable securities	(133,915)	(43,434)
Proceeds from maturities of marketable securities	50,690	91,382
Net cash provided by (used in) investing activities	(82,077)	44,405
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock under stock plans	2,563	8,323
Net cash provided by financing activities	2,563	8,323
Net increase (decrease) in cash, cash equivalents and restricted cash	(117,106)	14,575
Cash, cash equivalents and restricted cash, beginning of period	286,232	96,683
Cash, cash equivalents and restricted cash, end of period	$169,126	$111,258
Non-Cash Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$278	$1,228
Receivable due from stock option exercises	$14	$643
Impact of adopting ASC 606	$—	$5,511

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

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MOMENTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Common Stock					Treasury Stock		
	Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Shares	Amount	Total Stockholders' Equity
Balances at December 31, 2017	76,584	$ 8	$939,654	$ (140)	$(562,254)	(229)	$(3,114)	$ 374,154
Impact of adopting ASC 606	—	—	—	—	(5,511)	—	—	(5,511)
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	691	—	8,966	—	—	—	—	8,966
Issuance of restricted stock	101	—	—	—	—	—	—	—
Cancellation/forfeiture of restricted stock	(47)	—	—	—	—	—	—	—
Share-based compensation expense	—	—	4,874	—	—	—	—	4,874
Unrealized loss on marketable securities	—	—	—	(435)	—	—	—	(435)
Net loss	—	—	—	—	(47,631)	—	—	(47,631)
Balances at March 31, 2018	77,329	$ 8	$953,494	$ (575)	$(615,396)	(229)	$(3,114)	$ 334,417

	Common Stock					Treasury Stock		
	Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Shares	Amount	Total Stockholders' Equity
Balances at December 31, 2018	98,695	$ 10	$1,208,025	$ (87)	$(743,826)	(229)	$(3,114)	$ 461,008
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	237	—	2,577	—	—	—	—	2,577
Issuance of restricted stock	280	—	—	—	—	—	—	—
Cancellation/forfeiture of restricted stock	(36)	—	—	—	—	—	—	—
Share-based compensation expense	—	—	3,474	—	—	—	—	3,474
Unrealized gain on marketable securities	—	—	—	342	—	—	—	342
Net loss	—	—	—	—	(44,843)	—	—	(44,843)
Balances at March 31, 2019	99,176	$ 10	$1,214,076	$ 255	$(788,669)	(229)	$(3,114)	$ 422,558

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

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

1. Nature of Business and Basis of Presentation

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 novel therapeutics for rare immune-mediated diseases and other legacy products, including complex generics and biosimilars. The Company presently derives all of its revenue from its collaborations.

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, 2018 filed with the Securities and Exchange Commission, or the SEC, on February 22, 2019. 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, 2019 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.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," to the consolidated financial statements its Annual Report on Form 10-K for the year ended December 31, 2018, except as described below.

Leases

The Company determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, the Company does not recognize a right-of-use asset or lease liability. The Company's operating leases are recognized on its consolidated balance sheet as other long-term assets, other current liabilities, and other long-term liabilities. The Company does not have any finance leases.

Right-of-use assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company’s leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

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Operating lease right-of-use assets also include the effect of any lease payments made and excludes lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

The Company has lease agreements with lease and non-lease components, which are generally accounted for separately. Non-lease components as it pertains to the Company's leased premises generally refer to common area maintenance charges related to the premises.

Newly Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or 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 their leasing arrangements. In July 2018, the FASB issued ASU No. 2018-11, which provides entities with an additional transition method to adopt Topic 842. Under the new transition method, an entity initially applies the new lease requirements at the adoption date, not the earliest period presented, and recognizes a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. The Company elected to apply this transition method at the adoption date of January 1, 2019. The Company also elected to apply the package of practical expedients, under which an entity need not reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, or initial direct costs for any existing leases. The standard had a material impact on the Company's consolidated balance sheet, but did not have an impact on the Company's consolidated statement of operations and comprehensive loss in the period of adoption. The most significant impact was the recognition of right-of-use assets of $76.7 million and lease liabilities of $93.6 million for operating leases on January 1, 2019. Refer to Note 8, "Leases," for additional disclosures.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The new standard largely aligns the accounting for share-based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share-based transactions, as long as the transaction is not effectively a form of financing. The new guidance was effective for the Company on January 1, 2019. The adoption of the standard had no material impact on the Company's consolidated financial statements.

Newly Issued Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Requirements for Fair Value Measurement. The new standard added, modified or removed disclosure requirements under Topic 820 for clarity and consistency. ASU 2018-13 is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not expect the guidance will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendment updates the accounting for implementation, setup, and other upfront costs for a customer in a hosting arrangement that is a service contract. The amendment is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption of the amendment is permitted, including adoption in any interim period, for all entities. The amendment may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company expects to adopt this amendment prospectively when effective, and does not expect the amendment will have a material impact on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendment clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The amendment also adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. Lastly, the amendment requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. For public business entities, the amendments are effective for fiscal years beginning after December 15, 2019, and inte

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rim periods within those fiscal years. The Company is currently evaluating these clarifications in the accounting and presentation for its collaborative arrangements within the scope of Topic 808.

2. Supplemental Cash Flow Statement Information

The following table summarizes the Company's cash, cash equivalents and restricted cash as of March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$131,228	$ 248,334
Restricted cash, long-term	37,898	37,898
Total	$169,126	$ 286,232

3. 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, 2019	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	$63,157	$63,157	$—	$ —
Overnight repurchase agreements	7,999	—	7,999	—
Marketable securities:				
U.S. government-sponsored enterprise securities	40,972	—	40,972	—
Corporate debt securities	135,671	—	135,671	—
Certificates of deposit	3,061	—	3,061	—
Commercial paper obligations	77,494	—	77,494	—
Asset-backed securities	28,027	—	28,027	—
Total	$356,381	$63,157	$ 293,224	$ —

Description	Balance as of December 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	$ 119,955	$119,955	$—	$ —
Marketable securities:				
U.S. government-sponsored enterprise securities	12,424	—	12,424	—
Corporate debt securities	129,308	—	129,308	—
Certificates of deposit	3,003	—	3,003	—
Commercial paper obligations	30,935	—	30,935	—

Asset-backed securities	25,407	—	25,407	—
Total	$ 321,032	$ 119,955	$ 201,077	$ —

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Overnight repurchase agreements 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, 2019 and 2018. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three months ended March 31, 2019. 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," to the Company's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2018. The carrying amounts reflected in the Company's consolidated balance sheets for cash, collaboration receivable, other current assets, accounts payable, accrued restructuring, and accrued expenses approximate fair value due to their short-term maturities.

4. 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, 2019 and December 31, 2018. 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 U.S. government-sponsored enterprise securities, corporate debt securities, certificates of deposit, 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," to the Company's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2018 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, 2019 and December 31, 2018 (in thousands):

As of March 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$131,228	$ —	$ —	$131,228
U.S. government-sponsored enterprise securities due in one year or less	35,160	31	(1)	35,190
U.S. government-sponsored enterprise securities due in more than one year	5,768	14	—	5,782
Corporate debt securities due in one year or less	100,570	83	(21)	100,632
Corporate debt securities due in more than one year	34,959	82	(2)	35,039
Certificates of deposit due in one year or less	3,056	5	—	3,061
Certificates of deposit due in more than one year	—	—	—	$—
Commercial paper obligations due in one year or less	77,467	27	—	77,494
Asset-backed securities due in one year or less	—	—	—	—
Asset-backed securities due in more than one year	27,990	39	(2)	28,027
Total	$416,198	$ 281	$ (26)	$416,453
Reported as:				
Cash and cash equivalents	$131,228	$ —	$ —	$131,228
Marketable securities	284,970	281	(26)	285,225
Total	$416,198	$ 281	$ (26)	$416,453

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As of December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$248,334	$ —	$ —	$248,334
U.S. government-sponsored enterprise securities due in one year or less	12,428	—	(4)	12,424
Corporate debt securities due in one year or less	128,107	16	(110)	128,013
Corporate debt securities due in more than one year	1,300	—	(5)	1,295
Certificates of deposit due in one year or less	2,702	1	—	2,703
Certificates of deposit due in more than one year	300	—	—	300
Commercial paper obligations due in one year or less	30,911	25	(1)	30,935
Asset-backed securities due in one year or less	25,416	2	(11)	25,407
Total	$449,498	$ 44	$ (131)	$449,411
Reported as:				
Cash and cash equivalents	$248,334	$ —	$ —	$248,334
Marketable securities	201,164	45	(132)	201,077
Total	$449,498	$ 45	$ (132)	$449,411

5. Restricted Cash

The Company designated $36.1 million as collateral for a letter of credit that is security for a 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 13, "Commitments and Contingencies" herein. The $36.1 million is held on deposit with a bank. 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
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
Total			$ 1,849	

6. Other Assets

As of March 31, 2019 and December 31, 2018, other long-term assets consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Right-of-use operating lease asset	$74,759	$ —
Other	603	1,414
Total other long-term assets	$75,362	$ 1,414

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7. Other Liabilities

As of March 31, 2019 and December 31, 2018, other current and long-term liabilities consisted of the following (in thousands):

Other Current Liabilities

	March 31, 2019	December 31, 2018
Contract liability	$ 15,000	$ 15,000
Lease liability	8,812	—
Lease incentive	—	1,052
Deferred rent	—	47
Other	141	128
Total other current liabilities	$ 23,953	$ 16,227

Other Long-Term Liabilities

	March 31, 2019	December 31, 2018
Lease liability	$ 82,685	$ —
Lease incentive	—	7,877
Deferred rent	—	8,477
Other	884	916
Total other long-term liabilities	$ 83,569	$ 17,270

As of March 31, 2019, the Company included $15.0 million in other current liabilities in connection with the renegotiation with Human Genome Sciences, Inc., or GSK, of certain remaining contractual obligations under a manufacturing services agreement.

8. Leases

The Company's operating leases primarily relate to its two leased premises and are described in the “Notes to Consolidated Financial Statements” in its Annual Report on Form 10-K for the year ended December 31, 2018.

On January 1, 2019, the Company adopted ASU 2016-02, Leases. Refer to Note 1, "Nature of Business and Basis of Presentation" herein for additional disclosures. Lease cost and other information related to the Company's operating leases were as follows:

	Three Months Ended March 31, 2019	
Lease cost (in thousands)	$3,659	
Cash paid for amounts included in the measurement of lease liabilities included in operating cash flows (in thousands)	$3,801	
Weighted-average remaining lease term (years)	7.3	
Weighted-average discount rate	7.5	%

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Future minimum lease payments and lease liabilities as of March 31, 2019 were as follows (in thousands):

	Operating leases
April 1 to December 31, 2019	$11,490
2020	15,744
2021	16,138
2022	16,516
2023	16,655
2024 and beyond	43,709
Total future minimum lease payments	$120,252
Less: imputed interest	(28,755)
Total lease liability	$91,497
Reported as:	
Other current liabilities	$8,812
Other long-term liabilities	82,685
Total lease liabilities	$91,497

9. 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 Enoxaparin Sodium Injection 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 for the three months ended March 31, 2019 and 2018, 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 had 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.

In July 2018, Sandoz notified its customers and the FDA that it would discontinue supplying the licensed product. The Company expects any future revenues from Sandoz' sales of the licensed product, if any, to be minimal.

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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, 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. 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 $80.0 million in future post-launch commercial milestones payments. The Company is still eligible to receive up to $30.0 million in performance-based milestone payments for GLATOPA in the United States, although the Company believes it is not likely that the performance-based milestones will be achieved. 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 three months ended March 31, 2018, representing 50% of potential GLATOPA 40 mg/mL pre-launch inventory costs. In the three months ended March 31, 2018, the Company's product revenue was reduced by $9.8 million for the Company's 50% share of GLATOPA 40 mg/mL written off by Sandoz.

On March 28, 2019, the Company and Sandoz entered into a settlement agreement with Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, with respect to the suit against the Company in the United States District Court for the District of Delaware alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, with the Company's portion of the settlement payment offset against the Company's profit sharing interest from Sandoz on sales of GLATOPA. In the three months ended March 31, 2019, the Company's product revenue was reduced by $1.5 million for the Company's 50% share of the settlement payments.

The Company concluded that the license agreement is within the scope of Topic 606. As of January 1, 2018, the Company had 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.

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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, including M710.

In November 2018, the Company delivered formal notice of the partial termination of the Mylan Collaboration Agreement with respect to five of the collaboration programs. In January 2019, Mylan and the Company agreed that such partial termination would be effective as of January 31, 2019. As a result, the Company will only continue to advance its late-stage biosimilar candidate M710, its proposed biosimilar to EYLEA under the Mylan Collaboration Agreement.

Under the terms of the Mylan Collaboration Agreement, Mylan paid the Company a non-refundable upfront payment of $45.0 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. Mylan funded its share of collaboration expenses incurred by the Company, in part, through milestone payments totaling $60.0 million, which the Company received in 2016.

For the Company's remaining product candidate, M710, the Company and Mylan both have the right to terminate the program at each party's convenience. If one party decides not to continue development, manufacture and commercialization of this product candidate under the Mylan Collaboration Agreement, the other party will have the right to continue the development, manufacture and commercialization of such product candidate, and the terminating party will need to continue to fund its share of expenses for a pre-specified period, depending on the stage of the product candidate at the time of termination.

Under the Mylan Collaboration Agreement, the Company granted Mylan an exclusive license under the Company's intellectual property rights to develop, manufacture and commercialize the product candidates for all therapeutic indications, and Mylan granted the Company a co-exclusive license under Mylan's intellectual property rights for the Company to perform its development and manufacturing activities under the product work plans agreed by the parties, and to perform certain commercialization activities to be agreed by the joint steering committee for such product candidates if the Company exercises its co-commercialization option described below.

The Company and Mylan established a joint steering committee, or JSC, 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 JSC, 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; 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; 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 JSC is responsible for allocating responsibilities for other activities under the collaboration.

The term of the collaboration will continue throughout the development and commercialization of M710 on a country-by-country basis until development and commercialization by or on behalf of the Company and Mylan pursuant to the Mylan Collaboration Agreement has ceased for a continuous period of two years in a given country, unless earlier terminated by either party pursuant to the terms of the Mylan Collaboration Agreement.

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party will have the right to continue the development, manufacture and commercialization of the terminated product candidates in the terminated countries.

The Mylan Collaboration 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.

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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 $45.0 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 to date, as a proportion of the total estimated costs to bring each product candidate through FDA approval, depict the performance of the research and development services.

As a result of providing a notice of partial termination of the Mylan Collaboration Agreement in November 2018, specifically with respect to the five biosimilar programs other than M710, the Company concluded that it had changed the enforceable rights and obligations under the agreement, and therefore had modified the Mylan Collaboration Agreement. Because the remaining services to be performed prior to the effective date of termination for the five biosimilar programs are not distinct, the Company concluded that each represented a performance obligation that is partially satisfied as of the date the Company provided the notice of partial termination.

As of March 31, 2019, $4.3 million of the transaction price remains allocated to unsatisfied performance obligations and is included in deferred revenue in the condensed consolidated balance sheet. The license and related research and development services performance obligations are expected to be delivered over a period through estimated FDA approval for M710 and through the termination date of the remaining product candidates.

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, 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.

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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 CSL License Agreement, CSL paid the Company a non-refundable upfront payment of $50.0 million. On August 28, 2017, the Company exercised a 50% co-funding option. This exercise allows the Company to participate in a cost-and-profit sharing arrangement, under which the Company funds 50% of global research and development costs and 50% of U.S. commercialization costs for all products developed, in exchange for a 50% share of U.S. profits. Under this option, sales-based royalty payments in percentages ranging from a mid-single digit to low-double digits are payable for territories outside of the United States. The Company is also entitled to up to $297.5 million in contingent clinical, regulatory and sales milestone payments, and additional negotiated milestone payments for a named research stage product should that enter development. The contract allows the Company to opt-out of the program in the future at the Company's discretion. If the Company were to do so, the Company's U.S. profit share would be reduced to sales-based royalties ranging from mid-single to low double digits and the milestone payments for which the Company is eligible would be increased by up to $252.5 million, depending on the timing of the opt-out decision.

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.

The term of the agreement commenced on February 17, 2017 and, unless earlier terminated, 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 $50.0 million upfront payment reflected the transaction price at contract inception, all revenue related to the single performance obligation was recognized in prior periods. Development milestones, sales-based

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

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 balance - January 1, 2019	$ —	$ 11,281	$ 90	$ —	$ 11,371
Revenue / cost recovery	—	2,772	214	—	2,986
Cash receipts	—	(11,281)	(90)	—	(11,371)
Ending balance - March 31, 2019	$ —	$ 2,772	$ 214	$ —	$ 2,986
Contract liabilities					
Deferred revenue:					
Opening balance - January 1, 2019	$ —	$ —	$ 5,690	$ —	$ 5,690
Revenue recognition	—	—	(1,341)	—	(1,341)
Ending balance - March 31, 2019	—	—	4,349	—	4,349
Less: current portion	—	—	(3,606)	—	(3,606)
Deferred revenue, net of current portion - March 31, 2019	$ —	$ —	$ 743	$ —	$ 743
Collaboration liabilities:					
Opening balance - January 1, 2019	$ —	$ —	$ 1,412	$ 3,309	$ 4,721
Payments	—	—	—	(3,308)	(3,308)
Net collaboration costs incurred in the period	—	—	75	1,282	1,357
Ending balance - March 31, 2019	$ —	$ —	$ 1,487	$ 1,283	$ 2,770

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	For the Three Months Ended March 31, 2019				
	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	CSL Collaboration Agreement	Total
Product revenue	$—	$ 2,352	$ —	$ —	$2,352
Research and development revenue	—	420	1,341	—	1,761
Total collaboration revenue	$—	$ 2,772	$ 1,341	$ —	$4,113
Operating expenses:					
Research and development expense	—	54	2,778	58	2,890
General and administrative expense	4,300	25	268	9	4,602
Net amount (recovered from) / payable to collaborators	—	—	(139)	1,282	1,143
Total operating expenses	$4,300	$ 79	$ 2,907	$ 1,349	$8,635

	For the Three Months Ended March 31, 2018				
	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	CSL Collaboration Agreement	Total
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

10. Share-Based Payments

The table below presents share-based compensation expense for research and development, general and administrative , and restructuring expense, all of which are included in operating expenses, in the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Research and development	$ 1,087	$ 1,925
General and administrative	2,387	2,949
Total share-based compensation expense	$ 3,474	$ 4,874

The following table summarizes share-based compensation expense recorded in each of the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018

Stock options	$ 1,381	$ 2,076
Restricted stock awards and restricted stock units	2,014	2,700
Employee stock purchase plan	79	98
Total share-based compensation expense	$ 3,474	$ 4,874

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During the three months ended March 31, 2019, the Company granted 1,569,567 options to its employees and board members. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions are noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended March 31, 2019 and 2018 was $6.47 and $8.05, respectively.

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

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Expected volatility	51 %	48 %	49 %	49 %
Expected dividends	—	—	—	—
Expected life (years)	5.9	6.1	0.5	0.5
Risk-free interest rate	2.5 %	2.7 %	2.3 %	1.4 %

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 was subject to the Company achieving up to two of three possible performance milestones on or before April 13, 2019, subject to a requirement that recipients remain employees through each applicable vesting date. Upon achieving each of the first and second milestones, 25% of the shares would vest on the later of the milestone achievement date and the first anniversary of the grant date, and an additional 25% of the shares would vest on the one year anniversary of such achievement date. During the three months ended March 31, 2018, one of the performance milestones was met. As a result, approximately 25% of the awards vested in the first quarter of each of 2018 and 2019. The remaining performance milestones were not achieved. For the three months ended March 31, 2019, the Company recognized an immaterial amount of stock-based compensation costs related to these awards. The performance period ended April 13, 2019 and no additional stock-based compensation costs will be recognized.

Since October 2018, the Company has awarded 1,873,283 performance-based restricted stock units, or PSUs, to its employees. The vesting of these PSUs is subject to the Company achieving up to three possible performance milestones related to the Company's active novel programs. One sixth of the units will vest upon the achievement of each milestone and one sixth shall vest on the one-year anniversary of that date, with the first possible vesting date on October 17, 2019 and subject to acceleration upon certain events. At March 31, 2019, the Company concluded that it was not probable that any of the performance milestones would be achieved. For the three months ended March 31, 2019, the Company recognized no stock compensation costs related to these awards.

11. 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 restricted stock units determined by applying the treasury stock method.

The following table presents anti-dilutive shares for the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Outstanding stock options	4,683	3,635
Restricted stock awards and units	696	701

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12. Restructuring

On September 26, 2018, following the completion of a strategic review of its business, the Company's Board of Directors approved a plan, or the Workforce Reduction, to reduce its workforce headcount by approximately 50%. The Company evaluated the related employee severance and other benefits to employees in connection with the Workforce Reduction to determine whether the benefits were within the scope ASC 712, Compensation - Non-retirement Post-employment Benefits, or within the scope of ASC 420, Exit or Disposal Cost Obligations, depending on the nature of the benefit and whether it is part of an on-going benefit arrangement under ASC 712 or a one-time termination benefit unique to the Workforce Reduction. The Company does not expect to record significant restructuring charges associated with the Workforce Reduction in future periods.

The following table outlines the components of the restructuring charges during the three months ended March 31, 2019 included in the condensed consolidated statement of operations and comprehensive loss, and ending liability recorded in the condensed balance sheet as at March 31, 2019 (in thousands):

	Remaining liability at December 31, 2018	Adjustments during the period ended March 31, 2019	Amount paid during the period ended March 31, 2019	Remaining liability at March 31, 2019
Employee severance, bonus and other	$ 3,235	$ 26	$(1,705)	$ 1,556
Total restructuring charges	$ 3,235	$ 26	$(1,705)	$ 1,556

13. Commitments and Contingencies

Purchase Obligations

In June 2018, the Company amended a supply manufacturing agreement with GSK to provide for minimum purchase obligations of approximately $22.5 million during calendar years 2019 and 2020 and $28.3 million during calendar years 2021 and 2022.

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 and Yeda Research and Development Co., Ltd., or 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, 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 and November 2015, Teva and Yeda filed additional suits against us and Sandoz in the United States District Court for the District of Delaware alleging infringement related to additional Orange Book-listed patents for COPAXONE 40 mg/mL, which were consolidated with the initial suit. Teva and Yeda sought 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. On October 12, 2018, the CAFC affirmed the District Court's decision that the four patents were invalid. The time period for appeal by Teva and Yeda has expired so the CAFC decision is binding.

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. 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 Company's and Sandoz's motion to transfer the suit to the United States District Court for the

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District of Delaware. Pursuant to the Court's amended schedule a trial was scheduled to commence before the United States District Court for the District of Delaware on May 6, 2019. On March 28, 2019, the Company and Sandoz entered into a settlement agreement with Teva dismissing the suit and a stipulation of dismissal was filed with and entered by the Court the following day. Under the terms of the settlement agreement, the Company and Sandoz will provide certain payments to Teva, with the Company's portion of such payment being an offset to its profit share interest from Sandoz on sales of GLATOPA.

M834-Related Proceedings

On July 2, 2015, the Company 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. The Company filed a notice of appeal in the CAFC, on February 22, 2017. The parties have each briefed the CAFC on the question of whether a non-patent owner challenging a patented claim in IPR has constitutional standing to appeal by the PTAB that the challenged patented claim is valid. Oral argument before the Federal Circuit was held on December 5, 2017. On February 7, 2019 the CAFC dismissed the appeal of the IPR for lack of standing.

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 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 briefing was completed on November 19, 2018. On February 20, 2019, the Company and Sandoz filed with the District Court a motion for relief from judgment with respect to its final judgment.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 $36.1 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 July 16, 2018, the District Court denied Amphastar's motion to enforce liability on the security bond and allowed the Company's and Sandoz' motion to defer consideration. 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

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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. A trial is scheduled for September 2019. On February 19, 2019, Amphastar filed with the District Court a motion for partial summary judgment on issues previously litigated in the patent action.

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 District Court granted NGH's motion to amend. In January 2018, the Company and Sandoz filed three motions to dismiss the amended complaint. On December 6, 2018 the District Court granted one of the motions, granted one in part and denied one. As a result the suit will continue pursuant to the surviving portions of the amended complaint. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and intends to vigorously defend itself in this litigation.

M923-Related Proceedings

On March 19, 2019, UFCW Local 1500 Welfare Fund, or UFCW, filed a class action suit against AbbVie Inc., AbbVie Biotechnology Ltd., Amgen Inc., Samsung Bioepsis Co., Ltd., Mylan, Inc., Mylan Pharmaceuticals, Inc., Sandoz, Fresenius Kabi USA, LLC, Pfizer Pharmaceuticals, Inc. and the Company, in the United States District Court for the Northern District of Illinois on behalf of itself and all others similarly situated for alleged violations of state and federal antitrust and consumer protection laws. According to the complaint, UFCW is seeking injunctive and other equitable relief and damages. A second complaint mirroring that filed by UFCW, was filed on April 19, 2019 in United States District Court for the Northern District of Illinois by the Sheet Metal Workers' location Union No. 28 Welfare Fund on behalf of itself and all others similarly situated also names AbbVie Inc., AbbVie Biotechnology Ltd., Amgen Inc., Samsung Bioepsis Co., Ltd., Mylan, Inc., Mylan Pharmaceuticals, Inc., Sandoz, Fresenius Kabi USA, LLC, Pfizer Pharmaceuticals, Inc. and the Company as defendants. While the outcome of litigation is inherently uncertain, the Company believes both of these suits are without merit, and it intends to vigorously defend itself in these litigations.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2018.

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 primarily on discovering and developing novel drug candidates for rare immune-mediated diseases and developing two of our late stage biosimilar candidates.

Prior to 2018, Momenta had the dual focus of developing novel drug candidates and nurturing a portfolio of biosimilar and complex generic products and product candidates. In the beginning of 2018, we engaged in a strategic review of our business and made the decision that shareholder value could be enhanced by shifting our future investments to fully support our promising novel drug portfolio. Following this strategic review, we made the decision in September of 2018 to restructure the company.

We have terminated all future development of any new or early stage biosimilar and complex generic products. We retained our commercial partnership with Sandoz AG, or Sandoz, for our generic versions of COPAXONE and LOVENOX, which are approved products. We believe that Sandoz' sales of GLATOPA, our generic version of COPAXONE, can generate cash flow to help fund our novel pipeline. We have also retained our wholly owned HUMIRA biosimilar, which is fully developed and for which we are ready to submit an application for approval, subject to finalization of our commercialization strategy. In addition, we are developing our EYLEA biosimilar, in collaboration with Mylan Ireland Limited, or Mylan, a wholly-owned indirect subsidiary of Mylan N.V., which is currently in a pivotal clinical trial in patients. We believe both of these programs have the potential to generate revenue in the 2023 time frame to help fund our novel portfolio. Pursuant to our collaboration agreement with Mylan, we have delivered formal notice of our termination of participation in all other biosimilar programs, which became effective as of January 31, 2019. As a result of this restructuring, we announced in October 2018 that we would reduce our workforce by approximately 50%, which reduction was substantially completed as of the end of 2018.

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, 2019, we had an accumulated deficit of approximately $788.7 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 FDA approved the 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 collaboration agreement with Sandoz, 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. 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.

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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.

Since Sandoz' launch of GLATOPA 40mg/mL in February 2018, Sandoz has encountered aggressive pricing and contracting tactics from competitors, which has limited uptake of the product and, as a result, we expect modest revenues for the product in the future. As of March 31, 2019, 40 mg/mL glatiramer acetate injection accounted for approximately 84% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed.

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 collaboration agreement with Sandoz, Sandoz is obligated to pay us 50% of contractually defined profits on sales of Enoxaparin Sodium Injection. In July 2018, Sandoz notified its customers and the FDA that it will discontinue supplying Enoxaparin Sodium Injection. Sandoz continues to evaluate alternate acceptable contract manufacturers at a price point that will allow for profitable and competitive sales and may decide to relaunch Enoxaparin Sodium Injection at a later date following regulatory approval. We expect any future revenues from Sandoz' sales of Enoxaparin Sodium Injection, if any, to be minimal.

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

Biosimilars

M923—Biosimilar HUMIRA® (adalimumab) Candidate

In November 2016, following an interim analysis, we announced that the confirmatory, randomized, double-blind, multi-center, global study evaluating the efficacy, safety and immunogenicity of M923 in adult patients with moderate-to-severe chronic plaque psoriasis met its primary endpoint. Patients received up to 48 weeks treatment with M923, HUMIRA, or HUMIRA alternating with M923. The proportion of subjects who achieved the primary endpoint, at least 75% reduction in the Psoriasis Area and Severity Index, or PASI-75, following 16 weeks of treatment, was equivalent between M923 and HUMIRA.

On November 6, 2018, we executed global licensing agreements with AbbVie Inc, or AbbVie, with respect to M923, pursuant to which, subject to approval by health regulatory authorities, we may launch M923 in the United States as early as November 20, 2023 and in Europe upon approval by the European Medicines Agency. We are working on our commercialization strategy, including identifying a commercialization partner for this product candidate. We plan to submit a BLA for M923 with the FDA and a MAA in the European Union, subject to finalization of our commercialization strategy. Based on the settlement agreements entered into by AbbVie with respect to biosimilar candidates, we expect that U.S. market formation for biosimilar versions of HUMIRA will likely be in the 2023 time frame, subject to marketing approval, patent considerations and litigation timelines.

Legal proceedings related to M923 are described under "Part II. Item 1. Legal Proceedings - M923-Related Proceedings."

M710—Biosimilar EYLEA® (aflibercept) Candidate

M710 is being developed in collaboration with Mylan. In August 2018, Mylan initiated dosing of patients in the United States in our pivotal clinical trial. 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. Mylan has also received regulatory approval to dose patients in the European Union. 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.

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.

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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 IgG antibodies, 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. The full data from our Phase 1 study was published on November 7, 2018. A total of 50 patients were enrolled in both the single ascending dose, or SAD, and multiple ascending dose, or MAD portions of the study, both of which 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.

During the three months ended December 31, 2018, we commenced a Phase 2 proof-of-concept clinical trial for M281 in generalized myasthenia gravis, or gMG, and in hemolytic disease of the fetus and newborn, or HDFN.

M230 (CSL730) - Recombinant Fc Multimer Candidate

M230 is a novel recombinant trivalent human IgG1 Fc multimer containing three IgG Fc regions joined to maximize activity. Nonclinical data have shown that M230 enhances the molecules' avidity and affinity for the Fc receptors matching the potency and efficacy of IVIg at significantly lower doses.

Pursuant to the License and Option Agreement with CSL Behring Recombinant Facility AG (CSL), or the CSL License 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 9 "License Agreements and Collaboration Agreements" to our consolidated financial statements. CSL's Phase I study in healthy volunteers to evaluate safety and tolerability of M230 is ongoing and is targeted for completion in 2019.

M254 - hsIVIg Candidate

M254 is a hypersialylated immunoglobulin designed as a high potency alternative to IVIg, a therapeutic drug product that contains pooled, human immunoglobulin G, or IgG, antibodies purified from blood plasma. IVIg is used to treat several inflammatory diseases, including immune thrombocytopenic purpura (ITP) and chronic inflammatory demyelinating polyneuropathy (CIDP). In nonclinical studies, M254 has been shown to have up to ten times more enhanced anti-inflammatory activity than IVIg in a variety of animal models of autoimmune disease.

We have completed our IND-enabling toxicology study and initiated a Phase 1/2 proof of concept clinical study in healthy volunteers and patients with ITP in early 2019.

Results of Operations

Comparison of Three Months Ended March 31, 2019 and 2018

Product revenue includes our contractually defined profits earned on Sandoz’ sales of GLATOPA and Enoxaparin Sodium Injection.

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

	Three Months Ended March 31,				Change period over period
	2019	% of Total Collaboration Revenue	2018	% of Total Collaboration Revenue	2019 compared to 2018
Collaboration revenue:	(in thousands)		(in thousands)		(in thousands) %

Product revenue	$2,352	57	%	$ 3,521	73	%	$(1,169)	(33.2)%
Research and development revenue	1,761	43	%	1,331	27	%	430	32.3 %
Total collaboration revenue	$4,113	100	%	$ 4,852	100	%	$(739)	(15.2)%

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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 three months ended March 31, 2018 by up to an aggregate of approximately $9.8 million, representing 50% of potential GLATOPA 40 mg/mL pre-launch inventory costs.

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

Since Sandoz' launch of Glatopa 40mg/mL in February 2018, Sandoz has encountered aggressive pricing and contracting tactics from competitors, which has limited uptake of the product, and, as a result, we expect modest sales for the product in the future. As of March 31, 2019, 40 mg/mL glatiramer acetate injection accounted for approximately 84% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed.

Q1 2019 vs Q1 2018

The decrease in product revenue of $1.2 million, or 33.2%, from the three months ended March 31, 2018 to the three months ended March 31, 2019 was primarily due to lower net sales of GLATOPA driven by competition and a $1.5 million legal settlement payment to Teva, representing our 50% share. For the three months ended March 31, 2018, product revenue decreased $9.8 million, reflecting our 50% share of GLATOPA 40 mg/mL inventory written off by Sandoz.

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, profit on sales of Enoxaparin Sodium Injection in the periods presented were immaterial. In July 2018, Sandoz notified its customers and the FDA that it would discontinue production of Enoxaparin Sodium Injection. Sandoz continues to evaluate alternate acceptable contract manufacturers at a price point that will allow for profitable and competitive sales and may decide to relaunch Enoxaparin Sodium Injection at a later date following regulatory approval. We expect any future revenues from Sandoz' sales of Enoxaparin Sodium Injection, if any, to be minimal.

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.

We expect to recognize revenue from the remaining balance of $4.3 million from Mylan's $45.0 million upfront payment on a quarterly basis in an amount commensurate with our progress towards meeting performance obligations with respect to M710 under the Mylan Collaboration Arrangement.

Q1 2019 vs Q1 2018

The increase in research and development revenue of $0.4 million, or 32.3%, from the three months ended March 31, 2018 to the three months ended March 31, 2019 was due to higher revenue recognized on the collaborative upfront payment from Mylan of $0.6 million, offset in part by a $0.2 million decrease in reimbursement revenue for Glatopa expenses.

Operating Expenses

The following table summarizes our operating expenses for the periods indicated, in thousands and as a percentage of total operating expenses, together with the changes, in thousands:

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	Three Months Ended March 31,				Change period over period	
	2019	% of Total Operating Expenses	2018	% of Total Operating Expenses	2019 compared to 2018	
	(in thousands)	(%)	(in thousands)	(%)	(in thousands)	(%)
Operating expenses:						
Research and development	$27,972	54 %	$ 33,242	62 %	$(5,270)	(16)%
General and administrative	24,206	46 %	20,612	38 %	3,594	17 %
Restructuring	26	— %	—	— %	26	100 %
Total operating expenses	$52,204	100 %	$ 53,854	100 %	$(1,650)	(3)%

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 manufacturing clinical trial material, acquiring reference comparator materials and manufacturing nonclinical study 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.

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

The following table sets forth the primary components of our research and development external expenditures, including the amortization of our intangible assets, for each of our principal development programs for the three months ended March 31, 2019 and 2018. The figures in the table include project expenditures incurred by us and reimbursed by our collaborators, but exclude project expenditures incurred by our collaborators. Although we track and accumulate personnel effort by percentage of time spent on our programs, a significant portion of our internal research and development costs, including salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies are not directly charged to programs. Therefore, our methods for accounting for internal research and development costs preclude us from reporting these costs on a project-by-project basis.

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	Phase of Development as of March 31, 2019	Three Months Ended March 31, 2019	2018
External Costs Incurred by Product Area:			
Novel Therapeutics	Various (1)	$12,762	$6,493
Biosimilars	Various (2)	2,879	3,919
Complex Generics	(3)	54	117
Internal Costs		12,277	22,713
Total Research and Development Expenses		$27,972	$33,242

(1) Our novel therapeutic programs include M281, for which we commenced two Phase 2 clinical trials during the three months ended December 31, 2018; M230, for which our licensee's, CSL's, Phase I study in healthy volunteers to evaluate safety and tolerability of M230 is ongoing and is targeted for completion in 2019; M254, for which we have completed our IND-enabling toxicology study and have initiated a Phase 1/2 clinical study in early 2019; as well as other discovery and nonclinical stage programs.

(2) Biosimilars are M923, a biosimilar candidate of HUMIRA® (adalimumab), and M710, a biosimilar candidate of EYLEA® (aflibercept). We intend to submit a biologics license application for M923 with the FDA, subject to finalization of our regulatory and commercialization strategy. For M710, Mylan initiated a pivotal clinical trial in patients in the United States in August 2018. In November 2018, we provided notice to Mylan terminating our participation in the development of our biosimilar programs other than M710.

(3) 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 (glatiramer acetate injection) 40 mg/mL, see "-Overview-Complex Generics-GLATOPA® 40 mg/mL-Generic Three-times-weekly COPAXONE® (glatiramer acetate injection) 40 mg/mL."

Q1 2019 vs Q1 2018

External costs of our novel therapeutic programs increased by $6.3 million, or 96.6%, from the three months ended March 31, 2018 to the three months ended March 31, 2019, and were primarily driven by clinical trial activity for M281 as described in Note 1 in the above table. External expenditures for our biosimilars programs decreased by $1.0 million, or 26.5%, from the three months ended March 31, 2018 to the three months ended March 31, 2019, primarily due to decreased spending on M740 as we provided notice in November 2018 to terminate this program, among other biosimilar programs, under our Mylan collaboration, effective January 2019. Internal costs decreased by $10.4 million, or 45.9% from the three months ended March 31, 2018 to the three months ended March 31, 2019 primarily due to decreased personnel costs, due in part to the workforce reduction announced in October 2018 and reductions in lease costs.

General and Administrative

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, and 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.

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, litigation and development activities.

Q1 2019 vs Q1 2018

The increase of $3.6 million, or 17.4%, from the three months ended March 31, 2018 to the three months ended March 31, 2019 was driven by the increased depreciation of $4.8 million as we evaluate estimates of the useful lives of depreciable

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assets, primarily the shortening of the useful lives of our leasehold improvements, and legal costs of $1.1 million relating to our ongoing litigation. These were partially offset by decreased personnel salaries and stock based compensation of $2.1 million due in part to the workforce reduction announced in October 2018.

Restructuring

Restructuring charges consist of severance, bonus, share-based compensation, and impairment of equipment associated with our workforce reduction. See Note 12 "Restructuring" to our condensed consolidated financial statements contained in Part I, Item I of this Quarterly Report on Form 10-Q for further discussion.

Other Income, Net

Other income, net includes other items of non-operating income and expense. Other income, net was $3.2 million and $1.4 million for the three months ended March 31, 2019 and 2018, respectively. The increase of $1.8 million, or 15.0%, from the three months ended March 31, 2018 to the three months ended March 31, 2019 was the result of higher interest income due to higher invested balances arising from recent financing activities and the benefit of higher market yields on our investments.

Equity Financings

In December 2018, we sold an aggregate of 20.0 million shares of common stock through an underwritten public offering at a price to the public of $11.50 per share. As a result of the offering, which includes the exercise in full of the underwriter’s option to purchase additional shares of common stock, we received aggregate net proceeds of approximately $217.8 million, after deducting underwriting discounts and commissions and other offering expenses.

Liquidity and Capital Resources

At March 31, 2019, we had $416.5 million in cash, cash equivalents and marketable securities. In addition, we also held $37.9 million in restricted cash, of which $36.1 million serves as collateral for a security bond posted in the litigation against Amphastar.

We have funded our operations primarily through the sale of equity securities and payments received under our collaboration and license agreements, including our share of profits from Sandoz’ sales of Enoxaparin Sodium Injection and GLATOPA. 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 product revenues under existing collaboration agreements. We may also seek funding from new collaborations and strategic alliances, debt financings and other financial arrangements. Future funding transactions may or may not be similar to our prior funding transactions. There can be no assurance that future funding transactions will be available on favorable terms, or at all. We currently believe that our current capital resources and projected milestone payments and product revenues will be sufficient to meet our operating requirements through at least the end of 2020.

Cash, Cash Equivalents and Marketable Securities

Our funds at March 31, 2019 were primarily invested in commercial paper, overnight repurchase agreements, asset-backed securities, U.S. government-sponsored enterprise 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, 2019.

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$(37,592)	$(38,153)
Net cash provided by (used in) investing activities	$(82,077)	$44,405
Net cash provided by financing activities	$2,563	$8,323
Net increase (decrease) in cash, cash equivalents, and restricted cash	$(117,106)	$14,575

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Cash used in operating activities

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

Cash used in operating activities was $37.6 million for the three months ended March 31, 2019 reflecting a net loss of $44.8 million, which was partially offset by non-cash charges of $6.1 million for depreciation and amortization of property, equipment and intangible assets and $3.5 million in shared-based compensation. The net change in our operating assets and liabilities used cash of $1.3 million and resulted primarily from $1.7 million in payments of termination benefits from our Workforce Reduction, a decrease in collaboration liabilities of $2.0 million in connection with our collaboration agreements with CSL and Mylan, recognition of $1.3 million revenue recognized on the upfront payment from Mylan, and a $4.8 million change in other working capital, partially offset by a decrease of $8.4 million in receivables due from Sandoz for our profit share interest.

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 primarily resulted from the receipt of $13.4 million for Sandoz' sales of GLATOPA 20 mg/mL and Enoxaparin, partially offset by a 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 (used in) investing activities

Cash used in investing activities of $82.1 million for the three months ended March 31, 2019 includes cash outflows of $133.9 million for purchases of marketable securities and $0.1 million for purchases of property and equipment, partially offset by cash inflows of $50.7 million from maturities of marketable securities and $1.3 million in proceeds from the disposal of equipment.

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

Cash provided by financing activities

Cash provided by financing activities of $2.6 million for the three months ended March 31, 2019 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 $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.

Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations, including royalties payable to third parties, and operating lease obligations. Our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 22, 2019, have not

materially changed since we filed that report.

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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. 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 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, 2018 are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. There have been no material changes to our critical accounting policies since the filing of such Form 10-K.

New Accounting Standards

Please refer to Note 1 "Nature of Business and Basis of Presentation" 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, 2019, 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. In addition, we are not materially exposed to foreign currency risks. 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, 2019. 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, 2019, 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 three months ended March 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

GLATOPA 40 mg/mL-Related Proceedings

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz 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, and sought declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015 and November 2015, Teva and Yeda filed additional suits against us and Sandoz in the United States District Court for the District of Delaware alleging infringement related to additional Orange Book-listed patents for COPAXONE 40 mg/mL, which were consolidated with the initial suit. Teva and Yeda sought 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. On October 12, 2018, the CAFC affirmed the District Court's decision that the four patents were invalid. The time period for appeal by Teva and Yeda has expired so the CAFC decision is binding.

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. 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 our and Sandoz's motion to transfer the suit to the United States District Court for the District of Delaware. Pursuant to the Court's amended schedule a trial was scheduled to commence before the United States District Court for the District of Delaware on May 6, 2019. On March 28, 2019, we and Sandoz entered into a settlement agreement with Teva dismissing the suit and a stipulation of dismissal was filed with and entered by the Court the following day. Under the terms of the settlement agreement, we and Sandoz will provide certain payments to Teva, with our portion of such payment being an offset to our profit share interest from Sandoz on sales of GLATOPA.

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. The parties have each briefed the CAFC on the question of whether a non-patent owner challenging a patented claim in IPR has constitutional standing to appeal a decision by the PTAB that the challenged patented claim is valid. Oral argument before the CAFC was held on December 5, 2017. On February 7, 2019 the CAFC dismissed our appeal of our IPR for lack of standing.

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 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 briefing was completed on November 19, 2018. On

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February 20, 2019, we and Sandoz filed with the District Court a motion for relief from judgment with respect to its final judgment. 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 $35.0 million of the security bond. We posted $36.1 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 July 16, 2018, the District Court denied Amphastar's motion to enforce liability on the security bond and allowed our and Sandoz' motion to defer consideration. 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. A trial is scheduled for September 2019. On February 19, 2019, Amphastar filed with the District Court a motion for partial summary judgment on issues previously litigated in the patent action.

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 District Court granted NGH's motion to amend. In January 2018, we and Sandoz filed three motions to dismiss the amended complaint. On December 6, 2018 the District Court granted one of the motions, granted one in part and denied one. As a result the suit will continue pursuant to the surviving portions of 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.

M923-Related Proceedings

On March 19, 2019, UFCW Local 1500 Welfare Fund, or UFCW, filed a class action suit against AbbVie, Inc., AbbVie Biotechnology Ltd., Amgen Inc., Samsung Bioepsis Co.,Ltd, Mylan, Inc., Mylan Pharmaceuticals, Inc., Sandoz, Fresenius Kabi USA,LLC, Pfizer Pharmaceuticals, Inc. and us, in the United States District Court for the Northern District of Illinois on behalf of itself and all others similarly situated for alleged violations of state and federal antitrust and consumer protection laws. According to the complaint, UFCW is seeking injunctive and other equitable relief and damages. A second complaint mirroring that filed by UFCW, was filed on April 19, 2019 in United States District Court for the Northern District of Illinois by the Sheet Metal Workers' location Union No. 28 Welfare Fund on behalf of itself and all others similarly situated also names AbbVie Inc., AbbVie Biotechnology Ltd., Amgen Inc., Samsung Bioepsis Co.,Ltd, Mylan, Inc., Mylan Pharmaceuticals, Inc., Sandoz,

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Fresenius Kabi USA,LLC, Pfizer Pharmaceuticals, Inc. and us as defendants. While the outcome of litigation is inherently uncertain, we believe both of these suits are without merit, and we intend to vigorously defend ourselves in these litigations.

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 Annual Report on Form 10-K 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

Our new corporate strategy and restructuring may not be successful.

On October 1, 2018, as a result of the previously disclosed strategic business review, we announced our intention to focus our resources on the discovery and development of our pipeline of novel drug candidates for immune-mediated diseases and the advancement of two of our late stage biosimilar assets, M923, our proposed biosimilar to HUMIRA, and M710, our proposed biosimilar to EYLEA. The success of this strategic shift will depend on our ability to successfully develop our novel and biosimilar candidates, hire and retain senior management or other highly qualified personnel, prioritize competing projects and efforts and obtain sufficient resources, including additional capital. The early stage development of novel drug candidates is highly unpredictable due to the lengthy and expensive process of clinical drug development, potential for safety, efficacy or tolerability problems with such product candidates, unexpected expenses or inaccurate financial assumptions or forecasts, potential delays or unfavorable decisions of regulatory agencies and competition for targeted indications or within targeted markets. Our ability to develop our biosimilar candidates depends on our ability to identify a commercialization partner, litigation efforts by our competitors, potential disputes with collaboration partners and their ability to supply and commercialize our products. Accordingly, there are no assurances our change in strategic focus will be successful, which may have an adverse effect on our results of operations or financial condition.

Also on October 1, 2018, as a result of our strategic business review, we restructured our executive team and commenced a reduction of our workforce by 50%. Our executive team and workforce after these actions may not be sufficient to fully execute our shift to a novel drug biotechnology company, and we may not be able to effectively retain or attract qualified executive management or employees needed to implement this strategy.

We incurred $17.8 million in restructuring charges in connection with the reduction in workforce in 2018. We do not expect any material additional expenses. However, our restructuring activities may also result in unexpected risks or costs, such as termination or other costs relating to restructuring our real property leases, employee claims and contractual disputes and the risk that the actual financial and other impacts of the reductions could vary materially from the outcomes anticipated, which may have a material adverse effect on our results of operations or financial condition.

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 of proposed products or the delay or cessation of commercial sales of our approved products . 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

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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. Any additional interruption or delay in Pfizer Inc.'s manufacturing of GLATOPA 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 commercialization of the affected products could be delayed, which could have a material adverse effect on our business.

We rely upon third parties, including sole source suppliers, to produce material for nonclinical and clinical studies. 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. In addition, some of our third-party manufacturers are located in countries where the supply of materials to us may pose geopolitical risks, including import trade restrictions or significant tariffs or other economic sanctions. 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.

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 Incorporated, Baxalta US Inc. and Baxalta GmbH (collectively, 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 patient populations of the target indications for our novel therapeutic candidates are small and have not been established with precision. If the actual number of patients are smaller than we estimate, our revenue and ability to achieve profitability with respect to such candidates may be adversely affected.

We estimate that there are approximately 55,000 patients in the United States with generalized myasthenia gravis, or gMG, and approximately 4,000 to 8,000 patients in the United States with hemolytic disease of the fetus and newborn, or HDFN, both potential indications for our product candidate M281. We estimate that chronic idiopathic thrombocytopenic purpura, or ITP, a potential indication for our product candidate M230, affects approximately 30,000 to 40,000 patients in the United States. Our estimates of the size of these patient populations are based on published studies as well as internal analyses. If these studies or our analyses of them do not accurately reflect the number of patients with gMG, HDFN or ITP our assessment of the market may be inaccurate, making it difficult or impossible for us to meet our revenue goals if and when any of our product candidates receive regulatory approval, or to obtain or maintain profitability. The small population of gMG, HDFN or ITP patients may also delay the

enrollment of patients in our clinical trials, especially in light of competing clinical trials.

Since these candidates target small patient populations, the per-patient drug pricing must be higher in order to recover our development and manufacturing costs, fund adequate patient support programs, fund additional research and achieve profitability. Many of the other novel therapeutic product candidates will have indications in rare immune-mediated diseases and face similar risks. We may be unable to maintain or obtain sufficient sales volume at a price high enough to justify our product development efforts and our sales, marketing and manufacturing expenses.

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We rely on third parties to conduct our clinical trials, and if they fail to fulfill their obligations, our development plans may be adversely affected.

We rely on independent clinical investigators, contract research organizations, or CROs, and other third-party services providers to assist us in managing, monitoring and otherwise carrying out our clinical trials. We have contracted, and we plan to continue to contract with, certain third-parties to provide certain services, including site selection, enrollment, monitoring, auditing and data management services. Although we depend heavily on these parties, we control only certain aspects of their activity and therefore, we cannot be assured that these third parties will adequately perform all of their contractual obligations to us in compliance with regulatory and other legal requirements and our internal policies and procedures. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities, We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations.

If our third-party service providers cannot adequately and timely fulfill their obligations to us, or if the quality and accuracy of our clinical trial data is compromised due the failure by such third-party to adhere to our protocols or regulatory requirements or if such third parties otherwise fail to meet deadlines, our development plans and/or regulatory reviews for marketing approvals may be delayed or terminated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our current and near term product revenue is dependent on the continued successful commercialization of GLATOPA.

Our near-term ability to generate GLATOPA product revenue depends, in large part, on Sandoz’ ability to continue to successfully manufacture and profitably commercialize GLATOPA.

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. Since Sandoz' launch of Glatopa 40mg in February, Sandoz has encountered aggressive pricing and contracting tactics from competitors and as a result we expect modest sales for the product in the future. 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 March 31, 2019, 40 mg/mL glatiramer acetate injection accounted for approximately 84% 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 future Enoxaparin Sodium Injection product revenue is dependent on Sandoz being able to identify an acceptable contract manufacturer for enoxaparin injection at a price point that will allow for the successful manufacture and competitive commercialization of Enoxaparin Sodium Injection.

In July 2018, Sandoz notified its customers and the FDA that it will discontinue production of Enoxaparin Sodium Injection. Sandoz continues to evaluate alternate acceptable contract manufacturers at a price point that will allow for profitable and competitive sales and may decide to relaunch Enoxaparin Sodium Injection at a later date following regulatory approval of any such contract manufacturer. Sandoz has faced 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 profit share and 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, 2019. We expect future revenues from Sandoz' sales of Enoxaparin Sodium Injection, if any, to be minimal.

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If our appeal in the patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful or Amphastar 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. 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 U.S. Court of Appeals for the Federal Circuit, or CAFC. The appeal has been docketed and our opening brief was filed July 30, 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 $35.0 million of the security bond for such damages. We posted $36.1 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 July 16, 2018, the District Court denied Amphastar's motion to enforce liability on the security bond and allowed our and Sandoz' motion to defer consideration. Moreover, if Amphastar or 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 UFCW is successful in antitrust litigation against us relating to M923, we may be liable for damages and our business may be materially harmed.

On March 19, 2019, UFCW Local 1500 Welfare Fund, or UFCW, filed a class action suit against AbbVie and multiple other defendants, including us, in the United States District Court for the Northern District of Illinois on behalf of itself and all others similarly situated for alleged violations of state and federal antitrust and consumer protection laws. According to the complaint, UFCW is seeking injunctive and other equitable relief and damages. A second complaint mirroring that filed by UFCW, was filed on April 19, 2019 in United States District Court for the Northern District of Illinois by the Sheet Metal Workers' location Union No. 28 Welfare Fund, or SMW, on behalf of itself and all others similarly situated also names us as a defendant. If either of UFCW or SMW is successful in antitrust litigation against us, they may be able to recover damages, thereby negatively affecting our financial condition and results of operations.

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.

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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 our products;
- 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 recently restructured our management team and are dependent on the current members of our team for our business to succeed. In the restructuring we terminated a number of senior executives and many of the new members of our current management team have not had previous experience in senior executive positions and have duties that are in addition to those of our prior senior executives, all of which may affect our ability to further 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 qualified executives and 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. In addition, our recent restructuring may negatively affect employee morale and our corporate culture, which may have a negative impact on retention and recruitment. 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

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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 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.

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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.

Failure to comply with evolving data privacy and data protection laws and regulations or to otherwise protect personal data, may adversely impact our business and financial results.

Because we have commenced and will continue to conduct clinical trials in the European Union, we are subject to many rapidly evolving privacy and data protection laws and regulations in Europe. This requires us to operate in a complex environment where there are significant constraints on how we can process personal data across our business. The European General Data Protection Regulation (the GDPR), which became effective in May 2018, has established stringent data protection requirements for companies doing business in or handling personal data of individuals in the European Union. The GDPR

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imposes obligations on data controllers and processors including the requirement to maintain a record of their data processing and to implement policies and procedures as part of their mandated privacy governance framework. Breaches of the GDPR could result in substantial fines, which in some cases could be up to four percent of our worldwide revenue. In addition, a breach of the GDPR or other data privacy or data protection laws or regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, as well potential civil claims including class action type litigation. There is a risk that we may be subject to fines and penalties, litigation and reputational harm if we fail to properly process or protect the data or privacy of third parties or comply with the GDPR or other applicable data privacy and data protection regimes.

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, 2019, our accumulated deficit was $788.7 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, 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, 2019, we had cash, cash equivalents and marketable securities totaling approximately $416.5 million. For the three months ended March 31, 2019, we had a net loss of $44.8 million and our operations used cash of $37.6 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, nonclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development and commercialization of our 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 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 level of sales of GLATOPA 20 mg/mL and of GLATOPA 40 mg/mL;
- the successful commercialization of our other product candidates;

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- 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 receipt of milestone payments under our CSL License Agreement;
- the ability to enter into a strategic alliance for commercialization of M923 and 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, 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 2020. 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

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

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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.

If nonclinical studies and clinical trials are required for regulatory approval of our product candidates or any study or trial is delayed or 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 in November 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 health risks 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.

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Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may delay or prevent their regulatory approval, limit the commercial profile of an approved label, or, result in significant negative consequences following marketing approval, if any.

Serious adverse events or undesirable side effects caused our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of health risks or unexpected characteristics. If unacceptable health risks arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the data safety monitoring board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related health risks could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these health risks may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects significantly.

If any of our product candidates receives marketing approval, and we or others later identify undesirable health risks caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- the product could become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the product in question and could significantly harm our business, results of operations and prospects.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top-line or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Even if we successfully 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

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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.

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 has issued a series of draft and final guidance documents on certain matters concerning approval of biosimilars, interchangeable biologics, non-proprietary naming and labeling, as well as quality and scientific considerations. Experience will develop as the number of products and applications increase. The pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing reference product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the reference product and (2) interchangeable biologic products, which in addition to being biosimilar can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the reference product. Only interchangeable biosimilar products would be considered substitutable at the retail pharmacy level without the intervention of a physician. The legislation authorizes but does not require the FDA to establish standards or criteria for determining biosimilarity and interchangeability, and also authorizes the FDA to use its discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis.

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that our analytics, biocharacterization and protein engineering platform technology provides a level of scientific assurance that facilitates determinations of biosimilarity and/or interchangeability, reduces the need for large scale clinical trials or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly

similar to a reference product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach within the context of the biosimilar meeting and application review process. In addition, the FDA will likely require significant new resources and expertise to review biosimilar applications, and the timeliness of the review and approval of our future applications could be adversely affected if there were a decline or even limited growth in FDA funding. Our strategy to reduce and target clinical requirements by relying on analytical and functional nonclinical data may not be successful or may take longer than strategies that rely more heavily on clinical trial data.

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The regulatory pathway also creates a number of additional obstacles to the approval and launch of biosimilar and interchangeable products, including:

- a requirement for the applicant, as a condition to using the pre-approval patent exchange and clearance process, to share, in confidence, the information in its abbreviated pathway application with the reference product company's and patent owner's counsel;
- the inclusion of multiple potential patent rights in the patent clearance process; and
- a grant to each reference product company of 12 years of marketing exclusivity following the reference product approval.

Furthermore, the regulatory pathway creates the risk that the reference product company, during its 12-year marketing exclusivity period, will develop and replace its product with a non-substitutable or modified product that may also qualify for an additional 12-year marketing exclusivity period, reducing the opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. Finally, the legislation also creates the risk that, as reference product and biosimilar companies gain experience with the regulatory pathway, subsequent FDA determinations or court rulings could create additional areas for potential disputes and resulting delays in biosimilars approval.

In addition, there is reconsideration and legislative debate that could lead to the repeal or amendment of the healthcare legislation. If the legislation is significantly amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected. 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.

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Even if we are able to obtain regulatory approval for biosimilar product candidates as 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. 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 or exclusion from participation in the Medicare, Medicaid, or other government reimbursement programs. Additionally, we may be subject to federal and state health information privacy, security and data breach notification laws, which govern the collection, use, disclosure and protection of health-related and other personal information. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than federal privacy laws, and state laws may differ from each other, which may complicate compliance efforts.

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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. 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact our business and industry. Namely, the current administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on 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

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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. In the 2018 Physician Fee Schedule Final Rule, CMS reversed course and instead of classifying biosimilars with the same reference product in the same Healthcare Common Procedural System ("HCPCS") code, CMS will establish a unique code for each biosimilar product; and instead of calculating a single blended payment rate, starting January 1, 2018, CMS calculates a payment rate specific to each biosimilar product. In addition, for qualifying biosimilars, instead of considering only the first biosimilar product for the reference product for OPPS pass-through payment status, each biosimilar is now eligible. It is unclear what effect, if any, CMS's changes 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.

Healthcare reform legislation known as the Affordable Care Act that was enacted in 2010 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.

In 2017, members of Congress and the President sought to repeal and replace the Affordable Care Act, and, while those efforts did not succeed, it is possible that similar efforts will be made in the future. Recently, the Tax Cuts and

Jobs Act (the "Tax Act") was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. It is 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. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual

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mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. In 2019 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.

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.

Lastly, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for medical products. Individual states in the United States have also become increasingly aggressive active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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Risks Relating to Competition

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 other generic versions of the brand name drugs, or other biosimilars of the reference products, for which we have products or product candidates, including GLATOPA 20 mg/mL, GLATOPA 40 mg/mL, M923 and M710, 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

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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. Since Sandoz' launch of Glatopa 40mg in February 2018, Sandoz has encountered aggressive pricing and contracting tactics from competitors and as a result we expect modest sales for the product in the future. 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 or EYLEA prior to approval of M923 or M710 may therefore delay any determination that our product is interchangeable with the reference product, which may materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

If an alternative version of a reference product, such as COPAXONE, HUMIRA or EYLEA , 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 March 31, 2019, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 84% 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 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 seeking to delay the 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;

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- 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.

If the market for a reference product, such as COPAXONE, HUMIRA or EYLEA, 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 efficacies. 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 o ur ability to fund future discovery and development programs, would suffer.

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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.

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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 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

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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 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 our biosimilar candidate, 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. In October 2018, we announced that we would notify Mylan of our intention to discontinue participation in five of our collaboration programs, including M834, a proposed biosimilar to ORENCIA, and will only continue to advance our late-stage biosimilar candidate M710, our proposed biosimilar to EYLEA. We delivered a formal notice of this partial termination to Mylan in November 2018, which became effective as of January 31, 2019.

If the Mylan Collaboration Agreement were terminated and we had the right to continue the development and commercialization of M710, 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 M710, or alternatively we may decide to discontinue M710, which could have a material adverse effect on our business. If the Mylan Collaboration Agreement were terminated with respect to M710 and Mylan had the right to continue the development and commercialization of such product, 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

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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

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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 have been 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

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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 M710;
- 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;

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- 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	Certificate of Amendment to Third Amended and Restated Certificate of Incorporation of Momenta Pharmaceuticals, Inc.	8-K	3.1	1/30/2019	000-50797
3.3	Fourth Amended and Restated By-Laws of the Registrant, adopted on March 14, 2017.	8-K	3.1	3/17/2017	000-50797
#10.1	Executive Employment Agreement, dated April 16, 2019, by and between Momenta Pharmaceuticals, Inc. and Michelle Robertson.	8-K	10.1	4/19/2019	000-50797
*#10.2	Executive Employment Agreement, dated May 15, 2017, by and between Momenta Pharmaceuticals, Inc. and Santiago Arroyo, as amended.				
*#10.3	Executive Employment Agreement, dated July 29, 2011, by and between Momenta Pharmaceuticals, Inc. and Young Kwon, as amended.				
*#10.4	Executive Employment Agreement, dated May 9, 2016, by and between Momenta Pharmaceuticals, Inc. and Anthony Manning, as amended.				
*31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
*31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
**32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
*101.INS	XBRL Instance Document.				
*101.SCH	XBRL Taxonomy Extension Schema Document.				
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
*101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
*101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

*Filed herewith.

**Furnished herewith.

#Management contract or compensatory plan or arrangement.

The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at March 31, 2019 and December 31, 2018, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2019 and 2018, (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018, (iv) the Condensed Consolidated

Statements of Stockholders' Equity for the three months ended March 31, 2019 and 2018, and (v) Notes to Unaudited, Condensed Consolidated Financial Statements.

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SIGNATURES

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

Momenta Pharmaceuticals, Inc.

Date: May 3, 2019 By: /s/ Craig A. Wheeler
Craig A. Wheeler, President and Chief Executive Officer
(Principal Executive Officer)

Date: May 3, 2019 By: /s/ Michelle Robertson
Michelle Robertson, Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)