

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

(MARK ONE)

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

For the quarterly period ended **June 30, 2019**

or

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

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number **000-50797**

**Momenta Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**04-3561634**

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

**301 Binney Street**

(Address of Principal Executive Offices)

**Cambridge MA**

**02142**

(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)

**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           |

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

Indicate by check mark whether the registrant has submitted electronically 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  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 | <input checked="" type="checkbox"/> | Accelerated filer         | <input type="checkbox"/> |
| Non-accelerated filer   | <input type="checkbox"/>            | Smaller reporting company | <input type="checkbox"/> |
|                         |                                     | Emerging growth company   | <input type="checkbox"/> |

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

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

As of July 31, 2019, there were 98,707,302 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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Our logo, trademarks and service marks are the property of Momenta Pharmaceuticals, Inc. Other trademarks or service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Quarterly Report on Form 10-Q that are about future events or future results, or are otherwise not statements of historical fact, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management. In some cases, these statements can be identified by words such as “anticipate,” “approach,” “believe,” “can,” “contemplate,” “continue,” “could,” “ensure,” “estimate,” “expect,” “goal,” “intend,” “likely,” “may,” “might,” “objective,” “opportunity,” “plan,” “potential,” “predict,” “project,” “pursue,” “seek,” “schedule,” “should,” “strategy,” “target,” “typically,” “will,” “would,” and other similar words or expressions, or the negative of these words or similar words or expressions. These statements include, but are not limited to, statements regarding our 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, the advancement of our late stage biosimilar candidate, M710, and our plans regarding our M923 program; 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; the settlement of, and release of collateral for, certain 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.

## PART I. FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS

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

|   | June 30, 2019 | December 31, 2018 |
|---|---------------|-------------------|
| <b>Assets</b>   |               |                   |
| Current assets:   |               |                   |
| Cash and cash equivalents   | \$ 123,508    | \$ 248,334        |
| Marketable securities   | 146,866       | 174,076           |
| Collaboration receivable  | 4,398         | 11,371            |
| Prepaid expenses and other current assets   | 42,143        | 6,318             |
| Assets held-for-sale  | 180           | 1,324             |
| Total current assets  | 317,095       | 441,423           |
| Marketable securities, long-term  | 73,700        | 27,001            |
| Property and equipment, net   | 11,837        | 20,944            |
| Restricted cash, long-term  | 1,849         | 37,898            |
| Intangible assets, net  | 2,306         | 2,883             |
| Other long-term assets  | 72,899        | 1,414             |
| Total assets  | \$ 479,686    | \$ 531,563        |
| <b>Liabilities and Stockholders' Equity</b>   |               |                   |
| Current liabilities:  |               |                   |
| Accounts payable  | \$ 10,399     | \$ 9,352          |
| Accrued expenses  | 15,019        | 14,060            |
| Accrued restructuring   | 1,111         | 3,235             |
| Collaboration liabilities   | 4,272         | 4,721             |
| Deferred revenue  | 1,731         | 3,916             |
| Other current liabilities   | 9,223         | 16,227            |
| Total current liabilities   | 41,755        | 51,511            |
| Deferred revenue, net of current portion  | 1,112         | 1,774             |
| Other long-term liabilities   | 124,100       | 17,270            |
| Total liabilities   | 166,967       | 70,555            |
| Commitments and contingencies (Notes 8 and 13)  |               |                   |
| <b>Stockholders' Equity:</b>  |               |                   |
| Common stock, \$0.0001 par value per share; 200,000 shares authorized, 99,251 shares issued and 98,683 shares outstanding at June 30, 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  | 1,217,942     | 1,208,025         |
| Accumulated other comprehensive income (loss)   | 519           | (87)              |
| Accumulated deficit   | (902,638)     | (743,826)         |
| Treasury stock, at cost, 568 shares at June 30, 2019 and 229 shares at December 31, 2018  | (3,114)       | (3,114)           |
| Total stockholders' equity  | 312,719       | 461,008           |
| Total liabilities and stockholders' equity  | \$ 479,686    | \$ 531,563        |

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

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

|  | Three Months Ended<br>June 30, |                    | Six Months Ended<br>June 30, |                     |
|--|--------------------------------|--------------------|------------------------------|---------------------|
|  | 2019                           | 2018               | 2019                         | 2018                |
| <b>Collaboration revenue:</b>  |                                |                    |                              |                     |
| Product revenue  | \$ 3,333                       | \$ 11,779          | \$ 5,685                     | \$ 15,300           |
| Research and development revenue   | 1,849                          | 1,252              | 3,610                        | 2,583               |
| Total collaboration revenue  | 5,182                          | 13,031             | 9,295                        | 17,883              |
| <b>Operating expenses:</b>   |                                |                    |                              |                     |
| Research and development   | 32,131                         | 31,340             | 60,103                       | 64,582              |
| General and administrative   | 46,609                         | 22,531             | 70,815                       | 43,143              |
| Restructuring  | 132                            | —                  | 158                          | —                   |
| Other operating expense  | 42,936                         | 30,000             | 42,936                       | 30,000              |
| Total operating expenses   | 121,808                        | 83,871             | 174,012                      | 137,725             |
| Operating loss   | (116,626)                      | (70,840)           | (164,717)                    | (119,842)           |
| Other income, net  | 2,657                          | 955                | 5,905                        | 2,326               |
| Net loss   | <u>\$ (113,969)</u>            | <u>\$ (69,885)</u> | <u>\$ (158,812)</u>          | <u>\$ (117,516)</u> |
| <br>   |                                |                    |                              |                     |
| Basic and diluted net loss per share   | \$ (1.16)                      | \$ (0.91)          | \$ (1.61)                    | \$ (1.55)           |
| Weighted average shares used in computing basic and diluted net loss per share | 98,595                         | 76,543             | 98,396                       | 76,002              |
| <br>   |                                |                    |                              |                     |
| <b>Comprehensive loss:</b>   |                                |                    |                              |                     |
| Net loss   | \$ (113,969)                   | \$ (69,885)        | \$ (158,812)                 | \$ (117,516)        |
| Net unrealized holding gain (loss) on available-for-sale marketable securities | 264                            | 274                | 606                          | (161)               |
| Comprehensive loss   | <u>\$ (113,705)</u>            | <u>\$ (69,611)</u> | <u>\$ (158,206)</u>          | <u>\$ (117,677)</u> |

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

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

|   | <b>Six Months Ended June 30,</b> |                   |
|---|----------------------------------|-------------------|
|   | <b>2019</b>                      | <b>2018</b>       |
| <b>Cash Flows from Operating Activities:</b>  |                                  |                   |
| Net loss  | \$ (158,812)                     | \$ (117,516)      |
| Adjustments to reconcile net loss to net cash used in operating activities:           |                                  |                   |
| Depreciation and amortization of property and equipment                               | 10,032                           | 3,689             |
| Share-based compensation expense  | 7,136                            | 10,046            |
| Amortization of premium on investments  | (1,146)                          | 78                |
| Amortization of intangibles   | 577                              | 577               |
| (Gain) loss on disposal of assets   | (415)                            | 636               |
| Changes in operating assets and liabilities:  |                                  |                   |
| Collaboration receivable  | 6,973                            | 1,819             |
| Prepaid expenses and other current assets   | (668)                            | 2,313             |
| Other long-term assets  | 5,185                            | 15                |
| Accounts payable  | 690                              | (2,817)           |
| Accrued expenses  | 830                              | (4,658)           |
| Accrued restructuring   | (2,124)                          | —                 |
| Collaboration liabilities   | (449)                            | (3,301)           |
| Deferred revenue  | (2,847)                          | (1,265)           |
| Other liabilities   | 23,776                           | 35,386            |
| Net cash used in operating activities   | <u>(111,262)</u>                 | <u>(74,998)</u>   |
| <b>Cash Flows from Investing Activities:</b>  |                                  |                   |
| Purchases of property and equipment   | (1,057)                          | (6,711)           |
| Proceeds from disposal of equipment   | 2,449                            | 71                |
| Purchases of marketable securities  | (194,527)                        | (69,782)          |
| Proceeds from maturities of marketable securities                                     | 176,790                          | 137,002           |
| Net cash provided by (used in) investing activities                                   | <u>(16,345)</u>                  | <u>60,580</u>     |
| <b>Cash Flows from Financing Activities:</b>  |                                  |                   |
| Proceeds from issuance of common stock under stock plans                              | 2,781                            | 20,772            |
| Net cash provided by financing activities   | <u>2,781</u>                     | <u>20,772</u>     |
| Net increase (decrease) in cash, cash equivalents and restricted cash                 | (124,826)                        | 6,354             |
| Cash, cash equivalents and restricted cash, beginning of period                       | 286,232                          | 96,683            |
| Cash, cash equivalents and restricted cash, end of period                             | <u>\$ 161,406</u>                | <u>\$ 103,037</u> |
| <b>Non-Cash Activities:</b>   |                                  |                   |
| Purchases of property and equipment included in accounts payable and accrued expenses | \$ 529                           | \$ 863            |
| Impact of adopting ASC 606  | \$ —                             | \$ 5,511          |

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

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

|   | Common Stock  |             |                                  | Accumulated<br>Other<br>Comprehensive<br>Income (Loss) | Accumulated<br>Deficit | Treasury Stock |                   | Total<br>Stockholders'<br>Equity |
|---|---------------|-------------|----------------------------------|--|------------------------|----------------|-------------------|----------------------------------|
|   | Shares        | Par Value   | Additional<br>Paid-In<br>Capital |  |                        | Shares         | Amount            |                                  |
| Balances at<br>December 31, 2017  | 76,584        | \$ 8        | \$ 939,654                       | \$ (140)   | \$ (562,254)           | (229)          | \$ (3,114)        | \$ 374,154                       |
| Impact of adopting<br>ASU 2016-09   | —             | —           | —                                | —  | (5,511)                | —              | —                 | (5,511)                          |
| Issuance of common<br>stock pursuant to the<br>exercise of stock<br>options and employee<br>stock purchase plan | 691           | —           | 8,966                            | —  | —                      | —              | —                 | 8,966                            |
| Issuance of restricted<br>stock   | 101           | —           | —                                | —  | —                      | —              | —                 | —                                |
| Cancellation/forfeiture<br>of restricted stock  | (47)          | —           | —                                | —  | —                      | —              | —                 | —                                |
| Share-based<br>compensation expense   | —             | —           | 4,874                            | —  | —                      | —              | —                 | 4,874                            |
| Unrealized loss on<br>marketable securities   | —             | —           | —                                | (435)  | —                      | —              | —                 | (435)                            |
| Net loss  | —             | —           | —                                | —  | (47,631)               | —              | —                 | (47,631)                         |
| Balances at March 31,<br>2018   | <u>77,329</u> | <u>\$ 8</u> | <u>\$ 953,494</u>                | <u>\$ (575)</u>  | <u>\$ (615,396)</u>    | <u>(229)</u>   | <u>\$ (3,114)</u> | <u>\$ 334,417</u>                |
| Issuance of common<br>stock pursuant to the<br>exercise of stock<br>options and employee<br>stock purchase plan | 808           | —           | 11,713                           | —  | —                      | —              | —                 | 11,713                           |
| Issuance of restricted<br>stock   | 70            | —           | —                                | —  | —                      | —              | —                 | —                                |
| Cancellation/forfeiture<br>of restricted stock  | (38)          | —           | —                                | —  | —                      | —              | —                 | —                                |
| Share-based<br>compensation expense   | —             | —           | 5,172                            | —  | —                      | —              | —                 | 5,172                            |
| Unrealized gain on<br>marketable securities   | —             | —           | —                                | 274  | —                      | —              | —                 | 274                              |
| Net loss  | —             | —           | —                                | —  | (69,885)               | —              | —                 | (69,885)                         |
| Balances at June 30,<br>2018  | <u>78,169</u> | <u>\$ 8</u> | <u>\$ 970,379</u>                | <u>\$ (301)</u>  | <u>\$ (685,281)</u>    | <u>(229)</u>   | <u>\$ (3,114)</u> | <u>\$ 281,691</u>                |



|   | Common Stock |           |                                  | Accumulated<br>Other<br>Comprehensive<br>Income (Loss) | Accumulated<br>Deficit | Treasury Stock |            | Total<br>Stockholders'<br>Equity |
|---|--------------|-----------|----------------------------------|--|------------------------|----------------|------------|----------------------------------|
|   | Shares       | Par Value | Additional<br>Paid-In<br>Capital |  |                        | Shares         | Amount     |                                  |
| 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 for employees  | —            | —         | 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                       |
| Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan | 20           | —         | 204                              | —  | —                      | —              | —          | 204                              |
| Issuance of restricted stock  | 55           | —         | —                                | —  | —                      | —              | —          | —                                |
| Cancellation/forfeiture of restricted stock   | —            | —         | —                                | —  | —                      | (339)          | —          | —                                |
| Share-based compensation expense for employees  | —            | —         | 3,662                            | —  | —                      | —              | —          | 3,662                            |
| Unrealized gain on marketable securities  | —            | —         | —                                | 264  | —                      | —              | —          | 264                              |
| Net loss  | —            | —         | —                                | —  | (113,969)              | —              | —          | (113,969)                        |
| Balances at June 30, 2019   | 99,251       | \$ 10     | \$ 1,217,942                     | \$ 519   | \$ (902,638)           | (568)          | \$ (3,114) | \$ 312,719                       |

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

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

**1. 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 and six months ended June 30, 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

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interim 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 June 30, 2019 and December 31, 2018 (in thousands):

|                            | June 30, 2019     | December 31, 2018 |
|----------------------------|-------------------|-------------------|
| Cash and cash equivalents  | \$ 123,508        | \$ 248,334        |
| Restricted cash, current   | 36,049            | —                 |
| Restricted cash, long-term | 1,849             | 37,898            |
| Total                      | <u>\$ 161,406</u> | <u>\$ 286,232</u> |

**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<br>June 30, 2019 | Quoted<br>Prices in<br>Active<br>Markets<br>(Level 1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Other<br>Unobservable<br>Inputs<br>(Level 3) |
|---|--------------------------------|---|---|---|
| Assets:   |                                |   |   |   |
| Cash equivalents:                               |                                |   |   |   |
| Money market funds                              | \$ 10,254                      | \$ 10,254   | \$ —  | \$ —  |
| Overnight repurchase agreements                 | 8,000                          | —   | 8,000   | —   |
| Marketable securities:                          |                                |   |   |   |
| U.S. government-sponsored enterprise securities | 19,101                         | —   | 19,101  | —   |
| Corporate debt securities                       | 128,659                        | —   | 128,659   | —   |
| Certificates of deposit                         | 4,564                          | —   | 4,564   | —   |
| Commercial paper obligations                    | 34,408                         | —   | 34,408  | —   |
| Asset-backed securities                         | 33,834                         | —   | 33,834  | —   |
| Total   | <u>\$ 238,820</u>              | <u>\$ 10,254</u>                                      | <u>\$ 228,566</u>   | <u>\$ —</u>   |

| Description                                     | Balance as of<br>December 31, 2018 | Quoted<br>Prices in<br>Active<br>Markets<br>(Level 1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Other<br>Unobservable<br>Inputs<br>(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   | <u>\$ 321,032</u>                  | <u>\$ 119,955</u>                                     | <u>\$ 201,077</u>   | <u>\$ —</u>   |

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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 and six months ended June 30, 2019 and 2018. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three and six months ended June 30, 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 approximates cost at June 30, 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 June 30, 2019 and December 31, 2018 (in thousands):

| As of June 30, 2019   | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair<br>Value     |
|---|-------------------|------------------------------|-------------------------------|-------------------|
| Cash, money market funds and overnight repurchase agreements              | \$ 123,508        | \$ —                         | \$ —                          | \$ 123,508        |
| U.S. government-sponsored enterprise securities due in one year or less   | 17,176            | 37                           | —                             | 17,213            |
| U.S. government-sponsored enterprise securities due in more than one year | 1,876             | 12                           | —                             | 1,888             |
| Corporate debt securities due in one year or less                         | 90,228            | 181                          | (3)                           | 90,406            |
| Corporate debt securities due in more than one year                       | 38,069            | 184                          | —                             | 38,253            |
| Certificates of deposit due in one year or less                           | 4,559             | 5                            | —                             | 4,564             |
| Commercial paper obligations due in one year or less                      | 34,379            | 29                           | —                             | 34,408            |
| Asset-backed securities due in one year or less                           | 275               | —                            | —                             | 275               |
| Asset-backed securities due in more than one year                         | 33,485            | 74                           | —                             | 33,559            |
| <b>Total</b>  | <b>\$ 343,555</b> | <b>\$ 522</b>                | <b>\$ (3)</b>                 | <b>\$ 344,074</b> |
| Reported as:  |                   |                              |                               |                   |
| Cash and cash equivalents   | \$ 123,508        | \$ —                         | \$ —                          | \$ 123,508        |
| Marketable securities   | 220,047           | 522                          | (3)                           | 220,566           |
| <b>Total</b>  | <b>\$ 343,555</b> | <b>\$ 522</b>                | <b>\$ (3)</b>                 | <b>\$ 344,074</b> |

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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            |
| <b>Total</b>  | <b>\$ 449,498</b> | <b>\$ 44</b>           | <b>\$ (131)</b>         | <b>\$ 449,411</b> |

Reported as:

|                           |                   |              |                 |                   |
|---------------------------|-------------------|--------------|-----------------|-------------------|
| Cash and cash equivalents | \$ 248,334        | \$ —         | \$ —            | \$ 248,334        |
| Marketable securities     | 201,164           | 45           | (132)           | 201,077           |
| <b>Total</b>              | <b>\$ 449,498</b> | <b>\$ 45</b> | <b>\$ (132)</b> | <b>\$ 449,411</b> |

**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. The \$36.1 million was held on deposit with a bank. At June 30, 2019, the Company classified this restricted cash as current as the Company has entered into a settlement agreement with Amphastar and has since canceled the security bond and released the collateral effective on July 15, 2019. Additional information regarding the litigation and settlement is discussed within Note 13, "Commitments and Contingencies" herein.

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 at June 30, 2019 and December 31, 2018 (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            |
| <b>Total</b>                   |                            |                       | <b>\$ 1,849</b>         |                              |

**6. Other Assets**

As of June 30, 2019 and December 31, 2018, prepaid expenses and other current assets consisted of the following (in thousands):

|   | June 30, 2019    | December 31, 2018 |
|---|------------------|-------------------|
| Restricted cash                               | \$ 36,049        | \$ —              |
| Other   | 6,094            | 6,318             |
| <b>Total prepaid and other current assets</b> | <b>\$ 42,143</b> | <b>\$ 6,318</b>   |

As of June 30, 2019 and December 31, 2018, other long-term assets consisted of the following (in thousands):

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|                                     | June 30, 2019    | December 31, 2018 |
|-------------------------------------|------------------|-------------------|
| Right-of-use operating lease asset  | \$ 72,808        | \$ —              |
| Other                               | 91               | 1,414             |
| <b>Total other long-term assets</b> | <b>\$ 72,899</b> | <b>\$ 1,414</b>   |

**7. Other Liabilities**

As of June 30, 2019 and December 31, 2018, other current and long-term liabilities consisted of the following (in thousands):

**Other Current Liabilities**

|  | June 30, 2019   | December 31, 2018 |
|--|-----------------|-------------------|
| Contract liability                     | \$ —            | \$ 15,000         |
| Lease liability                        | 9,092           | —                 |
| Lease incentive                        | —               | 1,052             |
| Deferred rent                          | —               | 47                |
| Other                                  | 131             | 128               |
| <b>Total other current liabilities</b> | <b>\$ 9,223</b> | <b>\$ 16,227</b>  |

**Other Long-Term Liabilities**

|  | June 30, 2019     | December 31, 2018 |
|--|-------------------|-------------------|
| Lease liability                          | \$ 80,313         | \$ —              |
| Contractual obligations                  | 42,936            | —                 |
| Lease incentive                          | —                 | 7,877             |
| Deferred rent                            | —                 | 8,477             |
| Other                                    | 851               | 916               |
| <b>Total other long-term liabilities</b> | <b>\$ 124,100</b> | <b>\$ 17,270</b>  |

As of June 30, 2019, the Company included \$42.9 million in other long-term liabilities in connection with our contractual obligations to Human Genome Sciences, Inc., or GSK, under a manufacturing services agreement. Refer to Note 13, "*Commitments and Contingencies*" herein.

**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:

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|  | Three Months Ended June<br>30, 2019 | Six Months Ended June 30,<br>2019 |
|--|-------------------------------------|-----------------------------------|
| Lease cost (in thousands)  | \$ 3,659                            | \$ 7,318                          |
| Cash paid for amounts included in the measurement of lease liabilities included in operating cash flows (in thousands) | \$ 3,801                            | \$ 7,601                          |

  

|   | June 30, 2019 |
|---|---------------|
| Weighted-average remaining lease term (years) | 7.1           |
| Weighted-average discount rate                | 7.5%          |

Future minimum lease payments and lease liabilities as of June 30, 2019 were as follows (in thousands):

|                                     | Operating leases |
|-------------------------------------|------------------|
| July 1 to December 31, 2019         | \$ 7,689         |
| 2020                                | 15,744           |
| 2021                                | 16,138           |
| 2022                                | 16,516           |
| 2023                                | 16,655           |
| 2024 and beyond                     | 43,709           |
| Total future minimum lease payments | \$ 116,451       |
| Less: imputed interest              | (27,046)         |
| Total lease liability               | \$ 89,405        |
| Reported as:                        |                  |
| Other current liabilities           | \$ 9,092         |
| Other long-term liabilities         | 80,313           |
| Total lease liabilities             | \$ 89,405        |

On July 31, 2019, the Company entered into an amendment to its office and laboratory space lease at 320 Bent Street in Cambridge, Massachusetts. See Note 14, "Subsequent Events."

## 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 six months ended June 30, 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.



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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.

### *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

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

### **Collaborative Arrangements**

#### *Mylan Collaboration Agreement*

The Company and Mylan entered into a collaboration agreement, or the Mylan Collaboration Agreement, effective February 9, 2016, pursuant to which the Company and Mylan agreed to collaborate exclusively, on a worldwide basis, to develop, manufacture and commercialize six of the Company's biosimilar candidates, 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 is only advancing 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.

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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.

### 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 June 30, 2019, \$2.8 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

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collaboration costs and a contract liability to reflect the balance of any advance payment from Mylan to be applied towards Mylan's 50% share of future development-related collaboration costs.

### ***CSL License and Option Agreement***

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

Pursuant to the 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

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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 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.

|  | <b>2003 Sandoz<br/>Agreement</b> | <b>2006 Sandoz<br/>Agreement</b> | <b>Mylan<br/>Collaboration<br/>Agreement</b> | <b>CSL Collaboration<br/>Agreement</b> | <b>Total</b>    |
|--|----------------------------------|----------------------------------|--|--|-----------------|
| <b>Contract assets</b>                                   |                                  |                                  |  |  |                 |
| Collaboration receivables:                               |                                  |                                  |  |  |                 |
| Opening balance - January 1, 2019                        | \$ —                             | \$ 11,281                        | \$ 90  | \$ —                                   | \$ 11,371       |
| Revenue / cost recovery                                  | —                                | 6,448                            | 301  | —                                      | 6,749           |
| Cash receipts  | —                                | (13,632)                         | (90)   | —                                      | (13,722)        |
| Ending balance - June 30, 2019                           | <u>\$ —</u>                      | <u>\$ 4,097</u>                  | <u>\$ 301</u>                                | <u>\$ —</u>                            | <u>\$ 4,398</u> |
| <b>Contract liabilities</b>                              |                                  |                                  |  |  |                 |
| Deferred revenue:  |                                  |                                  |  |  |                 |
| Opening balance - January 1, 2019                        | \$ —                             | \$ —                             | \$ 5,690                                     | \$ —                                   | \$ 5,690        |
| Revenue recognition                                      | —                                | —                                | (2,847)                                      | —                                      | (2,847)         |
| Ending balance - June 30, 2019                           | —                                | —                                | 2,843  | —                                      | 2,843           |
| Less: current portion                                    | —                                | —                                | (1,731)                                      | —                                      | (1,731)         |
| Deferred revenue, net of current portion - June 30, 2019 | <u>\$ —</u>                      | <u>\$ —</u>                      | <u>\$ 1,112</u>                              | <u>\$ —</u>                            | <u>\$ 1,112</u> |
| Collaboration liabilities:                               |                                  |                                  |  |  |                 |
| Opening balance - January 1, 2019                        | \$ —                             | \$ —                             | \$ 1,412                                     | \$ 3,309                               | \$ 4,721        |
| Payments   | —                                | —                                | —  | (4,591)                                | (4,591)         |
| Net collaboration costs incurred in the period           | —                                | —                                | 614  | 3,528                                  | 4,142           |
| Ending balance - June 30, 2019                           | <u>\$ —</u>                      | <u>\$ —</u>                      | <u>\$ 2,026</u>                              | <u>\$ 2,246</u>                        | <u>\$ 4,272</u> |

**For the Three Months Ended June 30, 2019**

|  | <b>2003 Sandoz Agreement</b> | <b>2006 Sandoz Agreement</b> | <b>Mylan Collaboration Agreement</b> | <b>CSL Collaboration Agreement</b> | <b>Total</b>     |
|--|------------------------------|------------------------------|--------------------------------------|------------------------------------|------------------|
| Product revenue  | \$ —                         | \$ 3,333                     | \$ —                                 | \$ —                               | \$ 3,333         |
| Research and development revenue                       | —                            | 343                          | 1,506                                | —                                  | 1,849            |
| <b>Total collaboration revenue</b>                     | <b>\$ —</b>                  | <b>\$ 3,676</b>              | <b>\$ 1,506</b>                      | <b>\$ —</b>                        | <b>\$ 5,182</b>  |
| Operating expenses:                                    |                              |                              |                                      |                                    |                  |
| Research and development expense                       | —                            | 122                          | 3,765                                | 19                                 | 3,906            |
| General and administrative expense                     | 7,192                        | 19                           | 201                                  | 3                                  | 7,415            |
| Net amount (recovered from) / payable to collaborators | —                            | —                            | 452                                  | 2,245                              | 2,697            |
| <b>Total operating expenses</b>                        | <b>\$ 7,192</b>              | <b>\$ 141</b>                | <b>\$ 4,418</b>                      | <b>\$ 2,267</b>                    | <b>\$ 14,018</b> |

**For the Three Months Ended June 30, 2018**

|  | <b>2003 Sandoz Agreement</b> | <b>2006 Sandoz Agreement</b> | <b>Mylan Collaboration Agreement</b> | <b>CSL Collaboration Agreement</b> | <b>Total</b>     |
|--|------------------------------|------------------------------|--------------------------------------|------------------------------------|------------------|
| Product revenue  | \$ —                         | \$ 11,779                    | \$ —                                 | \$ —                               | \$ 11,779        |
| Research and development revenue                       | 3                            | 732                          | 517                                  | —                                  | 1,252            |
| <b>Total collaboration revenue</b>                     | <b>\$ 3</b>                  | <b>\$ 12,511</b>             | <b>\$ 517</b>                        | <b>\$ —</b>                        | <b>\$ 13,031</b> |
| Operating expenses:                                    |                              |                              |                                      |                                    |                  |
| Research and development expense                       | \$ —                         | \$ 133                       | \$ 7,137                             | \$ 286                             | \$ 7,556         |
| General and administrative expense                     | 3,140                        | 65                           | 534                                  | 10                                 | 3,749            |
| Net amount (recovered from) / payable to collaborators | —                            | —                            | (2,470)                              | 2,268                              | (202)            |
| <b>Total operating expenses</b>                        | <b>\$ 3,140</b>              | <b>\$ 198</b>                | <b>\$ 5,201</b>                      | <b>\$ 2,564</b>                    | <b>\$ 11,103</b> |

**For the Six Months Ended June 30, 2019**

|  | <b>2003 Sandoz Agreement</b> | <b>2006 Sandoz Agreement</b> | <b>Mylan Collaboration Agreement</b> | <b>CSL Collaboration Agreement</b> | <b>Total</b>     |
|--|------------------------------|------------------------------|--------------------------------------|------------------------------------|------------------|
| Product revenue  | \$ —                         | \$ 5,685                     | \$ —                                 | \$ —                               | \$ 5,685         |
| Research and development revenue                       | —                            | 763                          | 2,847                                | —                                  | 3,610            |
| <b>Total collaboration revenue</b>                     | <b>\$ —</b>                  | <b>\$ 6,448</b>              | <b>\$ 2,847</b>                      | <b>\$ —</b>                        | <b>\$ 9,295</b>  |
| Operating expenses:                                    |                              |                              |                                      |                                    |                  |
| Research and development expense                       | —                            | 176                          | 6,543                                | 77                                 | 6,796            |
| General and administrative expense                     | 11,492                       | 44                           | 469                                  | 13                                 | 12,018           |
| Net amount (recovered from) / payable to collaborators | —                            | —                            | 313                                  | 3,527                              | 3,840            |
| <b>Total operating expenses</b>                        | <b>\$ 11,492</b>             | <b>\$ 220</b>                | <b>\$ 7,325</b>                      | <b>\$ 3,617</b>                    | <b>\$ 22,654</b> |

**For the Six Months Ended June 30, 2018**

|  | 2003 Sandoz Agreement | 2006 Sandoz Agreement | Mylan Collaboration Agreement | CSL Collaboration Agreement | Total     |
|--|-----------------------|-----------------------|-------------------------------|-----------------------------|-----------|
| Product revenue  | \$ —                  | \$ 15,300             | \$ —                          | \$ —                        | \$ 15,300 |
| Research and development revenue                       | 7                     | 1,311                 | 1,265                         | —                           | 2,583     |
| Total collaboration revenue                            | \$ 7                  | \$ 16,611             | \$ 1,265                      | \$ —                        | \$ 17,883 |
| Operating expenses:                                    |                       |                       |                               |                             |           |
| Research and development expense                       | \$ —                  | \$ 250                | \$ 16,509                     | \$ 589                      | \$ 17,348 |
| General and administrative expense                     | 5,619                 | 81                    | 1,120                         | 21                          | 6,841     |
| Net amount (recovered from) / payable to collaborators | —                     | —                     | (4,852)                       | 4,133                       | (719)     |
| Total operating expenses                               | \$ 5,619              | \$ 331                | \$ 12,777                     | \$ 4,743                    | \$ 23,470 |

**10. Share-Based Payments**

The table below presents share-based compensation expense included in each of the financial statement line items (in thousands):

|  | Three Months Ended<br>June 30, |          | Six Months Ended<br>June 30, |           |
|--|--------------------------------|----------|------------------------------|-----------|
|  | 2019                           | 2018     | 2019                         | 2018      |
| Research and development               | \$ 1,153                       | \$ 2,138 | \$ 2,240                     | \$ 4,063  |
| General and administrative             | 2,509                          | 3,034    | 4,896                        | 5,983     |
| Total share-based compensation expense | \$ 3,662                       | \$ 5,172 | \$ 7,136                     | \$ 10,046 |

During the six months ended June 30, 2019, the Company granted 1,876,192 stock options with a per share weighted-average grant date fair value of \$6.48 and 126,006 restricted stock units to its employees and board members.

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. 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.

During the six months ended June 30, 2019, the Company granted performance-based restricted stock units, or PSUs, to its employees. As of June 30, 2019, up to 1,952,213 shares of the Company's common stock may be issued under outstanding PSUs. 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 June 30, 2019, the Company concluded that it was not probable that any of the performance milestones would be achieved. For the three and six months ended June 30, 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.

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The following table presents anti-dilutive shares for the three and six months ended June 30, 2019 and 2018 (in thousands):

|                                   | Three Months Ended<br>June 30, |       | Six Months Ended<br>June 30, |       |
|-----------------------------------|--------------------------------|-------|------------------------------|-------|
|                                   | 2019                           | 2018  | 2019                         | 2018  |
| Outstanding stock options         | 4,466                          | 2,798 | 4,531                        | 3,217 |
| Restricted stock awards and units | 175                            | 854   | 353                          | 778   |

## 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 six months ended June 30, 2019 included in the condensed consolidated statement of operations and comprehensive loss, and ending liability recorded in the condensed consolidated balance sheet as at June 30, 2019 (in thousands):

|                                     | Remaining liability at<br>December 31, 2018 | Adjustments during the six<br>months ended June 30, 2019 | Amount paid during the six<br>months ended June 30, 2019 | Remaining liability at June 30,<br>2019 |
|-------------------------------------|---|--|--|---|
| Employee severance, bonus and other | \$ 3,235                                    | \$ 158   | \$ (2,282)   | \$ 1,111                                |
| Total restructuring charges         | \$ 3,235                                    | \$ 158   | \$ (2,282)   | \$ 1,111                                |

## 13. Commitments and Contingencies

### 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 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 a 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 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.



*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 was 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.

On September 17, 2015, Amphastar filed a complaint against the Company and Sandoz in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that the court reverse and review the District Court's grant of transfer and in May 2016, the writ requested by Amphastar was denied. On July 27, 2016, the Company's and Sandoz' motion to dismiss was granted by the District Court, and the case was dismissed. On August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court of Appeals for the First Circuit reversed the District Court's dismissal and remanded the case to the District Court for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, the Company and Sandoz filed a renewed motion to dismiss which was denied by the District Court on March 20, 2018. A trial was 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.

The Company, Sandoz and Amphastar entered into a settlement agreement which became effective on June 18, 2019, upon the District Court's entry of a final order of vacatur of its final judgment entered March 20, 2018 ("Patent Judgment"). Pursuant to the settlement agreement the parties dismissed the appeal of the Patent Judgment with the CAFC and the patent and antitrust cases pending with the District Court. The Company paid \$21.0 million to Amphastar in June 2019 as its portion of the required payment to Amphastar under the settlement agreement. In July 2019, the security bond was canceled, releasing restricted cash of \$36.1 million in collateral.

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

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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 Bioepis 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 Bioepis 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.

### *Purchase Obligations*

Under the Company's manufacturing agreement with GSK, as amended in June 2018, the Company is obligated to purchase or pay 100% of committed volumes at specified prices during the calendar years 2019 through 2022. The minimum purchase obligations are subject to annual price increases indexed to a measure of inflation and exclude the cost of raw materials and certain other charges. Consistent with the Company's decision to cease active development of M923, the Company has canceled its manufacturing runs scheduled through 2020 and recorded a charge of \$20.9 million during the three months ended June 30, 2019 representing the minimum purchase obligation. Since the utility of the remaining minimum purchase commitments for the calendar years 2021 through 2022 was deemed impaired at June 30, 2019, the Company recorded an additional charge of \$22.0 million during the three-months ended June 30, 2019.

### *Other Funding Commitments*

As of June 30, 2019, the Company had several ongoing clinical and nonclinical studies for its various pipeline programs. The Company enters into contracts in the normal course of business with contract research organizations and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties.

### *Guarantees*

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, landlords and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has

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not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal.

**14. Subsequent Events**

On July 15, 2019, the Company canceled the security bond in the litigation against Amphastar and released \$36.1 million of previously restricted cash that served as collateral for a letter of credit and became available for the Company's general use. Refer to additional disclosures concerning the litigation and restricted cash in Note 13, "*Commitments and Contingencies*", and Note 5, "*Restricted Cash*", respectively.

On July 31, 2019, the Company entered into an amendment to its office and laboratory space lease at 320 Bent Street in Cambridge, Massachusetts. The amendment provided for the partial termination of the Company's obligations with respect to a portion of the space leased of approximately 89,000 square feet. The Company will continue to lease approximately 15,000 square feet. The Company incurred a \$3.1 million termination fee and reduced its remaining lease payments through February 2027 by approximately \$62.7 million.

## 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 actively developing one 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. 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 this program has 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. In August 2019, we announced that we will cease active development activities at this time for our wholly owned HUMIRA biosimilar, which is fully developed and ready for submission of an application for approval, due to changes in market opportunity relating to its launch. 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 June 30, 2019, we had an accumulated deficit of approximately \$902.6 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

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decreased contractual profit share revenue. We estimate that the number of prescriptions for GLATOPA 20 mg/mL currently represents approximately 39% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

### **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 June 30, 2019, 40 mg/mL glatiramer acetate injection accounted for approximately 85% 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. 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. In August 2019, we announced that we will cease active development activities for M923 at this time, which is fully developed and ready for submission of a BLA with the FDA and a MAA in Europe for approval, due to changes in market opportunity relating to its launch.

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

### **M710—Biosimilar EYLEA® (afibercept) 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.

### *M281 - Anti-FcRn Candidate*

M281 is a fully-human anti-neonatal Fc receptor, or anti 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. In August 2019, we announced we commenced a Phase 2/3 clinical trial for M281 in warm antibody hemolytic anemia, or wAIHA. In July 2019, the FDA granted Fast Track designation for our HDFN and wAIHA indications, which is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill unmet medical need.

### *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.

### *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 June 30, 2019 and 2018

Product revenue includes our contractually defined profits earned on Sandoz' sales of GLATOPA.

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

|                                  | Three Months Ended June 30, |                                  |                |                                  | Change period over period |       |
|----------------------------------|-----------------------------|----------------------------------|----------------|----------------------------------|---------------------------|-------|
|                                  | 2019                        | % of Total Collaboration Revenue | 2018           | % of Total Collaboration Revenue | 2019 compared to 2018     |       |
|                                  | (in thousands)              |                                  | (in thousands) |                                  | (in thousands)            | %     |
| Collaboration revenue:           |                             |                                  |                |                                  |                           |       |
| Product revenue                  | \$ 3,333                    | 64%                              | \$ 11,779      | 90%                              | \$ (8,446)                | (72)% |
| Research and development revenue | 1,849                       | 36%                              | 1,252          | 10%                              | 597                       | 48 %  |
| Total collaboration revenue      | \$ 5,182                    | 100%                             | \$ 13,031      | 100%                             | \$ (7,849)                | (60)% |

**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 39% 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 June 30, 2019, 40 mg/mL glatiramer acetate injection accounted for approximately 85% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed.

The decrease in product revenue of \$8.4 million, or 72%, from the three months ended June 30, 2018 to the three months ended June 30, 2019 was primarily due to lower net sales of GLATOPA driven by competition.

*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.

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 \$2.8 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.

The increase in research and development revenue of \$0.6 million, or 48%, from the three months ended June 30, 2018 to the three months ended June 30, 2019 was due to higher revenue recognized on the collaborative upfront payment from Mylan of \$1.0 million, offset in part by a \$0.4 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:

|                            | Three Months Ended June 30, |                               |                |                               | 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   | \$ 32,131                   | 26%                           | \$ 31,340      | 37%                           | \$ 791                    | 3%   |
| General and administrative | 46,609                      | 38%                           | 22,531         | 27%                           | 24,078                    | 107% |
| Restructuring              | 132                         | —%                            | —              | —%                            | 132                       | 100% |
| Other operating expense    | 42,936                      | 36%                           | 30,000         | 36%                           | 12,936                    | 43%  |
| Total operating expenses   | \$ 121,808                  | 100%                          | \$ 83,871      | 100%                          | \$ 37,937                 | 45%  |

## 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 June 30, 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.



|   | Phase of Development as of<br>June 30, 2019 | Three Months Ended<br>June 30, |                  |
|---|---|--------------------------------|------------------|
|   |   | 2019                           | 2018             |
| <b>External Costs Incurred by Product Area:</b> |   |                                |                  |
| Novel Therapeutics                              | Various (1)                                 | \$ 16,130                      | \$ 8,108         |
| Biosimilars                                     | Various (2)                                 | 4,295                          | 1,107            |
| Complex Generics                                | (3)   | 122                            | 133              |
| <b>Internal Costs</b>                           |   | <b>11,584</b>                  | <b>21,992</b>    |
| <b>Total Research and Development Expenses</b>  |   | <b>\$ 32,131</b>               | <b>\$ 31,340</b> |

- (1) Our novel therapeutic programs include M281, for which we commenced two Phase 2 clinical trials during the three months ended December 31, 2018 and announced in August 2019 that we commenced an additional Phase 2/3 clinical trial; M230, for which our licensee's, CSL's, Phase I study in healthy volunteers to evaluate safety and tolerability of M230 is ongoing; 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). In August 2019, we announced that we will cease active development activities for M923 at this time. 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."

External costs of our novel therapeutic programs increased by \$8.0 million, or 99%, from the three months ended June 30, 2018 to the three months ended June 30, 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 increased by \$3.2 million, or 288%, from the three months ended June 30, 2018 to the three months ended June 30, 2019, primarily due to increased spending on M710. Internal costs decreased by \$10.4 million, or 47%, from the three months ended June 30, 2018 to the three months ended June 30, 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.

The increase of \$24.1 million, or 107%, from the three months ended June 30, 2018 to the three months ended June 30, 2019 was primarily due to our payment of \$21.0 million to Amphastar in June 2019 reflecting our portion of the required settlement payment and a \$4.7 million increase in related legal costs.

**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 Operating Expense**

Other operating expense was \$42.9 million for the three months ended June 30, 2019 that included a take-or-pay purchase obligation under our manufacturing agreement with Human Genome Sciences, Inc., or GSK. Consistent with the Company's decision to cease active development of M923, the Company has canceled its manufacturing runs scheduled through 2020 and recorded a charge of \$20.9 million in the three months ended June 30, 2019, representing the minimum purchase obligation. Since the utility of the remaining minimum purchase commitments for the calendar years 2021 through 2022 was deemed impaired at June 30, 2019, the Company recorded an additional charge of \$22.0 million during the three months ended June 30, 2019. Other operating expense was \$30.0 million for the three months ended June 30, 2018 and was incurred in connection with the same supply agreement with GSK.

**Other Income, Net**

Other income, net includes other items of non-operating income and expense. Other income, net was \$2.7 million and \$1.0 million for the three months ended June 30, 2019 and 2018, respectively. The increase of \$1.7 million, or 178%, from the three months ended June 30, 2018 to the three months ended June 30, 2019 was primarily 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.

**Comparison of Six Months Ended June 30, 2019 and 2018**

Product revenue includes our contractually defined profits earned on Sandoz' sales of GLATOPA.

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

|                                  | Six Months Ended June 30, |                                  |                |                                  | Change period over period |       |
|----------------------------------|---------------------------|----------------------------------|----------------|----------------------------------|---------------------------|-------|
|                                  | 2019                      | % of Total Collaboration Revenue | 2018           | % of Total Collaboration Revenue | 2019 compared to 2018     |       |
|                                  | (in thousands)            |                                  | (in thousands) |                                  | (in thousands)            | %     |
| Collaboration revenue:           |                           |                                  |                |                                  |                           |       |
| Product revenue                  | \$ 5,685                  | 61%                              | \$ 15,300      | 86%                              | \$ (9,615)                | (63)% |
| Research and development revenue | 3,610                     | 39%                              | 2,583          | 14%                              | 1,027                     | 40 %  |
| Total collaboration revenue      | \$ 9,295                  | 100%                             | \$ 17,883      | 100%                             | \$ (8,588)                | (48)% |

**Product Revenue****GLATOPA**

The decrease in product revenue of \$9.6 million, or 63%, from the six months ended June 30, 2018 to the six months ended June 30, 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. During the six months ended June 30, 2018, product revenue decreased \$9.8 million, reflecting our 50% share of GLATOPA 40 mg/mL inventory written-off by Sandoz.

**Research and Development Revenue**

The increase in research and development revenue of \$1.0 million, or 40%, from the six months ended June 30, 2018 to the six months ended June 30, 2019 was due to higher revenue recognized on the collaborative upfront payment from Mylan of \$1.6 million, offset in part by a \$0.6 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:

|                            | Six Months Ended June 30, |                               |                |                               | 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   | \$ 60,103                 | 34%                           | \$ 64,582      | 47%                           | \$ (4,479)                | (7)%  |
| General and administrative | 70,815                    | 41%                           | 43,143         | 31%                           | 27,672                    | 64 %  |
| Restructuring              | 158                       | —%                            | —              | —%                            | 158                       | 100 % |
| Other operating expenses   | 42,936                    | 25%                           | 30,000         | 22%                           | 12,936                    | 43 %  |
| Total operating expenses   | \$ 174,012                | 100%                          | \$ 137,725     | 100%                          | \$ 36,287                 | 26 %  |

## Research and Development Expense

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 six months ended June 30, 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.

|  | Phase of Development as of June 30, 2019 | Six Months Ended June 30, |           |
|--|--|---------------------------|-----------|
|  |  | 2019                      | 2018      |
| External Costs Incurred by Product Area: |  |                           |           |
| Novel Therapeutics                       | Various (1)                              | \$ 28,893                 | \$ 14,601 |
| Biosimilars                              | Various (2)                              | 7,174                     | 5,026     |
| Complex Generics                         | (3)                                      | 176                       | 250       |
| Internal Costs                           |  | 23,860                    | 44,705    |
| Total Research and Development Expenses  |  | \$ 60,103                 | \$ 64,582 |

- (1) Our novel therapeutic programs include M281, for which we commenced two Phase 2 clinical trials during the three months ended December 31, 2018 and announced in August 2019 that we commenced an additional Phase 2/3 clinical trial; M230, for which our licensee's, CSL's, Phase I study in healthy volunteers to evaluate safety and tolerability of M230 is ongoing; 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). In August 2019, we announced that we will cease active development activities for M923 at this time. 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."

External costs of our novel therapeutic programs increased by \$14.3 million, or 98%, from the six months ended June 30, 2018 to the six months ended June 30, 2019, and were primarily driven by clinical trial activity for M281 and M254 as described in Note 1 in the above table. External expenditures for our biosimilars programs increased by \$2.1 million, or 43%.

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from the six months ended June 30, 2018 to the six months ended June 30, 2019, primarily due to increased spending on M710. Internal costs decreased by \$20.8 million, or 47% from the six months ended June 30, 2018 to the six months ended June 30, 2019 primarily due to decreased personnel costs, due in part to the workforce reduction announced in October 2018 and reductions in lease costs and lab supplies.

### **General and Administrative**

The increase of \$27.7 million, or 64%, from the six months ended June 30, 2018 to the six months ended June 30, 2019 was primarily due to our payment of \$21.0 million to Amphastar in June 2019 reflecting our portion of the required settlement payment, \$6.1 million increase in related legal costs, and increased depreciation of \$8.6 million associated with a change in the estimated useful life of certain leasehold improvements in the fourth quarter of 2018. These increases were partially offset by decreased personnel salaries and stock based compensation expense of \$4.5 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 Operating Expense**

Other operating expense was \$42.9 million for the six months ended June 30, 2019 that included a take-or-pay purchase obligation under our manufacturing agreement with GSK. Consistent with the Company's decision to cease active development of M923, the Company has canceled its manufacturing runs scheduled through 2020 and recorded a charge of \$20.9 million in the six months ended June 30, 2019, representing the minimum purchase obligation. Since the utility of the remaining minimum purchase commitments for the calendar years 2021 through 2022 was deemed impaired at June 30, 2019, the Company recorded an additional charge of \$22.0 million during the six months ended June 30, 2019. Other operating expense was \$30.0 million for the six months ended June 30, 2018 and was incurred in connection with the same supply agreement with GSK.

### **Other Income, Net**

Other income, net includes other items of non-operating income and expense. Other income, net was \$5.9 million and \$2.3 million for the six months ended June 30, 2019 and 2018, respectively. The increase of \$3.6 million, or 154%, from the six months ended June 30, 2018 to the six months ended June 30, 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 and net gains on assets sold in the period.

### **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 June 30, 2019, we had \$344.1 million in cash, cash equivalents and marketable securities. In addition, we also held \$37.9 million in restricted cash, of which \$36.1 million served as collateral for a security bond posted in the litigation against Amphastar, which was released from collateral on July 15, 2019 following the settlement of the related litigation.

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 June 30, 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 June 30, 2019.

|  | Six Months Ended June 30, |             |
|--|---------------------------|-------------|
|  | 2019                      | 2018        |
|  | (in thousands)            |             |
| Net cash used in operating activities                                  | \$ (111,262)              | \$ (74,998) |
| Net cash provided by (used in) investing activities                    | \$ (16,345)               | \$ 60,580   |
| Net cash provided by financing activities                              | \$ 2,781                  | \$ 20,772   |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | \$ (124,826)              | \$ 6,354    |

**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 \$111.3 million for the six months ended June 30, 2019 reflecting a net loss of \$158.8 million, which was partially offset by non-cash charges of \$10.6 million for depreciation and amortization of property, equipment and intangible assets and \$7.1 million in share-based compensation. The net change in our operating assets and liabilities provided cash of \$31.4 million resulted primarily from \$7.0 million in receivables due from Sandoz for our profit share interest and a \$42.9 million increase in liabilities due to contractual obligations payable to GSK in 2020 through 2022, partially offset by \$2.3 million in payments of termination benefits from our Workforce Reduction, recognition of \$2.8 million in revenue on the upfront payment from Mylan, and payment of our \$15.0 million contractual liability to GSK in respect to the June 2018 agreement amendment.

Cash used in operating activities was \$75.0 million for the six months ended June 30, 2018 reflecting a net loss of \$117.5 million, which was partially offset by non-cash charges of \$4.3 million for depreciation and amortization of property, equipment and intangible assets and \$10.0 million in share-based compensation. The net change in our operating assets and liabilities provided cash of \$27.5 million and resulted primarily from the increase in other current and other long-term liabilities of \$30.0 million in connection with the renegotiation with GSK of contractual liabilities, partially offset by a decrease in collaboration liabilities of \$3.3 million in connection with our collaboration agreements with CSL and Mylan.

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

Cash used in investing activities of \$16.3 million for the six months ended June 30, 2019 includes cash outflows of \$194.5 million for purchases of marketable securities and \$1.1 million for purchases of property and equipment, partially offset by cash inflows of \$176.8 million from maturities of marketable securities and \$2.4 million in proceeds from the disposal of equipment.

Cash provided by investing activities of \$60.6 million for the six months ended June 30, 2018 includes cash inflows of \$137.0 million from maturities of marketable securities partially offset by cash outflows of \$69.8 million for purchases of marketable securities and \$6.7 million for purchases of capital equipment and leasehold improvements.

**Cash provided by financing activities**

Cash provided by financing activities of \$2.8 million for the six months ended June 30, 2019 consists solely of proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

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Cash provided by financing activities of \$20.8 million for the six months ended June 30, 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 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.

### **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 June 30, 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 June 30, 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 June 30, 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 June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. LEGAL PROCEEDINGS

#### GLATOPA 40 mg/mL-Related Proceedings

On 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 a 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.

#### 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 was docketed and briefing was completed on November 19, 2018. On 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.

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

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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 was 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.

We, Sandoz and Amphastar entered into a settlement agreement which became effective on June 18, 2019, upon the District Court's entry of a final order of vacatur of its final judgment entered March 20, 2018 ("Patent Judgment"). Pursuant to the settlement agreement the parties dismissed the appeal of the Patent Judgment with the CAFC and the patent and antitrust cases pending with the District Court. We paid \$21.0 million to Amphastar in June 2019 as our portion of the required payment to Amphastar under the settlement agreement. In July 2019, the security bond was canceled, releasing restricted cash of \$36.1 million in collateral.

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 Bioepis 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 Bioepis Co.,Ltd, Mylan, Inc., Mylan Pharmaceuticals, Inc., Sandoz, 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. In August 2019, we announced that we will cease active development activities for M923 at this time, due to changes in market opportunity relating to its launch. 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 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

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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.

***We have ceased active development of our biosimilar product candidate, M923, and if we do not resume development of the program our business may be adversely affected.***

In August 2019, we announced that we will cease active development activities at this time for our wholly owned HUMIRA biosimilar, M923, which is fully developed and ready for submission of an application for approval, due to changes in market opportunity relating to its launch. We may seek to license M923 to a third party entirely or opt to otherwise monetize M923 or to terminate the program, which could have a material adverse effect on our business, including paying our remaining take or pay minimum purchase obligation under our manufacturing agreement with GSK without receiving a benefit therefor.

***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 M254, 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.

***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 to 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, 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 June 30, 2019, 40 mg/mL glatiramer acetate injection accounted for approximately 85% 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 June 30, 2019. We expect future revenues from Sandoz' sales of Enoxaparin Sodium Injection, if any, to be minimal.

***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

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establish and maintain relationships with GPOs and PBMs. The GPOs, PBMs and other customers with whom we or our collaborators have established contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of products to certain market segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by, or offered to, GPOs, PBMs, and customers, including wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our or our competitors' products. For example, if PBMs, distributors and other customers contracted with Teva for net price discounts or rebates on COPAXONE 20 mg/mL and 40 mg/mL, or with Mylan N.V. for net price discounts or rebates on its generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL, in exchange for exclusivity or preferred status for COPAXONE prior to the February 2018 approval and launch of GLATOPA 40 mg/mL, our opportunity to capture market share would be significantly restricted for the term of these contracts. If we or our collaborators are unable to establish and maintain competitive distribution arrangements with all of these customers, sales of our products, our revenue and our profits would suffer.

***Even if we receive approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which could adversely affect our ability to generate sufficient revenue from product sales to maintain or grow our business.***

Even if our product candidates are successfully developed and approved for marketing, our success and growth will also depend upon the acceptance of our products by patients, physicians and third-party payers. Acceptance of our products will be a function of our products being clinically useful, being cost effective and demonstrating sameness, in the case of our generic product candidate, and biosimilarity or interchangeability, in the case of our biosimilar product candidates, with an acceptable side effect profile as compared to existing or future treatments. In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time.

Factors that we believe will materially affect market acceptance of our product candidates under development include:

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the competitive pricing of our products;
- physician confidence in the safety and efficacy of 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

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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 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

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these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

***We may incur costs and allocate resources to identify and develop additional product candidates or acquire or make investments in companies or technologies without realizing any benefit, which could have an adverse effect on our business, results of operations and financial condition or cash flows.***

Along with continuing to progress our current product candidates, the long-term success of our business also depends on our ability to successfully identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs and product candidates that ultimately prove to be unsuccessful.

In addition, we may acquire or invest in companies, products and technologies. Such transactions involve a number of risks, including:

- we may find that the acquired company or assets does not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;
- difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;
- difficulty incorporating the acquired technologies;
- difficulties or failures with the performance of the acquired technologies or products;
- we may face product liability risks associated with the sale of the acquired company's products;
- disruption or diversion of management's attention by transition or integration issues and the complexity of managing diverse locations;
- difficulty maintaining uniform standards, internal controls, procedures and policies;
- the acquisition may result in litigation from terminated employees or third parties; and
- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

These factors could have a material adverse effect on our business, results of operations and financial condition or cash flows, particularly in the case of a larger acquisition or multiple acquisitions in a short period of time. From time to time, we may enter into negotiations for acquisitions that are not ultimately consummated. Such negotiations could result in significant diversion of management time, as well as out-of-pocket costs.

The consideration paid in connection with an acquisition also affects our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any acquisition. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted and earnings per share may decrease. In addition, acquisitions may result in the incurrence of debt, large one-time write-offs and restructuring charges. They may also result in goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges.

***If we fail to maintain appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business.***

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment requires the commitment of significant financial and managerial resources.

Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002, as amended. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of

registered broker dealers to make a market in our stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

***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 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 June 30, 2019, our accumulated deficit was \$902.6 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 June 30, 2019, we had cash, cash equivalents and marketable securities totaling approximately \$344.1 million. For the six months ended June 30, 2019, we had a net loss of \$158.8 million and our operations used cash of \$111.3 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, nonclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development and commercialization of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

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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;
- 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 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, 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 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.

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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.

***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 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.

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.

***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, or 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 inseparable 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.

### ***Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.***

As of December 31, 2018, we had federal and state net operating loss carryforwards of approximately \$569.0 million and \$548.5 million, respectively. Our net operating loss carryforwards generated before January 1, 2018 are subject to expiration and will expire at various dates through 2038. As of December 31, 2018, we also had federal and state research and development and other tax credit carryforwards, including the orphan drug credit, of approximately \$37.9 million and \$12.2 million, respectively, available to reduce future tax liabilities. The federal and state research and development and other tax credit carryforwards expire at various dates through 2038, while the orphan drug credit does not expire. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss



carryforwards and other deferred tax assets available to us. Furthermore, under the TCJA, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond will only be able to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

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

In some foreign countries, particularly the countries of the European Union, the pricing and/or reimbursement of prescription pharmaceuticals are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development involves, and may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Insurance may not provide adequate coverage against potential liabilities, and we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

### **Risks Relating to 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;

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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 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 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 EYLEA prior to approval of 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 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 June 30, 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;
- 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;

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- 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 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 our ability to fund future discovery and development programs, would suffer.

### **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

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compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the U.S. PTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

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

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

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

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

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

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

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

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

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

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

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

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

***The 2006 Sandoz Collaboration Agreement is important to our business. If Sandoz AG fails to adequately perform under this collaboration, or if we or Sandoz AG terminate all or a portion of this collaboration, the commercialization of some of our products and product candidates, including GLATOPA 20 mg/mL and GLATOPA 40 mg/mL, would be impacted, delayed or terminated and our business would be adversely affected.***

Either we or Sandoz AG may terminate the 2006 Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. For some of the products, for any termination of the 2006 Sandoz Collaboration Agreement other than a termination by Sandoz AG due to our uncured breach or bankruptcy, or a termination by us alone due to the need for clinical trials, we will be granted an exclusive license under certain intellectual property of Sandoz AG to develop and commercialize the particular product. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. For some products, if Sandoz AG terminates the 2006 Sandoz Collaboration Agreement due to our uncured breach or bankruptcy, or if there is a termination by us alone due to the need for clinical trials, Sandoz AG would retain the exclusive right to develop and commercialize the applicable product. In that event, we would no longer have any influence over the development or commercialization strategy of such product. In addition, for other products, if Sandoz AG terminates due to our uncured breach or bankruptcy, Sandoz AG retains a right to license certain of our intellectual property without the obligation to make any additional payments for such licenses. For certain products, if the 2006 Sandoz Collaboration Agreement is terminated other than due to our uncured breach or bankruptcy, neither party will have a license to the other party's intellectual property. In that event, we would need to expand our internal capabilities or enter into another collaboration, which, if we were able to do so, could cause significant delays that could prevent us from completing the development and commercialization of such product. Any alternative collaboration could also be on less favorable terms to us. Accordingly, if the 2006 Sandoz Collaboration Agreement is terminated, our introduction of certain products may be significantly delayed, or our revenue may be significantly reduced, either of which could have a material adverse effect on our business.

Under our collaboration agreement, we are dependent upon Sandoz AG to successfully continue to commercialize GLATOPA 20 mg/mL and GLATOPA 40 mg/mL. We do not fully control Sandoz AG's commercialization activities or the resources it allocates to our products. While the 2006 Sandoz Collaboration Agreement contemplates joint decision making and alignment, our interests and Sandoz AG's interests may differ or conflict from time-to-time or we may disagree with Sandoz AG's level of effort or resource allocation. Sandoz AG may internally prioritize our products and product candidates differently

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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 negatively impact our ability to work effectively with one another. If these events were to occur, our business would be adversely affected.

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

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

If the CSL License Agreement were terminated and we had the right to continue the research, development, and commercialization of one or more terminated products, to fully exercise that right, we would need to expand our internal capabilities or enter into another collaboration, which, if we were able to do so, could cause significant delays that could prevent us from commercializing those products. Any alternative collaboration could be on less favorable terms to us. In

addition, we may need to seek additional financing to support the research, development and commercialization of any terminated products, or alternatively we may decide to discontinue one or more terminated products, which could have a material adverse effect on our business. If the CSL License Agreement were terminated and CSL had the right to continue the development and commercialization of one or more terminated products, we would have no influence or input into those activities.

Under the CSL License Agreement, we are dependent upon CSL to successfully perform its responsibilities and activities, including the research, development and commercialization of M230 and research on other Fc multimer proteins. We do not control CSL's execution of its responsibilities or the resources it allocates to our products and product candidates. Our interests and CSL's interests may differ or conflict from time to time, or we may disagree with CSL's level of effort or resource allocation. CSL may internally prioritize our products and product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally execute its responsibilities or activities. If these events were to occur, our business would be adversely affected.

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

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

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

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

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



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

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

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

Since many of our product candidates are developed under collaborations or licenses with third parties, we do not have sole decision making authority with respect to commercialization or development of those product candidates. We have built relationships and work collaboratively with our third-party collaborators and manufacturers to ensure the success of our development and commercialization efforts. A significant change in the senior management team, a change in the financial condition or a change in the business operations, including a change in control or internal corporate restructuring, of any of our collaboration partners or third-party manufacturers, could result in delayed timelines on our products. In addition, we may have to re-establish working relationships and familiarize new counterparts with our products and business. Any such change may result in the collaboration partner or third party manufacturer internally re-prioritizing our programs or decreasing resources or funding allocated to support our programs. Changes with respect to any of our collaborators may negatively impact our business operations.

### **General Company Related Risks**

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

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

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

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

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

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

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- 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 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 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;
- 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, or changes in our development or commercialization strategy for wholly-owned product candidates;
- 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

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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            | <a href="#">Third Amended and Restated Certificate of Incorporation.</a>   | S-3                          | 3.1         | 4/30/2013            | 333-188227      |
| 3.2            | <a href="#">Certificate of Amendment to Third Amended and Restated Certificate of Incorporation of Momenta Pharmaceuticals, Inc.</a>                                       | 8-K                          | 3.1         | 1/30/2019            | 000-50797       |
| 3.3            | <a href="#">Fourth Amended and Restated By-Laws of the Registrant, adopted on March 14, 2017.</a>  | 8-K                          | 3.1         | 3/17/2017            | 000-50797       |
| *#10.1         | <a href="#">Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan, as amended and restated.</a>  |                              |             |                      |                 |
| *31.1          | <a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>  |                              |             |                      |                 |
| *31.2          | <a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>  |                              |             |                      |                 |
| **32.1         | <a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>                            |                              |             |                      |                 |
| *101.INS       | Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are not embedded within the Inline XBRL document. |                              |             |                      |                 |
| *101.SCH       | Inline XBRL Taxonomy Extension Schema Document.  |                              |             |                      |                 |
| *101.CAL       | Inline XBRL Taxonomy Extension Calculation Linkbase Document.  |                              |             |                      |                 |
| *101.DEF       | Inline XBRL Taxonomy Extension Definition Linkbase Document.   |                              |             |                      |                 |
| *101.LAB       | Inline XBRL Taxonomy Extension Label Linkbase Document.  |                              |             |                      |                 |
| *101.PRE       | Inline XBRL Taxonomy Extension Presentation Linkbase Document.   |                              |             |                      |                 |
| *104           | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)   |                              |             |                      |                 |

\* 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 June 30, 2019, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at June 30, 2019 and December 31, 2018, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2019 and 2018, (iii) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2019 and 2018, (iv) the Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2019 and 2018, and (v) Notes to Unaudited, Condensed Consolidated Financial Statements.

**SIGNATURES**

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

Momenta Pharmaceuticals, Inc.

Date: August 7, 2019

By: /s/ Craig A. Wheeler

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

Date: August 7, 2019

By: /s/ Michelle Robertson

Michelle Robertson, Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

**MOMENTA PHARMACEUTICALS, INC.**  
**2013 INCENTIVE AWARD PLAN**  
**(as amended and restated)**

**ARTICLE 1.**  
**PURPOSE**

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

**ARTICLE 2.**  
**DEFINITIONS AND CONSTRUCTION**

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

2.1 “*Administrator*” shall mean the entity that conducts the general administration of the Plan as provided in Article 12. With reference to the duties of the Committee under the Plan which have been delegated to one or more persons pursuant to Section 12.6, or as to which the Board has assumed, the term “*Administrator*” shall refer to such person(s) unless the Committee or the Board has revoked such delegation or the Board has terminated the assumption of such duties.

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

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

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

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

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

2.7 “*Board*” shall mean the Board of Directors of the Company.

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

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any “*person*” or related “*group*” of “*persons*” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a “*person*” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.8(a) or 2.8(c)) whose election by the Board or

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nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

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

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

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

(d) The liquidation or dissolution of the Company.

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

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

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

2.10 "*Committee*" shall mean the Compensation Committee of the Board, or another committee or subcommittee of the Board or the Compensation Committee, appointed as provided in Section 12.1.

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

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

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

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

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

2.16 "*Dividend Equivalent*" shall mean a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 9.2.

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

2.18 “Effective Date” shall mean March 5, 2013.

2.19 “Eligible Individual” shall mean any person who is an Employee, a Consultant or a Non-Employee Director, as determined by the Committee.

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

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

2.22 “Exchange Act” shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.23 “Expiration Date” shall have the meaning given to such term in Section 13.1.

2.24 “Fair Market Value” shall mean, as of any given date, the value of a Share determined as follows:

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

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

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

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

2.27 “Holder” shall mean a person who has been granted an Award.

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

2.29 “Non-Employee Director” shall mean a Director of the Company who is not an Employee.

2.30 “Non-Employee Director Equity Compensation Policy” shall have the meaning set forth in Section 4.6.

2.31 “Non-Qualified Stock Option” shall mean an Option that is not an Incentive Stock Option.

2.32 “Option” shall mean a right to purchase Shares at a specified exercise price, granted under Article 5. An Option shall be either a Non-Qualified Stock Option or an Incentive Stock Option; *provided, however*, that Options granted to Non-Employee Directors and Consultants shall only be Non-Qualified Stock Options.

2.33 “Option Term” shall have the meaning set forth in Section 5.4.

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

2.35 “Performance Award” shall mean a cash bonus award, stock bonus award, performance award or incentive award that is paid in cash, Shares or a combination of both, awarded under Section 9.1.



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

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

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

2.37 “*Performance Goals*” shall mean, for a Performance Period, one or more goals established in writing by the Administrator for the Performance Period based upon one or more Performance Criteria. Depending on the Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of a Subsidiary, division, business unit, or an individual.

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

2.39 “*Performance Stock Unit*” shall mean a Performance Award awarded under Section 9.1 which is denominated in units of value including dollar value of Shares.

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

2.41 “*Plan*” shall have the meaning set forth in Article 1.

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

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

2.44 “*Restricted Stock*” shall mean Common Stock awarded under Article 7 that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase.

2.45 “*Restricted Stock Units*” shall mean the right to receive Shares awarded under Article 8.

2.46 “*Securities Act*” shall mean the Securities Act of 1933, as amended.

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2.47 “Shares” shall mean shares of Common Stock.

2.48 “Stock Appreciation Right” shall mean a stock appreciation right granted under Article 10.

2.49 “Stock Appreciation Right Term” shall have the meaning set forth in Section 10.4.

2.50 “Stock Payment” shall mean (a) a payment in the form of Shares, or (b) an option or other right to purchase Shares, as part of a bonus, deferred compensation or other arrangement, awarded under Section 9.3.

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

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

2.53 “Termination of Service” shall mean:

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

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

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

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

### ARTICLE 3. SHARES SUBJECT TO THE PLAN

#### 3.1 *Number of Shares.*

(a) Subject to adjustment as provided in Section 3.1(b) and Section 13.2, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is the sum of (i) 21,200,000 Shares, plus (ii) the number of Shares subject to any option or stock appreciation right granted under a Prior Plan on or prior to December 31, 2012 to the extent such Shares become available for issuance under this Plan pursuant to Section 3.1(b) below thereafter, plus (iii) (A) 1.35 Shares multiplied by the number of Shares subject to any award granted under a Prior Plan on or prior to December 31, 2012 other than an option or stock appreciation right to the extent such Shares became available for issuance under this Plan pursuant to Section 3.1(b) below prior to June 9, 2015 and (B) 1.67 Shares multiplied by the number of Shares subject to any award granted under a Prior Plan on or prior to December 31, 2012 to the extent such Shares become available for issuance under this

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Plan pursuant to Section 3.1(b) below on or after June 9, 2015; provided, however, that in no event shall the number of Shares which shall become available for issuance or transfer pursuant to Awards under the Plan pursuant to clauses (ii) and (iii) above exceed an aggregate of 5,288,836 Shares. Any Shares that are subject to Awards of Options or Stock Appreciation Rights granted under the Plan shall be counted against this limit as one (1) Share for every one (1) Share granted. Any Shares that are subject to Awards granted under the Plan that are other than Options or Stock Appreciation Rights shall be counted against this limit as 1.35 Shares if the Award is granted prior to June 9, 2015 and as 1.67 Shares if the Award is granted on or after June 9, 2015 for every one (1) Share granted. After the date that the Plan is approved by the Company's shareholders, no awards may be granted under any Prior Plan, however, any awards under any Prior Plan that are outstanding as of the date that the Plan is approved by the Company's shareholders shall continue to be subject to the terms and conditions of such Prior Plan. Notwithstanding anything in this Section 3.1 to the contrary, the number of Shares that may be issued or transferred pursuant to Awards under the Plan (including Incentive Stock Options) shall not exceed an aggregate of 26,488,836 Shares, subject to adjustment pursuant to Section 13.2.

(b) If (i) any Shares subject to an Award are forfeited or expire or an Award is settled for cash (in whole or in part), or (ii) after the Effective Date any Shares subject to an award granted under any Prior Plan on or prior to December 31, 2012 are forfeited or expire or an award granted under any Prior Plan on or prior to December 31, 2012 is settled for cash (in whole or in part), the Shares subject to such Award or award under the Prior Plan shall, to the extent of such forfeiture, expiration or cash settlement, again be available for Awards under the Plan, in accordance with Section 3.1(d) below. Notwithstanding anything to the contrary contained herein, the following Shares shall not be added to the Shares authorized for grant under Section 3.1(a) and shall not be available for future grants of Awards: (i) Shares tendered by a Holder or withheld by the Company in payment of the exercise price of an Option; (ii) Shares tendered by the Holder or withheld by the Company to satisfy any tax withholding obligation with respect to an Award; (iii) Shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the Stock Appreciation Right on exercise thereof; and (iv) Shares purchased on the open market with the cash proceeds from the exercise of Options. Any Shares repurchased by the Company under Section 7.4 at the same or lower price paid by the Holder so that such Shares are returned to the Company shall again be available for Awards. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan. Notwithstanding the provisions of this Section 3.1(b), no Shares may again be optioned, granted or awarded if such action would cause an Incentive Stock Option to fail to qualify as an incentive stock option under Section 422 of the Code.

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

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

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

3.3 *Limitation on Number of Shares Subject to Awards.* Notwithstanding any provision in the Plan to the contrary, and subject to Section 13.2, the maximum aggregate number of Shares with respect to one or more Awards that may be granted to any one person other than a Non-Employee Director during any calendar year shall be 2,500,000, the maximum aggregate number of Shares with respect to one or more Awards that may be granted to a Non-Employee Director during any calendar year shall be 100,000 and the maximum aggregate amount of cash that may be paid in cash to any one person during any calendar year with respect to one or more Awards initially payable in cash shall be five million dollars.

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**ARTICLE 4.**  
**GRANTING OF AWARDS**

4.1 *Participation.* The Administrator may, from time to time, select from among all Eligible Individuals, those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not be inconsistent with the requirements of the Plan. Except as provided in Section 4.6 regarding the grant of Awards pursuant to the Non-Employee Director Equity Compensation Policy, no Eligible Individual shall have any right to be granted an Award pursuant to the Plan.

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

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

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

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

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

4.7 *Stand-Alone and Tandem Awards.* Awards granted pursuant to the Plan may, in the sole discretion of the Administrator, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the Plan. Awards granted in addition to or in tandem with other Awards may be granted either at the same time as or at a different time from the grant of such other Awards.

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**ARTICLE 5.**  
**GRANTING OF OPTIONS**

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

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

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

5.4 *Option Term.* The term of each Option (the "Option Term") shall be set by the Administrator in its sole discretion; *provided, however*, that the Option Term shall not be more than ten (10) years from the date the Option is granted, or five (5) years from the date an Incentive Stock Option is granted to a Greater Than 10% Stockholder. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Options, which time period may not extend beyond the last day of the Option Term. Except as limited by the requirements of Section 409A, the Administrator may extend the Option Term of any outstanding Option, and may extend the time period during which vested Options may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 13.1, any other term or condition of such Option relating to such a Termination of Service.

5.5 *Option Vesting.*

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

(b) No portion of an Option which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the applicable Program, the Award Agreement evidencing the grant of an Option, or by action of the Administrator following the grant of the Option. Unless otherwise determined by the Administrator in the Award Agreement or by action of the Administrator following the grant of the Option, the portion of an Option that is unexercisable at a Holder's Termination of Service shall automatically expire thirty (30) days following such Termination of Service.

5.6 *Substitute Awards.* Notwithstanding the foregoing provisions of this Article 5 to the contrary, in the case of an Option that is a Substitute Award, the price per share of the Shares subject to such Option may be less than the Fair Market Value per share on the date of grant; *provided* that the excess of: (a) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the Shares subject to the Substitute Award, over (b) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

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**ARTICLE 6.**  
**EXERCISE OF OPTIONS**

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

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

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

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

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

(d) Full payment of the exercise price and applicable withholding taxes to the stock administrator of the Company for the Shares with respect to which the Option, or portion thereof, is exercised, in a manner permitted by 11.1 and 11.2.

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

**ARTICLE 7.**  
**AWARD OF RESTRICTED STOCK**

7.1 *Award of Restricted Stock.*

(a) The Administrator is authorized to grant Restricted Stock to Eligible Individuals, and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock, which terms and conditions shall not be inconsistent with the Plan, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate.

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

7.2 *Rights as Stockholders.* Subject to Section 7.4, upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all the rights of a stockholder with respect to said Shares, subject to the restrictions in the applicable Program or in each individual Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares; *provided, however,* that, in the sole discretion of the Administrator, any extraordinary distributions with respect to the Shares shall be subject to the restrictions set forth in Section 7.3. In addition, with respect to a share of Restricted Stock, dividends which are paid prior to vesting shall only be paid out to the Holder to the extent that the vesting conditions are subsequently satisfied and the share of Restricted Stock vests.

7.3 *Restrictions.* All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, in the terms of the applicable Program or in each individual Award Agreement, be subject to such restrictions and vesting requirements as the Administrator shall provide. Such restrictions may include, without limitation, restrictions concerning voting rights and transferability and such restrictions may lapse separately or in combination at such times and pursuant to such circumstances or based on such criteria as selected by the Administrator, including, without limitation, criteria based on the Holder's duration of

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employment, directorship or consultancy with the Company, the Performance Criteria, Company performance, individual performance or other criteria selected by the Administrator. By action taken after the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting of such Restricted Stock by removing any or all of the restrictions imposed by the terms of the applicable Program or Award Agreement. Restricted Stock may not be sold or encumbered until all restrictions are terminated or expire.

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

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

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

## **ARTICLE 8. AWARD OF RESTRICTED STOCK UNITS**

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

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

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

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

8.5 *Maturity and Payment.* At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units, which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted by the applicable Award Agreement); *provided* that, except as otherwise determined by the Administrator, set forth in any applicable Award Agreement, and subject to compliance with Section 409A of the Code, in no event shall the maturity date relating to each Restricted Stock Unit occur following the later of (a) the 15th day of the third month following the end of calendar year in which the applicable portion of the Restricted Stock Unit vests; or (b) the 15th day of the third month following the end of the Company's fiscal year in which the applicable portion of the Restricted Stock Unit vests. On the maturity date, the Company shall, subject to Section 11.4(e), transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously

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forfeited, or in the sole discretion of the Administrator, an amount in cash equal to the Fair Market Value of such Shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator.

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

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

## ARTICLE 9. AWARD OF PERFORMANCE AWARDS, DIVIDEND EQUIVALENTS AND STOCK PAYMENTS

### 9.1 *Performance Awards.*

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

(b) Without limiting Section 9.1(a), the Administrator may grant Performance Awards to any Eligible Individual in the form of a cash bonus payable upon the attainment of objective Performance Goals, or such other criteria, whether or not objective, which are established by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator.

9.2 *Dividend Equivalents.* Dividend Equivalents may be granted by the Administrator based on dividends declared on the Common Stock, to be credited as of dividend payment dates with respect to dividends with record dates that occur during the period between the date an Award is granted to a Holder and the date such Award vests, is exercised, is distributed or expires, as determined by the Administrator. Such Dividend Equivalents shall be converted to cash or additional Shares by such formula and at such time and subject to such restrictions and limitations as may be determined by the Administrator. In addition, Dividend Equivalents with respect to an Award (including, without limitation, an Option or Stock Appreciation Right) that are based on dividends paid prior to the vesting of such Award shall only be paid out to the Holder to the extent that the vesting conditions are subsequently satisfied and the Award vests.

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

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

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

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

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**ARTICLE 10.**  
**AWARD OF STOCK APPRECIATION RIGHTS**

10.1 *Grant of Stock Appreciation Rights.*

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

(b) A Stock Appreciation Right shall entitle the Holder (or other person entitled to exercise the Stock Appreciation Right pursuant to the Plan) to exercise all or a specified portion of the Stock Appreciation Right (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying the difference obtained by subtracting the exercise price per share of the Stock Appreciation Right from the Fair Market Value on the date of exercise of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right shall have been exercised, subject to any limitations the Administrator may impose. Except as described in (c) below, the exercise price per Share subject to each Stock Appreciation Right shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value on the date the Stock Appreciation Right is granted.

(c) Notwithstanding the foregoing provisions of Section 10.1(b) to the contrary, in the case of a Stock Appreciation Right that is a Substitute Award, the price per share of the Shares subject to such Stock Appreciation Right may be less than 100% of the Fair Market Value per share on the date of grant; *provided* that the excess of: (i) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the Shares subject to the Substitute Award, over (ii) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

10.2 *Stock Appreciation Right Vesting.*

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

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

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

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

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

(c) In the event that the Stock Appreciation Right shall be exercised pursuant to this Section 10.3 by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Stock Appreciation Right, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes to the stock administrator of the Company for the Shares with respect to which the Stock Appreciation Right, or portion thereof, is exercised, in a manner permitted by 11.1 and 11.2.

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10.4 *Stock Appreciation Right Term.* The term of each Stock Appreciation Right (the “*Stock Appreciation Right Term*”) shall be set by the Administrator in its sole discretion; *provided, however,* that the Stock Appreciation Right Term shall not be more than ten (10) years from the date the Stock Appreciation Right is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Stock Appreciation Rights, which time period may not extend beyond the last day of the Stock Appreciation Right Term applicable to such Stock Appreciation Right. Except as limited by the requirements of Section 409A of the Code and regulations and rulings thereunder or the first sentence of this Section 10.4, the Administrator may extend the Stock Appreciation Right Term of any outstanding Stock Appreciation Right, and may extend the time period during which vested Stock Appreciation Rights may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 13.1, any other term or condition of such Stock Appreciation Right relating to such a Termination of Service.

10.5 *Payment.* Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 10 shall be in cash, Shares (based on its Fair Market Value as of the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

#### ARTICLE 11. ADDITIONAL TERMS OF AWARDS

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

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

#### 11.3 *Transferability of Awards.*

(a) Except as otherwise provided in Section 11.3(b) and 11.3(c):

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

(ii) No Award or interest or right therein shall be liable for the debts, contracts or engagements of the Holder or the Holder’s successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by Section 11.3(a)(i); and

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

(b) Notwithstanding Section 11.3(a), the Administrator, in its sole discretion, may determine to permit a Holder to transfer an Award other than an Incentive Stock Option to any one or more Permitted Transferees, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee other than by will or the laws of descent and distribution or pursuant to a DRO; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award); and (iii) the Holder and the Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer.

(c) Notwithstanding Section 11.3(a), a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Program or Award Agreement applicable to the Holder, except to the extent the Plan, the Program and the Award Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as the Holder's beneficiary with respect to more than 50% of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner. If no beneficiary has been designated or survives the Holder, payment shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; *provided* that the change or revocation is filed with the Administrator prior to the Holder's death.

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

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

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

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

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

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

11.5 *Forfeiture and Claw-Back Provisions.* Pursuant to its general authority to determine the terms and conditions applicable to Awards under the Plan, the Administrator shall have the right to provide, in an Award Agreement or otherwise, or to require a Holder to agree by separate written or electronic instrument, that: (i) any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of the Award, or upon the

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receipt or resale of any Shares underlying the Award, shall be paid to the Company, and (ii) the Award shall terminate and any unexercised portion of the Award (whether or not vested) shall be forfeited, if (x) a Termination of Service occurs prior to a specified date, or within a specified time period following receipt or exercise of the Award, or (y) the Holder at any time, or during a specified time period, engages in any activity in competition with the Company, or which is inimical, contrary or harmful to the interests of the Company, as further defined by the Administrator or (z) the Holder incurs a Termination of Service for “cause” (as such term is defined in the sole discretion of the Administrator, or as set forth in a written agreement relating to such Award between the Company and the Holder). All Awards (including any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of Applicable Law, including without limitation the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

11.6 *Prohibition on Repricing.* Subject to Section 13.2, the Administrator shall not, without the approval of the stockholders of the Company, (i) authorize the amendment of any outstanding Option or Stock Appreciation Right to reduce its price per share, or (ii) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares. Subject to Section 13.2, the Administrator shall have the authority, without the approval of the stockholders of the Company, to amend any outstanding Award to increase the price per share or to cancel and replace an Award with the grant of an Award having a price per share that is greater than or equal to the price per share of the original Award. Furthermore, for purposes of this Section 11.6, except in connection with a corporate transaction involving the Company (including, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination or exchange of shares), the terms of outstanding Awards may not be amended to reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights without the approval of the stockholders of the Company.

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

## ARTICLE 12. ADMINISTRATION

12.1 *Administrator.* The Committee (or another committee or a subcommittee of the Board assuming the functions of the Committee under the Plan) shall administer the Plan (except as otherwise permitted herein). To the extent necessary to comply with Rule 16b-3 of the Exchange Act, the Committee (or another committee or subcommittee of the Board assuming the functions of the Committee under the Plan) shall take all action with respect to such Awards, and the individuals taking such action shall consist solely of two or more Non-Employee Directors appointed by and holding office at the pleasure of the Board, each of whom is intended to qualify as a “non-employee director” as defined by Rule 16b-3 of the Exchange Act or any successor rule and, to the extent necessary with respect to Awards made under the Plan prior to November 2, 2017 that are intended to qualify as “performance-based compensation” as described in Section 162(m)(4)(C) of the Code prior to its repeal or are otherwise not subject to the deduction limitation of Section 162(m) of the Code because they were granted to an individual who was not considered a “covered employee” under Section 162(m) (such Awards, “*Section 162(m) Awards*”), an “outside director” for purposes of Section 162(m) of the Code. Additionally, to the extent required by Applicable Law, each of the individuals constituting the Committee (or another committee or subcommittee of the Board assuming the functions of the Committee under the Plan) shall be an “independent director” under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded. Notwithstanding the foregoing, any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section 12.1 or otherwise provided in any charter of the Committee. Except as may otherwise be provided in any charter of the Committee, appointment of Committee members shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written or electronic notice to the Board. Vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the terms “Administrator” and “Committee” as used in the Plan shall be deemed to refer to the Board and (b) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 12.6.

12.2 *Duties and Powers of Committee.* It shall be the duty of the Committee to conduct the general administration of the Plan in accordance with its provisions. The Committee shall have the power to interpret the Plan, the Program and the Award Agreement, and to adopt such rules for the administration, interpretation and application of the Plan as are not inconsistent therewith, to interpret, amend or revoke any such rules and to amend any Program or Award Agreement; *provided* that the rights or obligations of the Holder of the Award that is the subject of any such Program or Award Agreement are not affected adversely by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 11.5 or Section 13.10. Any such grant or award under the Plan need not be the same with respect to each Holder. Any such interpretations and rules with respect to Incentive Stock Options shall be consistent with the provisions of Section 422 of the Code. In its sole discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee under the Plan except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded are required to be determined in the sole discretion of the Committee.

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

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

- (a) Designate Eligible Individuals to receive Awards;
- (b) Determine the type or types of Awards to be granted to each Eligible Individual;
- (c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;
- (d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, purchase price, any Performance Criteria, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;
- (e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;
- (f) Prescribe the form of each Award Agreement, which need not be identical for each Holder;
- (g) Decide all other matters that must be determined in connection with an Award;
- (h) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;
- (i) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement;
- (j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan; and
- (k) Accelerate wholly or partially the vesting or lapse of restrictions of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects and Section 13.2.

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

12.6 *Delegation of Authority.* To the extent permitted by Applicable Law, the Board or Committee may from time to time delegate to a committee of one or more members of the Board or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to this Article 12; *provided, however*, that in no event

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shall an officer of the Company be delegated the authority to grant awards to, or amend awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act, (b) Covered Employees or (c) officers of the Company (or Directors) to whom authority to grant or amend Awards has been delegated hereunder; *provided, further*, that any delegation of administrative authority shall only be permitted to the extent it is permissible under Applicable Law. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation, and the Board may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 12.6 shall serve in such capacity at the pleasure of the Board and the Committee.

12.7 *Provisions Applicable to Section 162(m) Awards.* Notwithstanding any other provision of the Plan or any Award, each Section 162(m) Award shall be subject to any additional limitations as the Committee determines necessary for such Section 162(m) Award to qualify as “performance-based compensation” as described in Section 162(m)(4)(C) of the Code prior to its repeal or to otherwise be exempt from Section 162(m) pursuant to the transition relief rules in the Tax Cuts and Jobs Act of 2017, and to the extent any of the provisions of the Plan or any Award would cause any Section 162(m) Awards to fail to so qualify or to otherwise be so exempt, any such provisions shall not apply to such Awards to the extent necessary to ensure the continued qualification or exemption of such Awards. To the extent permitted by Applicable Law, the Plan and any such Awards shall be deemed amended to the extent necessary to conform to such requirements.

### ARTICLE 13. MISCELLANEOUS PROVISIONS

13.1 *Amendment, Suspension or Termination of the Plan.* Except as otherwise provided in this Section 13.1, the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board or the Committee. However, without approval of the Company’s stockholders given within twelve (12) months before or after the action by the Administrator, no action of the Administrator may, except as provided in Section 13.2, (a) increase the limits imposed in Section 3.1 on the maximum number of Shares which may be issued under the Plan, (b) reduce the price per share of any outstanding Option or Stock Appreciation Right granted under the Plan or take any action prohibited under Section 11.6, or (c) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares. Except as provided in Section 11.5 and Section 13.10, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, impair any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides. No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and notwithstanding anything herein to the contrary, in no event may any Award be granted under the Plan after March 13, 2029 (the “*Expiration Date*”). Any Awards that are outstanding on the Expiration Date shall remain in force according to the terms of the Plan and the applicable Award Agreement.

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

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

(b) In the event of any transaction or event described in Section 13.2(a) or any unusual or nonrecurring transactions or events affecting the Company, any Subsidiary of the Company, or the financial statements of the Company or any Subsidiary, or of changes in Applicable Law or accounting principles, the Administrator, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Holder’s request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Holder’s rights

(and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 13.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder's rights, then such Award may be terminated by the Company without payment) or (B) the replacement of such Award with other rights or property selected by the Administrator, in its sole discretion, having an aggregate value not exceeding the amount that could have been attained upon the exercise of such Award or realization of the Holder's rights had such Award been currently exercisable or payable or fully vested;

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

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

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

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

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Section 13.2(a) and 13.2(b):

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

(ii) The Administrator shall make such equitable adjustments, if any, as the Administrator, in its sole discretion, may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in 3.1 and 3.3 on the maximum number and kind of Shares which may be issued under the Plan, adjustments of the Award Limit, and adjustments of the manner in which Shares subject to Full Value Awards will be counted). The adjustments provided under this Section 13.2(c) shall be nondiscretionary and shall be final and binding on the affected Holder and the Company.

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

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

(f) For the purposes of this Section 13.2, an Award shall be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); *provided, however*, that if such consideration received in the Change in Control was not solely common stock of the successor corporation or its parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Award, for each Share subject to an Award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per-share consideration received by holders of Common Stock in the Change in Control.

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

(h) No adjustment or action described in this Section 13.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to violate Section 422(b)(1) of the Code.

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Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 or violate the exemptive conditions of Rule 16b-3 unless the Administrator determines that the Award is not to comply with such exemptive conditions.

(i) The existence of the Plan, the Program, the Award Agreement and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(j) No action shall be taken under this Section 13.2 which shall cause an Award to fail to be exempt from or comply with Section 409A of the Code or the Treasury Regulations thereunder.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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## CERTIFICATION

I, Craig A. Wheeler, certify that:

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

Dated: August 7, 2019

/s/ Craig A. Wheeler

Craig A. Wheeler

President and Chief Executive Officer

## CERTIFICATION

I, Michelle Robertson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.
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Dated: August 7, 2019

/s/ Michelle Robertson

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Michelle Robertson

Senior Vice President and Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Michelle Robertson, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

Dated: August 7, 2019

/s/ Craig A. Wheeler  
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Craig A. Wheeler  
President and Chief Executive Officer

Dated: August 7, 2019

/s/ Michelle Robertson  
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Michelle Robertson  
Senior Vice President and Chief Financial Officer