MOMENTA PHARMACEUTICALS INC
Form 10-K
February 22, 2019
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 000-50797
MOMENTA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	04-3561634
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

301 Binney Street, Cambridge, Massachusetts 02142
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (617) 491-9700
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ
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 þ No o
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes þ No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o
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. (Check one):

Large accelerated filer	þ	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
Emerging growth company	o		

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 Section13(a) of the Exchange Act. o

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 29, 2018, based on $20.45 per share, the last reported sale price of Common Stock on The Nasdaq Global Select Market on that date, was $1,577.3 million.

As of February 11, 2019, the registrant had 98,509,095 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the information required by Part III of Form 10-K will appear in the registrant's definitive Proxy Statement on Schedule 14A for its 2019 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

Table of Contents

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this Annual Report on Form 10-K 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," "hope," "likely," "opportunity," "pursue," "target," "project," "goal," "objective," "plan," "potential," "predict," "might," "estimate," "expect," "intend," "may," "seek", "should," "will," "would," "look forward" 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 immune-mediated diseases, including M281, M254 and M230 and the advancement of our late stage biosimilar candidates, M923 and M710; the use, efficacy, safety, potency, convenience, differentiation and commercial potential of our products and product candidates; design, timing and goals of clinical trials and the availability, timing and announcement of data and results; estimates of incidence of disease and patient populations, market potential and acceptance of our products and product candidates; the timing of regulatory filings, reviews and approvals; our expectations regarding the development and utility of our products and product candidates; development timelines for our product candidates; development, manufacture and commercialization of our products and product candidates; efforts to seek and manage relationships with collaboration partners, including without limitation for our novel therapeutic and biosimilar programs; the timing of launch of products and product candidates; market share and product revenues of our products and product candidates, including GLATOPA and Enoxaparin Sodium Injection; the timing, merits, strategy, impact and outcome of, and decisions regarding, legal proceedings; timing of biosimilar market formation; collaboration revenues and research and development revenues; manufacturing; 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; future capital requirements; reliance on our collaboration partners and other third parties; the competitive landscape; changes in, impact of and compliance with laws, rules and regulations; product reimbursement policies and trends; pricing of pharmaceutical products, including our products and product candidates; our stock price; our intellectual property strategy and position; sufficiency of insurance; attracting and retaining qualified personnel; our internal controls and procedures; acquisitions or investments in companies, products and technologies; entering into collaboration and/or license arrangements; marketing plans; financing our planned operating and capital expenditure; the terms and conditions of our facility leases; materials used in our research and development; dilution; royalty rates; and vesting of equity awards.

Any forward-looking statements in this Annual Report on Form 10-K 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 I, Item 1A. "Risk Factors" and discussed elsewhere in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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.

Table of Contents

PART I

Item 1. BUSINESS

OUR COMPANY

We are a biotechnology company focused on the discovery and development of novel biologic therapies for the treatment of rare immune-mediated diseases. Our goal is to develop molecules that drive significant advances in the control over or cure of immune-driven disease. To do this, we draw on our strong analytic heritage to interrogate immune biology to identify and validate high-priority targets. We then use our protein design expertise to refine the structure of our biological product candidates to optimize their potency and pharmacokinetics, while minimizing potential toxicities.

Our initial focus in immune biology has been to explore the interaction between antibodies, which are components of the humoral immune system, and the receptors which bind to the fragment crystallizable (Fc) region of antibodies and modulate the immune cascade. Our objective is to reduce immune driven tissue damage resulting from autoimmune disease. Specifically, we have been working with the Fc gamma receptor system which controls immune activation, and the neonatal Fc receptor (FcRn) system which recycles immunoglobulin G (IgG) to preserve its half-life. This work has led to three programs currently in clinical development, all of which have shown high potency against their respective targets in preclinical studies, and all with unique, differentiated and carefully designed biologic structures. The targets our programs modulate have the potential to impact core areas of humoral immune activation, and therefore we believe our programs have the potential to treat a variety of immune-mediated disorders.

Our research platform continues to develop additional programs to build our pipeline. We have two areas of focused research activities. The first area of focus is to continue to explore immune biology, expanding our efforts beyond the Fc gamma and FcRn systems. This effort has yielded several promising leads which we hope to add to our development pipeline in the next two years.

The second area of focus seeks to exploit the properties of our uniquely designed product candidates to create molecules that more effectively modulate established targets. This effort seeks to reduce program risk by pursuing well known biology with well-engineered biologics. We have two areas of focus, based on two of our technologies used for programs in the clinic:

1. Sialylation Platform - We have optimized our tools for the terminal sialylation of glycans attached to biologic molecules during our development of M254, our investigational tetra-sialylated IgG program now in the clinic. This technology can be used for the sialylation of other biologics. Most notably, this technology can be used to create effective sialylation on recombinant versions of blood proteins. This approach has dramatically increased their observed half-life and we believe could enable recombinant versions of these proteins, if successfully developed and approved, to become viable products.
2. SIFbody Platform - We are seeking to take advantage of the enhanced Fc gamma receptor binding we have seen in our M230 trimer program to create more potent versions of antibodies which activate the immune system through their Fc signaling and binding. We have observed significant enhancements in potency in laboratory models using CD38 SIFbody molecules compared to existing marketed CD38 antibodies. There are over 40 marketed products whose mechanisms are driven by their Fc activities and which we believe may be enhanced with this technology.

We believe both of these platforms have the potential to yield multiple programs for our own, or potential collaboration partner's, pipelines in the coming years.

Our Restructuring and Legacy Business

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.

4

Table of Contents

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's sales of GLATOPA, our generic version of COPAXONE, can generate cash flow to help fund our novel pipeline. We have also retained our wholly owned HUMIRA biosimilar, which is fully developed and for which we are ready to submit an application for approval, subject to finalization of our commercialization strategy. In addition, we are developing our EYLEA biosimilar, in collaboration with Mylan Ireland Limited, or Mylan, a wholly-owned indirect subsidiary of Mylan N.V., which is currently in a pivotal clinical trial in patients. We believe both of these programs have the potential to generate revenue in the 2023 time frame to help fund our novel portfolio. Pursuant to our collaboration agreement with Mylan, we have delivered formal notice of our termination of participation in all other biosimilar programs. 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.

Today, we have two product development areas: Novel Therapeutic Candidates and Legacy Products, which include biosimilars and complex generics. A summary of our programs in each area is set forth below.

Novel Therapeutics

Our Approach

We believe that dramatic progress in the treatment of autoimmune disease can be achieved through a combination of focused research which provides a deep understanding of the pathways of the immune system and a careful design of biologic therapeutics that optimally interact with and influence these pathways. Our approach to immune biology has yielded insights into the interactions of antibodies and the Fc receptors that modulate the immune system, leading to three programs we have in the clinic. Our deep experience in protein design has yielded what we believe are best in class drug candidates. We are currently working to expand our research, and our portfolio of product candidates, into additional areas of immune biology.

Autoimmune Diseases

Many autoimmune diseases are characterized by the formation of autoantibodies that bind self-antigens to form immune complexes. These immune complexes can recruit and activate immune cells leading to tissue inflammation and damage. Few therapeutic agents exist today that interfere directly with these autoantibodies or immune complex-immune cell activation processes, or that effectively modulate the immune cascades that result. The most commonly used treatments for autoantibody-

Table of Contents

driven disease are systemic immunosuppressants, which do not specifically target disease pathogenesis and which carry significant safety risks such as opportunistic infection and cancer. In addition to these treatments, intravenous immunoglobulin (IVIg), a therapeutic drug product that contains pooled IgG antibodies purified from blood plasma may be used to treat several inflammatory diseases. We believe that, despite currently available agents that do offer some relief for patients, there is an unmet medical need in patients with immune-mediated diseases.

There are approximately 45 rare autoimmune disorders driven by autoantibodies, and we estimate there are one to two million patients in the United States with these rare disorders. We are developing therapeutics for autoimmune diseases with a focus on these diseases. Initially we have applied our complex systems analysis and biological protein engineering platforms to develop an improved IVIg. We utilized our proprietary sialylation technology, a method to add sialic acid to protein, to create M254, a high potency alternative to IVIg that we believe improves upon the limitations of that therapeutic approach. By gaining a deeper understanding of IVIg and immune complex driven autoimmune diseases, we have designed two novel recombinant therapeutic candidates, M281 and M230, to leverage what we believe are key biologies associated with autoimmune diseases. The discovery of these candidates is based on our analysis of the role of the Fc region of IgG autoantibodies in maintaining persistence in circulation and in mediating tissue damage and inflammation in rare autoimmune diseases. The design of these agents is based on our expertise in biological protein engineering and proprietary Fc multimerization technology.

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.

Our Programs

M281 - Anti-FcRn Candidate

M281 is a fully-human anti-neonatal Fc receptor (FcRn), aglycosylated immunoglobulin G, or IgG1, monoclonal antibody, designed to reduce circulating IgG antibodies by completely blocking endogenous IgG recycling via FcRn. M281 has exhibited high affinity to human and non-human FcRn in nonclinical studies and shown selective induction of human and non-human IgG clearance. Based on this data, we believe M281 has the potential for use as an acute and chronic/intermittent therapies in a broad range of autoantibody driven disease.

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 results of the Phase 1 study were published on November 7, 2018. A total of 50 patients were enrolled in both the single ascending dose and multiple ascending dose 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.

In the fourth quarter of 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. We estimate that there are approximately 55,000 patients in the United States with gMG and approximately 4,000 to 8,000 patients in the United States with HDFN.

M230 (CSL730) - Recombinant Fc Multimer Candidate

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

Pursuant to the License and Option Agreement, effective February 17, 2017, with CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited, we granted CSL an exclusive worldwide license to research, develop, manufacture and commercialize M230. In August 2017, we exercised our 50% co-funding option, which is discussed further in Note 9 " Collaboration and License Agreements - CSL License and Option Agreement ". The terms of our CSL collaboration are further discussed below under "Collaborations and Licenses—CSL."

CSL's Phase I study in healthy volunteers to evaluate the safety and tolerability of M230 is ongoing and is targeted for completion in 2019.

Table of Contents

M254 - Hyper-sialylated IgG Candidate

M254 is a hyper-sialylated 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 idiopathic thrombocytopenic purpura and chronic inflammatory demyelinating polyneuropathy. 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. If approved, we believe M254 has the potential to remediate the limitations of IVIg because sialylation of the Fc region of IgG has been seen to augment the anti-inflammatory attributes of IVIg.

We have completed our IND-enabling toxicology study and initiated a Phase 1/2 proof of concept clinical study in normal, healthy volunteers and patients with idiopathic thrombocytopenic purpura (ITP) in early 2019. We estimate that chronic ITP affects approximately 30,000 to 40,000 patients in the United States. We continue to identify and explore potential collaboration opportunities to further develop and commercialize this product candidate.

Legacy Products

Our Approach

In October 2018, we announced and later completed a restructuring of our business in order to focus the majority of our resources on our promising new drug pipeline. Prior to that restructuring, we were heavily involved in developing a portfolio of biosimilar and complex generic products. In connection with the restructuring, we have terminated all development of early stage biosimilar and complex generic programs, and have only retained our late stage or commercial products in these business areas. We delivered a formal notice of partial termination to Mylan, our biosimilar partner, in November 2018, as provided for in our collaboration agreement with Mylan, enabling us to exit ongoing early stage programs. The programs remaining in our portfolio are our wholly owned biosimilar to HUMIRA, a biosimilar program for ELYEA (the only remaining program in our Mylan collaboration), which is currently in Phase 3, and our marketed complex generics, GLATOPA, a generic to COPAXONE, and Enoxaparin Sodium Injection, a generic to LOVENOX. Both GLATOPA and Enoxaparin Sodium Injection are marketed by our collaboration partner, Sandoz. The retained programs, with the exception of Enoxaparin Sodium Injection for which we expect minimal revenues, provide the potential for revenue to help fund our growing novel drug pipeline and, with the majority of development activities behind us, do not require a large staff to support.

Our Programs

M923—Biosimilar HUMIRA® (adalimumab) Candidate

We are developing M923 as a biosimilar of HUMIRA. HUMIRA is a monoclonal antibody that can bind to a substance in the body known as tumor necrosis factor, or TNF, thereby inhibiting the known effect of TNF as a potent mediator of inflammation. HUMIRA is indicated for the treatment of patients with rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis, among other diseases. HUMIRA is the largest selling therapeutic in the world. HUMIRA is marketed globally by AbbVie Inc, or AbbVie. Based on the settlement agreements entered into by AbbVie, with respect to other biosimilar candidates, we expect that U.S. market formation for biosimilar versions of HUMIRA will likely be in the 2023 time frame, subject to market approval, patent considerations and litigation timelines.

In November 2016, we announced that the confirmatory, randomized, double-blind, multi-center, global study evaluating the efficacy, safety and immunogenicity of M923 in adult patients with moderate-to-severe chronic plaque psoriasis met its primary endpoint. Patients received up to 48 weeks of treatment with M923, HUMIRA, or HUMIRA alternating with M923. The proportion of subjects who achieved the primary endpoint of 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 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 following approval by the European Medicines Agency. We are working on our commercialization strategy, including identifying a commercialization partner for this product candidate.We plan to submit a biologics license application (BLA) for M923 with the FDA and a market authorization application (MAA)

in the European Union, subject to finalization of our commercialization strategy.
AbbVie reported approximately $19.9 billion in worldwide sales of HUMIRA in 2018, including approximately $13.7 billion in the United States.

Table of Contents

M710—Biosimilar EYLEA® (aflibercept) Candidate

M710 is being developed as a biosimilar of EYLEA. EYLEA is the market leading vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR) in patients with DME.

M710 is being developed in collaboration with Mylan. Under our collaboration agreement, we and Mylan share equally costs and profits (losses) for M710. We and Mylan will share development and manufacturing responsibilities, and Mylan will lead commercialization of M710, if approved. The terms of our Mylan collaboration are further discussed below under "Collaborations and Licenses—Mylan."

In August 2018, Mylan initiated dosing of patients in the United States in our pivotal clinical trial. This trial is a 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, patent considerations and litigation timelines, we expect U.S. market formation for biosimilar versions of EYLEA to be in the 2023 timeframe.

EYLEA is marketed by Regeneron Pharmaceuticals, Inc. in the United States and by Bayer HealthCare in the EU and rest of the world. Regeneron Pharmaceuticals, Inc. reported approximately $6.7 billion in worldwide sales of EYLEA in 2018, including $4.1 billion in the United States.

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

GLATOPA 20 mg/mL is a generic version of once-daily COPAXONE 20 mg/mL indicated for the treatment of patients with relapsing forms of multiple sclerosis, a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. COPAXONE is available in both a once-daily 20 mg/mL formulation, which was approved by the FDA in 1996, and a three-times-weekly 40 mg/mL formulation, which was approved in January 2014. COPAXONE is marketed in the United States by Teva Neuroscience, Inc., a subsidiary of Teva Pharmaceutical Industries, Ltd.

GLATOPA 20 mg/mL was approved by the FDA in April 2015 and was launched in June 2015. GLATOPA 20 mg/mL, the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE, was developed and is being commercialized in collaboration with Sandoz, the generic pharmaceuticals division of Novartis Pharma AG, or Novartis. Under our collaboration agreement, Sandoz is responsible for commercialization of GLATOPA 20 mg/mL, and we earn 50% of contractually defined profits on GLATOPA 20 mg/mL sales. The terms of our Sandoz collaboration for GLATOPA 20 mg/mL are further discussed below under "Collaborations and Licenses—Sandoz."

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

GLATOPA 40 mg/mL is a generic version of three-times-weekly COPAXONE 40 mg/mL. GLATOPA 40 mg/mL was developed in collaboration with Sandoz. Under our collaboration agreement, Sandoz is responsible for commercialization of GLATOPA 40 mg/mL and we will earn 50% of contractually defined profits on GLATOPA 40 mg/mL sales. The terms of our Sandoz collaboration for GLATOPA 40 mg/mL are further discussed below under "Collaborations and Licenses—Sandoz."

We announced on February 13, 2018 that GLATOPA 40 mg/mL was approved by the FDA and was launched by our collaborator, Sandoz. Legal proceedings related to GLATOPA 40 mg/mL are described below under "Item 3. Legal Proceedings -- GLATOPA 40 mg/mL-Related Proceedings."

GLATOPA refers to GLATOPA 20 mg/mL and our generic product for three-times-weekly COPAXONE 40 mg/mL, GLATOPA 40 mg/mL, collectively.

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 pricing or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue. Since Sandoz’s launch of GLATOPA 40mg/mL in February 2018, Sandoz has encountered aggressive pricing and contracting tactics from competitors and

as a result we expect modest revenues for this product in the future.

Table of Contents

As of the end of 2018, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 84% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed. We estimate that the number of prescriptions for GLATOPA 20 mg/mL currently represents approximately 40% of the once-daily 20 mg/mL U.S. glatiramer acetate market. Teva reported $1.7 billion and $3.0 billion in U.S. sales of COPAXONE (combined 20 mg/mL and 40 mg/mL) in 2018 and 2017, respectively.

Enoxaparin Sodium Injection—Generic LOVENOX®

Enoxaparin Sodium Injection is a generic version of LOVENOX indicated for the prevention and treatment of deep vein thrombosis and to support the treatment of acute coronary syndromes. LOVENOX is marketed in the United States by Sanofi. Our Enoxaparin Sodium Injection was developed and is being commercialized in the United States in collaboration with Sandoz. Under our amended 2003 collaboration agreement with Sandoz, or the 2003 Sandoz Agreement, Sandoz is responsible for commercialization of Enoxaparin Sodium Injection and we earn 50% of contractually defined profits on Enoxaparin Sodium Injection sales.

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 future revenues from Sandoz' sales of Enoxaparin Sodium Injection, if any, to be minimal.

Legal Proceedings related to Enoxaparin Sodium Injection are described under "Item 3. Legal Proceedings-Enoxaparin Sodium Injection-Related Proceedings".

Collaborations and Licenses

CSL

We and CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited, entered into a License and Option Agreement, or the CSL License Agreement, effective February 17, 2017, pursuant to which we 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 CSL License Agreement also provides, on an exclusive basis, for us 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.

Pursuant to the CSL License Agreement, CSL paid us a non-refundable upfront payment of $50 million. On August 28, 2017, we exercised our 50% co-funding option. This exercise allows us to participate in a cost-and-profit sharing arrangement, under which we fund 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 for M230 and a named research stage product should that enter development and be commercialized. For the development and commercialization of M230 we are 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 one enter development. The contract allows us to opt-out of the program in the future at our discretion. If we were to do so, our 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 we are eligible would be increased by up to $252.5 million, depending on the timing of our opt-out decision.

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

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

The term of the CSL License Agreement commenced on February 17, 2017 and continues until the later of (i) the expiration of all payment obligations with respect to products under the CSL License Agreement, (ii) the date on which we are no longer co-funding development or commercialization of any products and (iii) the date on which we and CSL are not otherwise collaborating on the development and commercialization of products or product candidates. CSL may terminate the CSL License Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. We may terminate the CSL License Agreement under certain circumstances related to the development of M230

Table of Contents

and if no activities are being conducted under the CSL License Agreement. Either party may terminate the CSL License Agreement (i) on a product-by-product basis if certain patent challenges are made, (ii) on a product-by-product basis for material breaches, or (iii) due to the other party's bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, 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.

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

Mylan

We and Mylan, entered into a collaboration agreement, or the Mylan Collaboration Agreement, effective February 9, 2016, pursuant to which we and Mylan agreed to collaborate exclusively, on a worldwide basis, to develop, manufacture and commercialize six of our biosimilar candidates, including M834 and M710.

In November 2018, we delivered a formal notice of the partial termination of the Mylan Collaboration Agreement with respect to five of our collaboration programs, including M834, a proposed biosimilar to ORENCIA. As a result, we will only continue to advance our late-stage biosimilar candidate M710, our proposed biosimilar to EYLEA under the Mylan Collaboration Agreement.

Under the terms of the Mylan Collaboration Agreement, Mylan paid us a non-refundable upfront payment of $45 million. In addition, we and Mylan agreed to share equally costs (including development, manufacturing, commercialization and certain legal expenses) and profits (losses) with respect to such product candidates, with Mylan funding its share of collaboration expenses incurred by us.

For our remaining product candidate, M710, we and Mylan both have the right to terminate the program at our own convenience. As with the five discontinued collaboration programs, if one party decides not to continue development, manufacture and commercialization of M710 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 it share of expenses for a pre-specified period, depending on the stage of the product at the time of termination.

Under the Mylan Collaboration Agreement, we granted Mylan an exclusive license under our intellectual property rights to develop, manufacture and commercialize the product candidates for all therapeutic indications, and Mylan has granted us a co-exclusive license under Mylan's intellectual property rights for us to perform our 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, or JSC, for such product candidates if we exercise our co-commercialization option described below. We and Mylan have established a joint steering committee, or JSC, consisting of an equal number of members from us 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) we will be primarily responsible for nonclinical development activities and initial clinical development activities for the product candidates; and regulatory activities for the 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 the 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. As provided in the Mylan Collaboration Agreement, Mylan will commercialize any approved products, with us having an option to co-commercialize, in a supporting commercial role, any approved products in the United States. The JSC will allocate 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 us 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 shall have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries.

Table of Contents

Sandoz

In 2006 and 2007, we entered into a series of agreements, including a collaboration and license agreement, as amended, or the 2006 Sandoz Collaboration Agreement, with Sandoz and a stock purchase agreement and an investor rights agreement with Novartis. Under the 2006 Sandoz Collaboration Agreement, we and Sandoz agreed to exclusively collaborate on the development and commercialization of GLATOPA, among other potential products. Costs, including development costs and the costs of clinical studies, are borne by the parties in varying proportions depending on the type of expense. For GLATOPA, we were generally responsible for all of the development costs in the United States. For GLATOPA outside of the United States, we shared development costs in proportion to our profit sharing interest, unless otherwise agreed. We are reimbursed at a contractual FTE rate for any full-time equivalent employee expenses as well as any external costs incurred in the development of products to the extent development costs are born by Sandoz. All commercialization costs are to be borne by Sandoz as they are incurred for all products.

Under the 2006 Sandoz Collaboration Agreement, as amended in November, 2017, Sandoz has granted us an exclusive license under its intellectual property rights, and we have granted an exclusive license under our know-how and data to the GLATOPA products and a non-exclusive license under our intellectual patent rights to develop and commercialize such products for all medical indications in the relevant regions. We have agreed to provide development and related services on a commercially reasonable best-efforts basis, which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. We have the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and which prepares and approves the annual collaboration plans. Sandoz is responsible for commercialization activities and exclusively distributes and markets the products.

The term of the 2006 Sandoz Collaboration Agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party pursuant to the provisions of the agreement. The 2006 Sandoz Collaboration Agreement may be terminated if either party breaches the 2006 Sandoz Collaboration Agreement or files for bankruptcy.

Sandoz commenced United States sales of GLATOPA 20 mg/mL in June 2015 and of GLATOPA 40 mg/mL in February 2018. Under the 2006 Sandoz Collaboration Agreement, we earn 50% of contractually defined profits on Sandoz' worldwide net sales of GLATOPA 20 mg/mL and of GLATOPA 40 mg/mL. Profits on net sales of GLATOPA are calculated by deducting from net sales the costs of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. With respect to GLATOPA, Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement, except for our FTE costs with respect to certain legal activities for GLATOPA; however, a portion of certain legal expenses, including any patent infringement damages, can be offset by Sandoz against the profit-sharing amounts in proportion to our 50% profit sharing interest. In 2015, we earned a $10 million regulatory milestone payment upon GLATOPA 20 mg/mL receiving sole FDA approval and an additional $10 million milestone payment upon the first commercial sale of GLATOPA 20 mg/mL. In July 2017, we earned a $10 million commercial milestone payment in connection with GLATOPA 20 mg/mL's being the sole FDA-approved generic of COPAXONE when earned and achieving a certain level of contractually defined profits in the United States, for which Sandoz was entitled to reduce our contractually defined profits by a corresponding amount. 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, we are no longer eligible to earn $80 million in future post-launch commercial milestones; however, we may still be eligible to receive up to $30 million in sales-based milestones for GLATOPA in the United States, although we believe that it is unlikely the performance based milestones will be achieved. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. Sandoz has agreed to indemnify us for various claims, and a certain portion of such costs may be offset against certain future payments received by us.

Patents and Property Rights

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology and product candidates, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology and product candidates that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Table of Contents

We license or own a patent portfolio of around 150 patent families, each of which includes United States patent applications and/or issued patents as well as foreign counterparts to certain of the United States patents and patent applications. Our patent portfolio includes issued or pending claims covering:

- composition of matter, methods of use, and methods of making novel therapeutics for autoimmune disease, including our novel product candidates such as M230, M281 and M254;
- composition of matter, methods of use, and methods of making certain novel low molecular weight heparins;
- methods and technologies for characterizing complex generics and biosimilars, including our biosimilar HUMIRA candidate;
- composition of matter and use of certain heparinases, heparinase variants and other enzymes; and
- methods and technologies for the analysis and synthesis of polysaccharides.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents. Moreover, any issued patent does not guarantee us the right to practice the patented technology or to commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of the term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our generic, biosimilar and novel products. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by confidentiality agreements with our employees, consultants, advisors, contractors and collaborators. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Manufacturing

We do not own or operate facilities for commercial scale manufacturing of our products. We do own a process development scale manufacturing facility used in the development of our biologics. While we have personnel with experience and expertise in manufacturing, as well as process development, analytical development, quality assurance and quality control, we rely on contract manufacturers and our collaboration partners for manufacturing and supply activities. Under the 2006 Sandoz Collaboration Agreement, Sandoz is responsible for commercial manufacture of GLATOPA. Under the Mylan Collaboration Agreement, Mylan is responsible for contracting with contract manufacturers for commercial supply for M710. Under the CSL License Agreement, CSL is responsible for manufacturing activities, except that we are responsible, at CSL's direction, for contracting with contract manufacturers for certain clinical supply of M230. We rely on third parties for the manufacture, process development, analytical development, quality assurance and quality control of all our solely-owned novel product candidates.

We have entered into various agreements with third party contractors for process development, analytical services and manufacturing. In each of our agreements with contractors, we retain ownership of our intellectual property and generally own and/or are assigned ownership of processes, developments, data, results and other intellectual property generated during the course of the performance of each agreement that primarily relate to our products. Where applicable, we are granted non-exclusive licenses to certain contractor intellectual property for purposes of exploiting

the products that are the subject of the agreement and in a few instances we grant non-exclusive licenses to the contract manufacturers for use outside of our product area. The agreements also typically contain provisions for both parties to terminate for material breach, bankruptcy and insolvency.

Table of Contents

Sales, Marketing and Distribution

We do not currently have any sales, marketing and distribution capabilities other than strategic sales and marketing expertise, nor do we currently have any plans to build a sales, marketing and distribution capability to support any of our products. While we have personnel with experience and expertise in sales and marketing, we rely on our collaboration partners for these activities. In order for us to commercialize any products we would have to either develop a sales, marketing and distribution infrastructure or collaborate or contract with third parties that have sales, marketing and distribution capabilities. Under the 2006 Sandoz Collaboration Agreement, Sandoz is responsible for commercializing GLATOPA. Under the Mylan Collaboration Agreement, we have an option to participate in the commercialization of products, in a supporting commercial role, with Mylan in the United States. Under the CSL License Agreement, CSL is responsible for commercialization of products and we have an option to co-promote products in the United States.

Regulatory and Legal Matters

Government authorities in the United States, at the federal, state and local level, the European Union and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and exporting and importing of products such as those we are developing.

United States Government Regulation

In the United States, the information that must be submitted to the FDA in order to obtain market approval of a new drug or biologic varies depending on whether the drug or biologic is a new product whose safety and effectiveness has not previously been demonstrated in humans, or a drug or biologic whose active ingredient(s) and certain other properties are the same as those of a previously approved drug or biologic, i.e., biosimilar. Approval of new drugs and biologics follows the new drug application, or NDA, and biologics license application, or BLA routes, respectively. A drug that claims to be the same as an already approved NDA drug may be able to file for approval under the ANDA approval pathway. Pursuant to the Biologics Price Competition and Innovation Act, or BPCI Act, a marketing application may also be submitted for a biosimilar to a biologic previously approved under a BLA seeking approval of the biosimilar under the abbreviated pathway established by Section 351(k) of the Public Health Service Act.

NDA and BLA Approval Processes for New Drugs and Biologics

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, and, in the case of biologics, also under the Public Health Service Act, and implementing regulations. The steps required before a new drug or biologic may be marketed in the United States include:

- completion of nonclinical laboratory tests, nonclinical studies and formulation studies under the FDA's good laboratory practices;
- completion of developmental chemistry, manufacturing and controls activities and manufacture under current Good Manufacturing Practices, or cGMP;
- submission to the FDA of an Investigational New Drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin and must include independent Institutional Review Board, or IRB, approval at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the investigational drug product for each indication or the safety, purity and potency of the biological product for its intended indication;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity or to meet standards designed to ensure the biologic's continued safety, purity and potency;
- satisfactory completion of FDA inspections of nonclinical and or clinical testing sites;
- satisfactory completion of an FDA Advisory Committee review, if applicable; and
- FDA review and approval of the NDA or BLA.

13

Table of Contents

Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as nonclinical studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical and stability data, to the FDA as part of the IND. An IND will automatically become effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects or patients in accordance with specific protocols and under the supervision of qualified investigators in accordance with good clinical practices, or GCPs. Each clinical trial protocol must be submitted to the FDA as part of the IND, and an IRB at each site where the study is conducted must also approve the study. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase 1 trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance, pharmacokinetics and pharmacodynamics. If feasible, Phase 1 studies also attempt to detect any early indication of a drug's potential effectiveness. Phase 2 trials usually involve controlled trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and evaluate the preliminary efficacy of the drug for specific indications. Phase 3 trials usually test a specific hypothesis to evaluate clinical efficacy and test further for safety in an expanded patient population, to establish the overall benefit-risk relationship of the product and to provide adequate information for the labeling of the product. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA, an IRB or a sponsor may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional clinical trials be conducted as a condition of product approval. Finally, sponsors are required to publicly disseminate information about ongoing and completed clinical trials on a government website administered by the National Institutes of Health, or NIH, and are subject to civil money penalties and other civil and criminal sanctions for failing to meet these obligations.

Assuming successful completion of the required clinical testing, the results of the nonclinical studies and of the clinical studies, together with other detailed information, including information on the chemistry, manufacture and control of the product, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may refuse to accept and review insufficiently complete applications.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Moreover, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval of a new NDA or BLA, or NDA or BLA supplement, before the change can be implemented.

Approval Process for Biosimilars

The BPCI Act created an abbreviated approval pathway for biosimilars. This abbreviated pathway is codified in Section 351(k) of the Public Health Service Act. The Section 351(k) pathway creates a regulatory and legal pathway to encourage the development of biosimilars, which are defined as a biologic that:

- is "highly similar" to the reference product, notwithstanding minor differences in clinically inactive components; and
- has no clinically meaningful differences from the reference product in terms of safety, purity and potency.

Biosimilars may be approved for one or more, and possibly all, indications for which a reference product is approved. In some cases, clinical trial data successfully demonstrating the use of a biosimilar for one indication, and submitted to support approval for that indication, may be extrapolated to support approval for one or more other indications of the reference product. The Section 351(k) pathway further defines a subset of biosimilar products as "interchangeable" if an applicant can demonstrate that:

- the interchangeable biological product can be expected to produce the same clinical result as the reference product in any given patient; and

Table of Contents

- if the product is administered more than once in a patient, that the risk in terms of safety or diminished efficacy of alternating or switching between the use of the interchangeable biologic product and the reference product is no greater than the risk of using the reference product without switching.

The types of data that would ordinarily be required in an application to show biosimilarity would include:

- analytical data and studies to demonstrate similarity to the reference product;
- nonclinical studies (including toxicity studies); and
- clinical studies.

The FDA has the discretion to determine whether one or more of these elements are necessary and its guidance to date does not establish a single method for demonstrating biosimilarity but states that the degree of residual uncertainty that remains following analytical and nonclinical research will determine the nature and the extent of clinical studies that may be required. In 2012, the FDA implemented its biosimilar user fee program which includes a fee-based meeting process for consultation between applicants and the FDA reviewing division on biosimilar and interchangeable biologics applications under the biosimilar approval pathway. It provides for pre-application meetings where the applicant can propose and submit analytical, physicochemical and biologic characterization data along with a proposed development plan. The proposed development plan may have a reduced scope of clinical development based on the nature and extent of the characterization data. There are defined time periods for meetings and written advice. Since 2012, the FDA has published a series of draft and final guidance documents for the development and registration of biosimilars and interchangeable biologics, on topics ranging from demonstrating biosimilarity and interchangeability, non-proprietary naming, labeling and other scientific and regulatory issues. The draft and final guidance documents indicate that the FDA will consider the totality-of-the-evidence developed by an applicant in determining the nature and extent of the development, nonclinical and clinical requirements for a biosimilar or interchangeable biologic product. In addition, the guidance documents confirm the importance of analytical characterization to demonstrating biosimilarity and interchangeability in showing the absence of differences from the reference product. Where differences are identified, uncertainty associated with their clinical meaning or impact is expected to be resolved by nonclinical testing and clinical trials. The greater the similarity, the less uncertainty and the more likely the FDA will authorize an applicant to conduct targeted clinical trials or use extrapolation in support of demonstrating biosimilarity and interchangeability.

Under Section 351(k), the FDA must wait four years after approval of a biological product under a BLA before accepting a filing for a biosimilar version of the reference product, and the FDA cannot approve a biosimilar version of the reference product until 12 years after the reference product was approved under a BLA. The BPCI Act also provides for limited regulatory exclusivity for the first FDA-approved interchangeable biologic with respect to each reference product. This means that the FDA will defer approval of additional interchangeable biologics to the same reference product for defined periods of one year or more.

Upon filing a biosimilar application, an applicant may trigger the patent negotiation and clearance process. Under the BCPI Act provisions, an applicant and the reference product company are required to share information to seek to resolve any patent disputes prior to regulatory approval and launch. A failure to share information or participate in the process has defined consequences that include the loss of the right to seek patent clearance on the applicant's part and the loss of the right to seek lost profits or injunctive relief for infringement on the reference product patent right holder's part. The process, if initiated by the applicant, has several stages, including defining which patents to include in a pre-approval litigation proceeding, initiating litigation, notice 180 days prior to launch of a biosimilar, the initiation of a second round of litigation relating to patents the parties did not include in the first round litigation, and, following approval, litigation on patents brought by the reference product company or other patent holders not involved in the prior patent process.

The BPCI Act is complex and continues to be interpreted and implemented by the FDA. As a result, we believe its ultimate impact, implementation and meaning will be subject to uncertainty for years to come.

Manufacturing Requirements

Before approving an NDA, BLA, ANDA or Section 351(k) application, the FDA may inspect the facility or the facilities at which the product is manufactured. The FDA will not approve the product, and may delay an approval of

an application, unless or until it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, BLA, ANDA or Section 351(k) application, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the

Table of Contents

submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, BLA, ANDA or Section 351(k) application, the FDA may require post-marketing testing and surveillance to further assess and monitor the product's safety or efficacy after commercialization. Any post-approval regulatory obligations, and the cost of complying with such obligations, could expand in the future.

In addition, holders of an approved NDA, BLA, ANDA or Section 351(k) approval are required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Discovery of problems with a product or failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB of a clinical hold on or termination of studies, the FDA's refusal to approve pending applications or supplements, license suspension or revocation, withdrawal of an approval, restriction on marketing, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Also, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

Fraud and Abuse Laws

Pharmaceutical manufacturers are subject to healthcare fraud and abuse laws and other regulations and enforcement by the federal government as well as the state and foreign governments in which they conduct their business. Such laws include, without limitation, federal and state anti-kickback, false claims, privacy and security and transparency laws and regulations. Violations of any of such laws or any other governmental regulations may result in penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations, and individual imprisonment.

Coverage and Reimbursement

Sales of pharmaceutical products depend, in part, on the availability of coverage and the adequacy of reimbursement by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. Significant uncertainty exists as to the coverage and reimbursement status of any product and can differ significantly from payor to payor. One third party payor’s decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Payors are also increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Decreases in third-party reimbursement for pharmaceutical products or a decision by a third-party payor not to cover a product could reduce physician usage of such product.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products, implementing reductions in Medicare and other healthcare funding, and applying new payment methodologies. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was enacted, which,

among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new

Table of Contents

annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Recently, the Tax Cuts and Jobs Act (the "Tax Act") was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump Administration and CMS 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. Any changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on the pharmaceutical industry.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act to reduce healthcare expenditures. These changes include aggregate reductions of Medicare payments to providers of 2% per fiscal year that will remain in effect through 2027 and further reductions in Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently 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. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Foreign Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products in those markets. Whether or not we obtain FDA approval for a product, we must obtain approval of a clinical trial application or product from the applicable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products and provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions and is available at the request of the applicant for products that are not subject to the centralized procedure. Under this procedure, the holder of a national marketing authorization from one European Union member state (the Reference Member State) may submit an application to the remaining member states. Generally, each member state decides whether to recognize the Reference Member State's approval in its own country.

Related Matters

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA or

reimbursed under Medicare by the Center for Medicare Services. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Table of Contents

Hazardous Materials

Our research and development processes involve the controlled use of certain hazardous materials and chemicals, including radioactive materials and equipment. We are subject to federal, state and local environmental, health and workplace safety laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material.

Competition

The development and commercialization of pharmaceutical products is highly competitive due to existing product competition at the time of product launch and the development of subsequent therapeutics with different methods of action, efficacy and safety profiles. Many of our competitors, who already market or are developing products similar to those in our portfolio, have considerable experience in product development, obtaining regulatory approval, and commercializing pharmaceutical products. Further, certain of these competitive companies have substantially greater financial, marketing, research and development and human resources than we do.

We believe that our ability to successfully compete will depend on a number of factors, including our ability to successfully develop safe and efficacious products, the timing and scope of regulatory approval of our products and those of our competitors, our ability to collaborate with third parties, our ability to maintain favorable patent protection for our products, our ability to obtain market acceptance of our products and our ability to manufacture sufficient quantities of our products at commercially acceptable costs.

Novel Therapeutics

Our novel product pipeline will face substantial competition from major pharmaceutical and other biotechnology companies. Our development work focused on Fc biology has yielded three named product candidates: M230, an Fc multimer, M281, anti-FcRn, and M254, hypersialylated IVIg. These candidates face competition from a number of companies.

M230

CSL, our collaboration partner, is conducting a Phase 1 normal healthy volunteer study with M230. Pfizer (licensed from Gliknik), and Shire (licensed from AB Biosciences) have compounds in development that we believe to be mechanistically similar to M230. The Pfizer product recently started a Phase 1 clinical trial. Shire’s product is preclinical. Once the Phase 1 clinical trial for M230 is completed, we will assess the competitive landscape for M230 based on the selected disease indication for further development.

M281 Competing FcRn Antagonists

Several companies, including UCB, Immunovant (licensed from HanAll), Alexion (via acquisition of Syntimmune), Affibody and Argenx are developing FcRn targeted agents. UCB's candidate, an IgG4 monoclonal antibody, completed Phase 2 clinical trials in ITP and myasthenia gravis, and has announced a planned Phase 2 CIDP trial. Argenx’s candidate, a mutated Fc fragment, is in a Phase 3 trial for MG, a Phase 2 trial for pemphigus vulgaris, has completed a Phase 2 trial in ITP as well as a Phase 1 study with a subcutaneous presentation, and has announced a planned Phase 2 CIDP trial. Alexion’s candidate, an IgG4 monoclonal antibody, is in Phase Ib clinical trials for warm autoimmune hemolytic anemia and pemphigus vulgaris, and has announced a planned pivotal trial in MG. Immunovant’s candidate, believed to be an IgG1 monoclonal antibody, is in a Phase 1 clinical trial and Immunovant has announced plans to initiate a Phase 2 myasthenia gravis trial in early 2019. Affibody’s candidate is in a Phase 1 trial.

M281 Competing in Disease Indications

Momenta has commenced Phase 2 clinical trials in generalized myasthenia gravis (gMG) and hemolytic disease of the fetus and newborn (HDFN). Myasthenia gravis (MG) treatment is primarily with the acetylcholinesterase inhibitor, pyridostigmine, and most MG patients also require treatment with immunosuppressive medications. Some patients may require plasma exchange/plasmapheresis, immunoadsorption, intravenous immunoglobulin (IVIG), or Soliris (eculizumab), the sole monoclonal antibody approved for gMG by the FDA. Other complement antagonists in development for MG include agents from Alexion (ALXN1210) and Ra Pharmaceuticals’ zilucoplan. Several other FcRn antagonists are in development for MG. Argenx has initiated a Phase 3 trial, and UCB announced intentions to initiate a Phase 3 trial in the second half of 2019. Immunovant plans to initiate a Phase 2 trial in early 2019 and Alexion plans to initiate a pivotal trial in 2019. For HDFN, we are not aware of any other FcRn antagonists in

development nor any other novel biologic therapies.

Table of Contents

M254 Competing Immunoglobulins

We are not aware of other companies developing a hypersialylated immunoglobulin. M254 would compete with currently marketed intravenous and subcutaneous IgG products in the United States, including Octagam 5% and Octagam 10% marketed by Octapharma, Gammagard S/D, Gammagard Liquid 10%, Cuvitru 20% and HyQvia 10% marketed by Shire, Privigen Liquid 10%, Carimune NF, Hizentra 20% marketed by CSL Behring, Flebogamma 5% DIF, Gamunex-C, Flebogamma 10% DIF marketed by Grifols, Gammaplex marketed by BPL Holdings, and Bivigam marketed by ADMA Biologics, as well as other intravenous and subcutaneous IgG products marketed ex-US and those that are currently in development.

M254 Competing in Disease Indications

Momenta has commenced a Phase 1-2 clinical trial in ideopathis thrombocytopenic purpura, or ITP. Current therapies for ITP include IVIg, steroids, TPO receptor agonists, a syk inhibitor, Tavalisse (fostamatinib), Rituxanr (rituximab) and splenectomy. Several companies are in development with novel agents to treat ITP patients, including Argenx and UCB with FcRn antagonists, Principia with a BTK inhibitor and Protalex with a form of Staphylococcal protein A.

Biosimilars

If approved, our biosimilar candidates would compete with their applicable branded reference products, other biosimilars to those reference products, as well as other therapies used to treat the indications for which our biosimilars would be approved. Many of the companies developing biosimilars are significantly larger than us, have substantially greater financial resources and have significant pre-existing resources to devote to their biosimilars business.

HUMIRA

In the United States, Amgen, Boehringer Ingelheim and Sandoz have received FDA approval for their biosimilars to HUMIRA, and Samsung’s BLA was accepted for review. In Europe biosimilars to HUMIRA from Amgen, Sandoz, Samsung Bioepis and Mylan launched in October 2018, and Fresenius’s MAA was accepted for review. Other companies are in development with biosimilar HUMIRA including Coherus, Celltrion, LG Life Sciences, and Pfizer.

EYLEA

Coherus, Formycon, Alteogen, Insight Biopharmaceuticals, and Lupin Limited have announced plans to develop a biosimilar to EYLEA.

GLATOPA

GLATOPA 20 mg/mL is a substitutable generic equivalent for, and competes directly with, Teva's once-daily COPAXONE 20 mg/mL. It also competes with Teva's three-times-weekly COPAXONE 40 mg/mL. GLATOPA 40 mg/mL is a substitutable generic for, and competes directly with, Teva's three-times-weekly COPAXONE 40 mg/mL. In October 2017, Mylan N.V. announced the launch of its generic equivalents to once-daily COPAXONE 20 mg/mL and three-times-weekly COPAXONE 40 mg/mL.

ANDAs for generic versions of COPAXONE 20 mg/mL and/or 40 mg/mL have also been submitted to the FDA by Synthon Pharmaceuticals, Inc., Dr. Reddy's Laboratories, Amneal Pharmaceuticals, and Biocon Ltd. Other ANDAs or other regulatory applications may have been submitted or may be submitted in the future. In addition, GLATOPA 20 mg/mL and GLATOPA 40 mg/mL compete with other FDA approved multiple sclerosis therapies. These currently include, among others, Rebif (interferon-beta-1a), marketed by EMD Serono Inc. and Pfizer Inc.; Avonex (interferon beta-1a), Tysabri (natalizumab), Tecfidera (dimethyl fumarate), and Plegridy (peginterferon beta-1a), each marketed by Biogen Idec Inc.; Betaseron (interferon-beta-1b), marketed by Bayer Schering Pharma; Extavia (interferon-Beta-1b) and Gilenya (fingolimod), each marketed by Novartis Pharmaceuticals Corporation; Lemtrada (alemtuzumab), marketed by Sanofi and Bayer; Aubagio (teriflunomide), marketed by Sanofi; and Ocrevus (ocrelizumab) marketed by Genentech and Roche.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2018, we had 131 employees, including 28 employees who hold Ph.D. degrees and 2 employees who hold an M.D. degree. Our employees are not represented by any collective bargaining group or labor union, and we believe our relations with our employees are good.

19

Table of Contents

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, nonclinical and clinical trial costs, contract research and manufacturing costs, and the costs of laboratory equipment and facilities. Research and development expense for 2018 was $124.0 million, compared with $149.2 million in 2017 and $119.9 million in 2016.

Financial Information about
Segments and Geographic Areas

We view our business as one reportable operating segment—the discovery, development and commercialization of pharmaceutical products. We derive our revenues from our collaborations. All of our revenues through December 31, 2018 have come from our collaborators and are based solely on activities in the United States. Our long-lived assets were $23.8 million and $34.0 million at December 31, 2018, and 2017, respectively, and are located solely in the United States. See Part II, Item 6 "Selected Consolidated Financial Information" and the section entitled "Segment Reporting" appearing in Note 2 to our consolidated financial statements for further information about our segment. The notes to our consolidated financial statements are contained in Part II, Item 8 of this Annual Report on Form 10-K.

Company Background and
Securities Exchange Act Reports

We were incorporated in Delaware in May 2001 under the name Mimeon, Inc. In September 2002, we changed our name to Momenta Pharmaceuticals, Inc. Our principal executive offices are located at 301 Binney Street, Cambridge, Massachusetts 02142, and our telephone number is (617) 491-9700.

In this Annual Report on Form 10-K, the terms "Momenta," "we," "us" "the Company" and "our" refer to Momenta Pharmaceuticals, Inc. and its subsidiary.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission. The Securities and Exchange Commission maintains a web site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Securities and Exchange Commission.

Our internet address is www.momentapharma.com. We are not including the information contained on our web site as a part of, or incorporating it by reference into, this Annual Report on Form 10-K.

We make available free of charge on our website at http://ir.momentapharma.com/investor-relations our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

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

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

Table of Contents

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

Also on October 1, 2018, as a result of our strategic business review, we restructured our executive team and commenced a reduction of our workforce by 50%, 37% as of October 5, 2018, with an additional 13% reduction in workforce planned over the next two to 12 months. 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 have 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 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

Table of Contents

materials to us may pose geopolitical risks, including import trade restrictions or significant tariffs or other economic sanctions. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

The development and commercialization of our lead biosimilar product candidate, M923, could be delayed or terminated as a result of our inability to enter into an agreement with a collaboration partner, and our business may be adversely affected.

Our collaboration with Baxter terminated on December 31, 2016 and we have proceeded with the development program with the goal of entering into a new collaboration agreement to finance the launch and legal clearance of the product. There could be changes or delays in the timing of the M923 program should we fail to enter into a collaboration agreement with a suitable collaborative partner. In the event we elect to research, develop, manufacture and commercialize M923 by ourselves, we would need to expand our internal capabilities, in connection with which there could be significant delays in the M923 program. In the event we elect to license M923 to a third party, the terms of such a license and collaboration could be less favorable than those under the former collaboration agreement with Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH (collectively, Baxalta), and finding and negotiating a new collaboration could cause significant delays in the M923 program. Any of the delays described above could prevent us from commercializing M923. In addition, we may need to seek additional financing to support the research, development and commercialization of M923, or alternatively we may decide to discontinue M923, which could have a material adverse effect on our business.

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

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

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

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.

Table of Contents

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

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

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

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

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

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's launch of Glatopa 40mg in February, Sandoz has encountered aggressive pricing and contracting tactics from competitors and as a result we expect modest sales for the product in the future. Our near-term ability to generate GLATOPA 40 mg/mL product revenue will depend on Sandoz' ability to compete with Teva's three-times-weekly COPAXONE 40 mg/mL product and any generic equivalents. As of the end of 2018, 40 mg/mL glatiramer acetate injection accounted for approximately 84% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed. If other competitors receive approval to market generic versions of the 20 mg/mL or 40 mg/mL formulations of COPAXONE, our product revenue and profits would be further impacted, and as a result, our business, including our near-term financial results and our ability to utilize GLATOPA revenue to fund future discovery and development programs, may suffer.

Any future Enoxaparin Sodium Injection product revenue is dependent on Sandoz being able to identify an acceptable contract manufacturer for enoxaparin injection at a price point that will allow for the successful manufacture and competitive commercialization of Enoxaparin Sodium Injection.

In July 2018, Sandoz notified its customers and the FDA that it will discontinue production of Enoxaparin Sodium Injection. Sandoz continues to evaluate alternate acceptable contract manufacturers at a price point that will allow for profitable and competitive sales and may decide to relaunch Enoxaparin Sodium Injection at a later date following regulatory approval of any such contract manufacturer. Sandoz has faced increasing competition and pricing pressure from brand, authorized generic and other currently-approved generic competitors, which has and will continue to impact Sandoz' net sales and profits from

Table of Contents

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 December 31, 2018. We expect future revenues from Sandoz's sales of Enoxaparin Sodium Injection, if any, to be minimal.

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

The District Court trial in our patent litigation against Amphastar related to Enoxaparin Sodium Injection was held in July 2017, and the jury verdict found our patent to be infringed by Amphastar, but invalid and unenforceable. In February 2018, the District Court confirmed the jury’s opinion that the patent was infringed but invalid, and narrowed the jury’s recommendation on unenforceability by finding our patent to be unenforceable against only one of the two infringing methods used by Amphastar. We and Sandoz are considering all other available legal options to overturn the portions of the verdict that found our patent to be invalid and partially unenforceable, including a potential appeal to the U.S. Court of Appeals for the Federal Circuit, or CAFC. On March 20, 2018 the District Court entered its final judgment affirming its February 2018 rulings. On March 27, 2018 we and Sandoz filed a notice of appeal of the final judgment with the CAFC. The appeal has been docketed and our opening brief was filed July 30, 2018.

In the event that we are not successful in our continued prosecution of our suit against Amphastar and Amphastar is able to prove it suffered damages as a result of the preliminary injunction preventing it from selling its Enoxaparin product in the United States, we could be liable for up to $35.0 million of the security bond for such damages. We posted 36.1 million as collateral for the security bond and classified the collateral as restricted cash in our consolidated balance sheet. On March 23, 2018, Amphastar filed a motion to enforce liability on the security bond with the District Court. On April 3, 2018, we and Sandoz filed an emergency motion to defer consideration of Amphastar's motion to enforce liability on the security bond pending exhaustion of appeals. On July 16, 2018, the District Court denied Amphastar's motion to enforce liability on the security bond and allowed the Company's and Sandoz' motion to defer consideration. Moreover, if Amphastar or third parties are successful in antitrust litigation against us for asserting our Enoxaparin patent rights, they may be able to recover damages incurred as a result of enforcement of our patent rights, thereby negatively affecting our financial condition and results of operations.

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

Drug products and biologics are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. The distribution of such products is also managed by pharmacy benefit management firms, or PBMs, such as Express Scripts or CVS. These GPOs and PBMs rely on competitive bidding, discounts and rebates across their purchasing arrangements. We believe that we, in collaboration with commercial collaboration partners, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products to establish and maintain relationships with GPOs and PBMs.

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

24

Table of Contents

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

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

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

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the competitive pricing of our products;
- physician confidence in the safety and efficacy of complex generic products or biosimilars;
- the absence of, or limited clinical data available from, sameness testing of our complex generic products and biosimilarity or interchangeability testing of our biosimilar products;
- the success and extent of our physician education and marketing programs;
- the clinical, medical affairs, sales, distribution and marketing efforts of competitors; and
- the availability and amount of government and third-party payer reimbursement.

If our products do not achieve market acceptance, we will not be able to generate sufficient revenue from product sales to maintain or grow our business.

If we are not able to retain our current management team or attract and retain qualified scientific, technical and business personnel, our business will suffer.

We recently restructured our management team and are dependent on the current members of our team for our business to succeed. In the restructuring we terminated a number of senior executives and many of the new members of our current management team have not had previous experience in senior executive positions and have duties that are in addition to those of our prior senior executives, all of which may affect our ability to further our business success. Our employment arrangements with our executive officers are terminable by either party on short notice or no notice. We do not carry key person life insurance on the lives of any of our personnel. The loss of any of our executive officers would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. In addition, there is intense competition from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, for human resources, including qualified executives and management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates. Another component of retention is the intrinsic value of equity awards, including stock options. Stock options granted to our executives and employees may be under pressure given the volatility of our stock performance and at such times may not always provide a retentive effect. In addition, our recent restructuring may negatively affect employee morale and our corporate culture, which may have a negative impact on retention and recruitment. If we lose key members of our management team, or are unable to attract and retain qualified personnel, our business could be negatively affected.

There is a substantial risk of product liability claims in our business. If our existing product liability insurance is insufficient, a product liability claim against us that exceeds the amount of our insurance coverage could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in a recall of our products or a change in the approved

25

Table of Contents

indications for which they may be used. We cannot be sure that the product liability insurance coverage we maintain will be adequate to cover any incident or all incidents. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

Our business and operations would suffer in the event of system failures or security breaches.

Our operations rely on the secure processing, storage and transmission of confidential and other information in our and our third party contractors' computer systems and networks. Our internal computer systems are vulnerable to breakdown or breach, including as a result of computer viruses, security breaches by individuals with authorized access, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The increased use of mobile and cloud technologies can heighten these and other operational risks. Moreover, systems breaches are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Any breakdown or breach by employees or others may pose a risk that sensitive data, including clinical trial data, intellectual property, trade secrets or personal information belonging to us, our patients or our collaborators may be exposed to unauthorized persons or to the public. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture and commercialize our products and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our products and product candidates could be delayed, we could suffer reputational harm, we could be subject to regulatory action, and the trading price of our common stock could be adversely affected. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to breakdown or breach of our computer systems and other related breaches.

As we continue to evolve from a company primarily involved in discovery and development of pharmaceutical products into one that is also involved in the commercialization of multiple pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.

As we advance an increasing number of product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other organizations.

In addition, our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, some jurisdictions, such as the District of Columbia, have imposed licensing requirements for sales representatives. In addition, the District of Columbia and the Commonwealth of Massachusetts, as well as the federal government, by way of the Sunshine Act provisions of the Patient Protection and Affordable Care Act of 2010, have established reporting requirements that would require public reporting of consulting and research fees to health care professionals. Because the reporting requirements vary in each jurisdiction, compliance can be complex and expensive and may create barriers to entering the commercialization phase. The need to build new systems as part of our growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Such requirements may also impact our opportunities to collaborate with physicians at academic research centers as new restrictions on academic-industry relationships are put in place. In the past, collaborations between academia and industry have led to important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

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

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

Table of Contents

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.

Table of Contents

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 December 31, 2018, our accumulated deficit was $743.8 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 December 31, 2018, we had cash, cash equivalents and marketable securities totaling approximately 449.4 million. For the twelve months ended December 31, 2018, we had a net loss of $176.1 million and our operations used cash of $155.6 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, nonclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development and commercialization of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements will depend on many factors, including but not limited to:

- the cost of advancing our product candidates and funding our development programs, including the costs of nonclinical and clinical studies, obtaining reference product for nonclinical and clinical studies, manufacturing nonclinical and clinical supply material, and obtaining regulatory approvals;
- the level of sales of GLATOPA 20 mg/mL and of GLATOPA 40 mg/mL;
- the successful commercialization of our other product candidates;
- the impact of prior or contemporaneous competition on our products and product candidates, such as Mylan N.V.'s generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL on GLATOPA 20 mg/mL and GLATOPA 40 mg/mL;
- the receipt of milestone payments under our CSL License Agreement;
- the ability to enter into a strategic alliance for commercialization of M923 and the continuation without disruption of development and manufacturing activities of M923;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation maintaining and enforcing our intellectual property rights and defending intellectual property related claims, including with Amphastar relating to Enoxaparin Sodium Injection, that is not otherwise covered by

Table of Contents

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 and are delayed or are not successful, we may incur additional costs, experience delays in obtaining, or ultimately be unable to obtain regulatory approval for commercial sale of those product candidates.

To obtain regulatory approval for the commercial sale of our novel product candidates, we are required to demonstrate through nonclinical studies and clinical trials that our product candidates are safe and effective. Nonclinical studies and clinical trials of novel product candidates are lengthy and expensive and there is a high probability of significant

delays to or failure of novel product candidates during nonclinical studies or clinical trials.

Table of Contents

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

A delay or failure of one of our product candidates during nonclinical studies or clinical trials, if required, can occur at any stage of testing. For example, we announced on November 1, 2017 that the results of the Phase I clinical trial for M834 indicated that it did not meet its primary pharmacokinetic endpoints, requiring an evaluation of next steps for the program, which will delay any future development and cause us to incur additional costs. We may experience numerous unforeseen events during, or as a result of, nonclinical studies and clinical trials, if required, that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our nonclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional nonclinical studies or clinical trials or we may abandon projects that we previously expected to be promising;
- enrollment in our clinical trials may be slower than we anticipate, resulting in significant delays, and participants may drop out of our clinical trials at a higher rate than we anticipate;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or if, in their opinion, participants are being exposed to unacceptable health risks;
- the cost of our clinical trials may be greater than we anticipate;
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or our product candidates may have other unexpected characteristics; and
- we may decide to modify or expand the clinical trials we are undertaking if new agents are introduced that influence current standard of care and medical practice, warranting a revision to our clinical development plan.

The results from nonclinical studies of a product candidate and in initial human clinical studies of a product candidate may not predict the results that will be obtained in subsequent human clinical trials, if required. If we are required by regulatory authorities to conduct additional clinical trials or other testing of our product candidates that we did not anticipate, if we are unable to successfully complete our clinical trials or other tests, or if the results of these trials are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our product candidates or we may not be able to obtain marketing approval at all. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. If any of these events occur, our business will be materially harmed.

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 side effects or unexpected characteristics. If unacceptable side effects 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 side effects 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 side effects 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.

30

Table of Contents

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects 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 particular product candidate, if approved, 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,

31

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

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.

Table of Contents

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 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,

Table of Contents

CMS's changes this will have on private payers. Reimbursement uncertainty could adversely impact market acceptance of biosimilar products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payers for our products could have a material adverse effect on our operating results and our overall financial condition.

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

Healthcare reform legislation known as the Affordable Care Act that was enacted in 2010 could significantly change the United States health care system and the reimbursement of products. A primary goal of the law is to reduce or limit the growth of health care costs, which could change the market for pharmaceuticals and biological products. The law contains provisions that will affect companies in the pharmaceutical industry and other healthcare-related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include an increase to the mandatory rebates for pharmaceutical products sold into the Medicaid program, an extension of the rebate requirement to pharmaceutical products used in risk-based Medicaid managed care plans, an extension of mandatory discounts for pharmaceutical products sold to certain critical access hospitals, cancer hospitals and other covered entities, and discounts and fees applicable to brand-name pharmaceutical products. Although many of these provisions may not apply directly to us, they may change business practices in our industry and, assuming our products are approved for commercial sale, such changes could adversely impact our profitability.

In 2017, members of Congress and the President sought to repeal and replace the Affordable Care Act, and, while those efforts did not succeed, it is possible that similar efforts will be made in the future. Recently, the Tax Cuts and Jobs Act (the “Tax Act”) was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act’s individual mandate to carry health insurance. It is uncertain whether regulatory changes to the implementation of the Affordable Care Act will restrict patient access to affordable insurance and impact their access to novel, biosimilar and complex generic products. The full effects of any repeal and replacement of the Affordable Care Act, or regulatory changes to its implementation cannot be known until a new law is implemented through regulations or guidance is issued by the CMS and other federal and state health care agencies. Any legislative or regulatory changes could have a material adverse effect on our business, financial condition and potential profitability. In addition, litigation may prevent some or all of the legislation from taking effect. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. In 2019 and beyond, we may face additional uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Affordable Care Act. There is no assurance that the Affordable Care Act, as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

Additionally, the BPCI Act establishes an abbreviated regulatory pathway for the approval of biosimilars and provides that reference products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new approval pathway for biosimilars and adjusting reimbursement for biosimilars, the new law could promote the development and commercialization of biosimilars. However, given the uncertainty of how the

law will be interpreted and implemented, the impact of the law on our strategy for biosimilars as well as novel biologics remains uncertain. Other provisions in the law, such as the comparative effectiveness provisions, may ultimately impact positively or negatively both brand and biosimilars products alike depending on an applicant's clinical data, effectiveness and cost profile. If a reference product cannot be shown to provide a benefit over other therapies, then it might receive reduced coverage and reimbursement. While this might increase market share for biosimilars based on cost savings, it could also have the effect of reducing biosimilars' market share.

Table of Contents

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

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

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

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

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

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;

37

Table of Contents

- with regard to our generic products and our generic and biosimilar product candidates, the differential availability of clinical data and experience and willingness of physicians, payers and formularies to rely on biosimilarity data;
- the timing and scope of regulatory approvals for these products and regulatory opposition to any product approvals;
- the availability and cost of manufacturing, marketing, distribution and sales capabilities;
- the effectiveness of our marketing, distribution and sales capabilities;
- the price of our products;
- the availability and amount of discounts, rebates and third-party reimbursement for our products; and
- the strength of our patent positions.

Our competitors may develop or commercialize products with significant advantages in regard to any of these factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business.

If other generic versions of the brand name drugs, or other biosimilars of the reference products, for which we have products or product candidates, including GLATOPA 20 mg/mL, GLATOPA 40 mg/mL, M923 and M710, are approved and successfully commercialized, our business would suffer.

Pricing and market share of generic and biosimilar products may decline, often dramatically, as other generics or biosimilars of the same brand name drug or reference product, respectively, enter the market. Competing generics include brand name manufacturers' "authorized generics" of their own brand name products. Generally, earlier-to-market generics and biosimilars are better able to gain significantly greater market share than later-to-market competing generics and biosimilars, respectively. Accordingly, revenue and profits from our generic products and, if approved, our generic and biosimilar product candidates, may be significantly reduced based on the timing and number of competing generics and biosimilars, respectively. We expect our generic products and, if approved, certain of our generic and biosimilar product candidates may face intense and increasing competition from other generics and biosimilars. For example, in October 2017, Mylan N.V. announced the launch 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's launch of Glatopa 40mg in February, Sandoz has encountered aggressive pricing and contracting tactics from competitors and as a result we expect modest sales for the product in the future. In addition, several other companies have submitted ANDAs to the FDA for generic versions of COPAXONE. A launch of one or more additional generic versions of COPAXONE could further reduce anticipated revenue from GLATOPA 20 mg/mL and GLATOPA 40 mg/mL.

In addition, the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that reference product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). A determination that another company's product is interchangeable with HUMIRA or EYLEA prior to approval of M923 or M710 may therefore delay any determination that our product is interchangeable with the reference product, which may materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

Table of Contents

If an alternative version of a reference product, such as COPAXONE, HUMIRA or EYLEA , is developed that has a new product profile and labeling, the alternative version of the product could significantly reduce the market share of the original reference product, and may cause a significant decline in sales or potential sales of our corresponding generic or biosimilar product.

Brand companies may develop alternative versions of a reference product as part of a life cycle extension strategy, and may obtain approval of the alternative version under a supplemental new drug application, for a drug, or biologics license application, for a biologic. The alternative version may offer patients added benefits such as a more convenient form of administration or dosing regimen. Should the brand company succeed in obtaining an approval of an alternative product, it may capture a significant share of the collective reference product market and significantly reduce the market for the original reference product and thereby the potential size of the market for our generic or biosimilar products. For example, as of the end of 2018, Teva's three-times-weekly COPAXONE 40 mg/mL and Mylan N.V.'s three-times-weekly generic equivalent product accounted for approximately 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;

Table of Contents

- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- pursuing new patents for existing products or processes which could extend patent protection for a number of years or otherwise delay the launch of generic drugs or biosimilars; and
- influencing legislatures so that they attach special regulatory exclusivity or patent extension amendments to unrelated federal legislation.

The FDA's practice is to rule within 150 days on Citizen Petitions that seek to prevent approval of an ANDA if the petition was filed after the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA. If, at the end of the 150-day period, the ANDA is not ready for approval or rejection, then the FDA has typically denied and dismissed the petition without acting on the petition. For example, Teva Neuroscience, Inc. filed eight Citizen Petitions regarding GLATOPA 20 mg/mL, all of which have been denied, dismissed or withdrawn. Teva also sought reversal of the denial of a Citizen Petition in federal court. Other third parties may also file Citizen Petitions requesting that the FDA adopt specific approval standards for generic or biosimilar products.

If these efforts to delay or block competition are successful, we may be unable to sell our generic and biosimilar products, if approved, which could have a material adverse effect on our sales and profitability.

If the market for a reference product, such as COPAXONE, HUMIRA or EYLEA, significantly declines, sales or potential sales of our corresponding generic and biosimilars product and product candidates may suffer and our business would be materially impacted.

Competition in the biotechnology industry is intense. Reference products face competition on numerous fronts as technological advances are made or new products are introduced that may offer patients a more convenient form of administration, increased efficacy or improved safety profile. As new products are approved that compete with the reference product to our generic products and product candidates and our biosimilar product candidates, respectively, sales of reference products and biosimilar and generics may be significantly and adversely impacted and may render the reference products obsolete.

Current injectable treatments commonly used to treat multiple sclerosis, including COPAXONE, are competing with novel therapeutic products, including oral therapies. These oral therapies may offer patients a more convenient form of administration than COPAXONE and may provide increased efficacies. If the market for the reference product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and o ur ability to fund future discovery and development programs, would suffer.

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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, as provided for in the collaboration agreement.

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

Table of Contents

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.

44

Table of Contents

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

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

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

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

General Company Related Risks

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

Provisions in our certificate of incorporation and our by-laws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our 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.

45

Table of Contents

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

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

- delays in achievement of, or failure to achieve, program milestones that are associated with the valuation of our company or significant milestone revenue;
- failure of GLATOPA 20 mg/mL to sustain or GLATOPA 40 mg/mL to achieve profitable sales or market share that meet expectations of securities analysts;
- litigation involving our company or our general industry or both;
- a decision in favor of, or against, Amphastar in our patent litigation suits, a settlement related to any case; or a decision in favor of third parties in antitrust litigation filed against us;
- announcements by other companies regarding the status of their ANDAs for generic versions of COPAXONE;
- FDA approval of other companies' ANDAs for generic versions of COPAXONE;
- marketing and/or launch of other companies' generic versions of COPAXONE, such as Mylan N.V.'s October 2017 launch of its generic equivalents of COPAXONE 20 mg/mL and 40 mg/mL;
- adverse FDA decisions regarding the development requirements for one of our biosimilar product candidates or failure of our other product applications to meet the requirements for regulatory review and/or approval;
- results or delays in our or our competitors' clinical trials or regulatory filings;
- enactment of legislation that repeals the law enacting the biosimilar regulatory approval pathway or amends the law in a manner that is adverse to our biosimilar development strategy;
- failure to demonstrate biosimilarity or interchangeability with respect to our biosimilar product candidates such as M923 or M710;
- demonstration of or failure to demonstrate the safety and efficacy for our novel product candidates;
- our inability to manufacture any products in conformance with cGMP or in sufficient quantities to meet the requirements for the commercial sale of the product or to meet market demand;
- failure of any of our product candidates, if approved, to achieve commercial success;
- the discovery of unexpected or increased incidence in patients' adverse reactions to the use of our products or product candidates or indications of other safety concerns;
- developments or disputes concerning our patents or other proprietary rights;
- changes in estimates of our financial results or recommendations by securities analysts;
- termination of any of our product development and commercialization collaborations;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- investors' general perception of our company, our products, the economy and general market conditions;
- rapid or disorderly sales of stock by holders of significant amounts of our stock; or
- significant fluctuations in the price of securities generally or biotechnology company securities specifically.

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

Table of Contents

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of February 5, 2019, pursuant to our sublease agreements, we lease office and laboratory space in Cambridge, Massachusetts:

Property Location	Approximate Square Footage	Use	Lease Expiration Date
320 Bent Street Cambridge, Massachusetts 02141	105,000	Laboratory and Office	02/28/2027
301 Binney Street, Fifth Floor Cambridge, Massachusetts 02142	80,000	Laboratory and Office	06/29/2025
	185,000		

Item 3. LEGAL PROCEEDINGS

GLATOPA 40 mg/mL-Related Proceedings

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz in the United States District Court for the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, and sought declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015 and November 2015, Teva and Yeda filed additional suits against us and Sandoz in the United States District Court for the District of Delaware alleging infringement related to additional Orange Book-listed patents for COPAXONE 40 mg/mL, which were consolidated with the initial suit. Teva and Yeda sought declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of the patents at issue. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. In February 2017, Teva and Yeda appealed the District Court's January 30, 2017 decision to the U.S. Court of Appeals for the Federal Circuit, or CAFC. On October 12, 2018, the CAFC affirmed the District Court's decision that the four patents were invalid. The time period for appeal by Teva and Yeda has expired so the CAFC decision is binding.

On January 31, 2017, Teva filed a suit against us and Sandoz in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775. 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 is scheduled to commence before the United States District Court for the District of Delaware on May 6, 2019.

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

Table of Contents

M834-Related Proceedings

On July 2, 2015, we filed a petition for Inter Partes Review, or IPR, with the Patent Trial and Appeal Board, or PTAB, to challenge the validity of U.S. Patent No. 8,476,239, a patent for ORENCIA owned by Bristol-Myers Squibb, or BMS. The PTAB issued a decision instituting the IPR proceedings in January 2016, and BMS filed for a rehearing by the full PTAB. Oral arguments took place in September 2016. On December 22, 2016, the PTAB issued a decision upholding the validity of the patent. We filed a notice of appeal in the CAFC, on February 22, 2017. The parties have each briefed the CAFC on the question of whether a non-patent owner challenging a patented claim in IPR has constitutional standing to appeal a decision by the PTAB that the challenged patented claim is valid. Oral argument before the CAFC was held on December 5, 2017. On February 7, 2019 the CAFC dismissed our appeal of our IPR for lack of standing. We are in the process of evaluating our options with respect to our IPR.

Enoxaparin Sodium Injection-Related Proceedings

On September 21, 2011, we and Sandoz sued Amphastar and Actavis in the United States District Court for the District of Massachusetts for patent infringement. Also in September 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar and Actavis from selling their Enoxaparin product in the United States. In October 2011, the District Court granted our motion for a preliminary injunction and entered an order enjoining Amphastar and Actavis from advertising, offering for sale or selling their Enoxaparin product in the United States until the conclusion of a trial on the merits and required us and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the CAFC and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded the case to the District Court.

In April 2017, we, Sandoz and Actavis, or the Settling Parties, settled and signed reciprocal releases of all claims, and filed a voluntary stipulation with the District Court, pursuant to which the Settling Parties stipulated and agreed to dismiss with prejudice all claims and counterclaims among the Settling Parties, without fees or costs to any party, and with the Settling Parties waiving any and all right of appeal. The District Court trial was held in July 2017, and the jury verdict found our patent to be infringed, but invalid and unenforceable. In February 2018, the District Court confirmed the jury’s opinion that the patent was infringed but invalid, but narrowed the jury’s recommendation on unenforceability by finding our patent to be unenforceable against only one of the two infringing methods used by Amphastar. On March 20, 2018, the District Court entered its final judgment affirming its February 2018 rulings. On March 27, 2018, we and Sandoz filed a notice of appeal of the final judgment with the CAFC. The appeal has been docketed and briefing was completed on November 19, 2018.On 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 the Company's and Sandoz' motion to defer consideration. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against us and Sandoz in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, we and Sandoz filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that the court reverse and review the District Court’s grant of transfer, and in May 2016, the writ requested

by Amphastar was denied. On July 27, 2016, our and Sandoz motion to dismiss was granted by the District Court, and the case was dismissed. On August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court of Appeals for the First Circuit reversed the District Court's dismissal and remanded the case to the District Court for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, we and Sandoz filed our renewed motion to dismiss which was denied by the District Court on March 20, 2018. A trial is scheduled for September 2019. On February

Table of Contents

19, 2019, Amphastar filed with the District Court a motion for partial summary judgment on issues previously litigated in the patent action.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against us and Sandoz in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic Enoxaparin Sodium Injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, we and Sandoz filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. On March 21, 2017, the United States District Court for the Middle District of Tennessee dismissed NGH’s claim for damages against us and Sandoz, but allowed the case to move forward, in part, for NGH’s claims for injunctive and declaratory relief. In the same opinion, the United States District Court for the Middle District of Tennessee denied our motion to transfer. On June 9, 2017, NGH filed a motion to amend its complaint to add a new named plaintiff, the American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan, or DC37. NGH and DC37 seek to assert claims for damages under the laws of more than 30 different states, on behalf of a putative class of indirect purchasers of Lovenox or generic enoxaparin. On June 30, 2017, we and Sandoz filed a brief opposing the motion to amend the complaint. On December 14, 2017, the District Court granted NGH's motion to amend. In January 2018, we and Sandoz filed three motions to dismiss the amended complaint. On December 6, 2018 the District Court granted one of the motions, granted one in part and denied one. As a result the suit will continue pursuant to the surviving portions of the amended complaint. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourselves in this litigation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded publicly on The Nasdaq Global Select Market under the symbol "MNTA."

Quarter ended	High	Low
March 31, 2017	$19.90	$13.05
June 30, 2017	18.65	13.05
September 30, 2017	19.25	14.90
December 31, 2017	18.60	11.85
March 31, 2018	$19.00	$13.40
June 30, 2018	24.90	16.95
September 30, 2018	32.20	20.05
December 31, 2018	26.48	10.10

Holders

On February 11, 2019, the approximate number of holders of record of our common stock was 20.

Dividends

We have never declared or paid any cash dividends on our common stock. We anticipate that, in the foreseeable future, we will continue to retain any earnings for use in the operation of our business and will not pay any cash dividends.

Equity Compensation Plan Information

Information relating to compensation plans under which our equity securities are authorized for issuance is set forth below in Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” of this Annual Report.

Table of Contents

Stock Performance Graph

The comparative stock performance graph below compares the cumulative total stockholder return (assuming reinvestment of dividends, if any) from investing $100 on December 31, 2013 through December 31, 2018, in each of (i) our common stock, (ii) The Nasdaq Composite Index and (iii) The Nasdaq Biotechnology Index (capitalization weighted).

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Momenta Pharmaceuticals, Inc., the Nasdaq Composite Index, and the Nasdaq Biotechnology Index

*$100 invested on 12/31/13 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

	12/13	12/14	12/15	12/16	12/17	12/18
Momenta Pharmaceuticals, Inc.	100.00	68.10	83.94	85.12	78.90	62.44
Nasdaq Composite	100.00	113.40	119.89	128.89	165.29	158.87
Nasdaq Biotechnology	100.00	134.10	149.42	117.02	141.66	128.45

The information included under the heading "Stock Performance Graph" in Item 5 of this Annual Report on Form 10-K is "furnished" and not "filed" and shall not be deemed to be "soliciting material" or subject to Regulation 14A, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data set forth below with respect to our statements of operations and comprehensive loss data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 are derived from our audited financial statements included in this Annual Report on Form 10-K. The statements of operations and comprehensive loss data for the years ended December 31, 2015 and 2014 and the balance sheet data as of December 31, 2016, 2015 and 2014 are derived from our audited financial statements, which are not included herein. Historical results are not necessarily indicative of future results. See the notes to the consolidated financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per share. The selected consolidated

Table of Contents

financial data set forth below should be read in conjunction with and is qualified in its entirety by our audited consolidated financial statements and related notes thereto found under Item 8 "Financial Statements and Supplementary Data" and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this Annual Report on Form 10-K.

Momenta Pharmaceuticals, Inc.

Selected Financial Data

	2018	2017	2016	2015	2014
	(in thousands, except per share information)				
Statements of Operations and Comprehensive Loss Data:					
Collaboration revenues:					
Product revenue	$39,684	$66,803	$74,648	$48,503	$19,963
Research and development revenue	35,905	72,079	34,971	41,147	32,287
Total collaboration revenue	75,589	138,882	109,619	89,650	52,250
Operating expenses:					
Research and development	124,004	149,226	119,880	126,033	106,482
General and administrative	85,105	82,207	64,466	48,051	45,164
Other operating expense	30,000	—	—	—	—
Restructuring	17,807	—	—	—	—
Total operating expenses	256,916	231,433	184,346	174,084	151,646
Operating loss	(181,327)	(92,551)	(74,727)	(84,434)	(99,396)
Interest income	6,194	4,427	2,226	808	548
Other (expense) income, net	(928)	28	51,498	313	248
Net loss	$(176,061)	$(88,096)	$(21,003)	$(83,313)	$(98,600)
Basic and diluted net loss per share	$(2.26)	$(1.20)	$(0.31)	$(1.32)	$(1.91)
Shares used in calculating basic and diluted net loss per share	77,845	73,136	68,656	63,130	51,664
Comprehensive loss	$(176,008)	$(88,322)	$(20,921)	$(83,293)	$(98,641)

	As of December 31,				
	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	$248,334	$73,651	$150,738	$61,461	$61,349
Marketable securities	201,077	306,239	202,413	288,583	130,180
Working capital	389,912	322,439	357,324	335,926	181,541
Total assets	531,563	459,431	477,737	421,040	256,216
Deferred revenue	5,690	33,617	38,632	21,983	30,998
Other liabilities	64,865	51,660	67,197	29,081	18,850
Total liabilities	70,555	85,277	105,829	51,064	49,848
Accumulated deficit	(743,826)	(562,254)	(473,375)	(452,372)	(369,059)
Total stockholders' equity	461,008	374,154	371,908	369,976	206,368

Table of Contents

Item 7. 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 consolidated financial statements and the notes to those financial statements appearing elsewhere in this Annual Report on Form 10-K. 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 Item 1A of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Business Overview

Introduction

We are a biotechnology company focused primarily on discovering and developing novel drug candidates for immune-mediated diseases and developing two of our late stage biosimilar candidates.

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

We have terminated all future development of any new or early stage biosimilar and complex generic products. We retained our commercial partnership with Sandoz AG, or Sandoz, for our generic versions of COPAXONE and LOVENOX, which are approved products. We believe that Sandoz's sales of GLATOPA, our generic version of COPAXONE, can generate cash flow to help fund our novel pipeline. We have also retained our wholly owned HUMIRA biosimilar, which is fully developed and for which we are ready to submit an application for approval, subject to finalization of our commercialization strategy. In addition, we are developing our EYLEA biosimilar, in collaboration with Mylan Ireland Limited, or Mylan, a wholly-owned indirect subsidiary of Mylan N.V., which is currently in a pivotal clinical trial in patients. We believe both of these programs have the potential to generate revenue in the 2023 time frame to help fund our novel portfolio. Pursuant to our collaboration agreement with Mylan, we have delivered formal notice of our termination of participation in all other biosimilar programs. 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 December 31, 2018, we had an accumulated deficit of approximately $743.8 million. We will need to generate significant revenue to return to profitability. We expect that our return to profitability, if at all, will most likely come from the commercialization of the products in our drug development portfolio.

Complex Generics

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

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

In October 2017, Mylan N.V. announced the launch of its generic equivalents of once-daily COPAXONE 20 mg/mL and three-times-weekly COPAXONE 40 mg/mL. Following Mylan N.V.’s entry into the market, Sandoz has defended GLATOPA’s share of the 20 mg/mL glatiramer acetate injection market by using one or more contracting strategies, including but not limited to, lowering its GLATOPA 20 mg/mL price or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue. We estimate that the number of prescriptions for GLATOPA 20 mg/mL currently represents approximately 40% of the once-daily 20 mg/mL U.S.

glatiramer acetate market.

Table of Contents

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

Legal proceedings related to GLATOPA 40 mg/mL are described under "Item 3. 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 "Item 3. Legal Proceedings - Enoxaparin Sodium Injection-Related Proceedings."

Biosimilars

M923—Biosimilar HUMIRA® (adalimumab) Candidate

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

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

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

M710—Biosimilar EYLEA® (aflibercept) Candidate

M710 is being developed in collaboration with Mylan. In August 2018, Mylan initiated dosing of patients in the United States in our pivotal clinical trial. This trial is randomized, double-blind, active-control, multi-center study in patients with diabetic macular edema to compare the safety, efficacy and immunogenicity of M710 with EYLEA.

Mylan has also received

Table of Contents

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 (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.

In the fourth quarter of 2018, we commenced a Phase 2 proof-of-concept clinical trial for M281 in generalized myasthenia gravis, or gMG, and in hemolytic disease of the fetus and newborn, or HDFN.

M230 (CSL730) - Recombinant Fc Multimer Candidate

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

Pursuant to the License and Option Agreement with CSL Behring Recombinant Facility AG (CSL), or the CSL License Agreement, effective February 17, 2017, we granted CSL an exclusive worldwide license to research, develop, manufacture and commercialize M230. On August 28, 2017, we exercised our 50% co-funding option, which is discussed further in Note 9 "Collaboration and License Agreements - CSL License and Option Agreement" to our consolidated financial statements. CSL's Phase I study in healthy volunteers to evaluate safety and tolerability of M230 is ongoing and is targeted for completion in 2019.

M254 - hsIVIg Candidate

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

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

Results of Operations

Comparison of Years Ended December 31, 2018, 2017 and 2016

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

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

Table of Contents

	2018	2017	2016
Collaboration revenue:			
Product revenue	$39,684	$66,803	$74,648
Research and development revenue	35,905	72,079	34,971
Total collaboration revenue	$75,589	$138,882	$109,619

Product Revenue

GLATOPA

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

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

In October 2017, Mylan N.V. announced the launch of its generic equivalents of once-daily COPAXONE 20 mg/mL and three-times-weekly COPAXONE 40 mg/mL. Following Mylan N.V.'s entry into the market, Sandoz has defended GLATOPA's share of the 20 mg/mL glatiramer acetate injection market by using one or more contracting strategies, including but not limited to, lowering its GLATOPA 20 mg/mL price or increasing the discounts or rebates it offers for GLATOPA 20 mg/mL, which has decreased contractual profit share revenue.

Since Sandoz's launch of Glatopa 40mg/mL 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. As of the end of 2018, 40 mg/mL glatiramer acetate injection accounted for approximately 84% of the overall U.S. glatiramer acetate injection market (20 mg/mL and 40 mg/mL) based on volume prescribed.

2018 vs 2017

The decrease in product revenue of $27.1 million, or 41%, from 2017 to 2018 was primarily due to lower net sales of GLATOPA driven by Mylan N.V.'s entry into the COPAXONE market in October 2017 and a $9.8 million decrease in product revenue in the first quarter of 2018 for our 50% share of GLATOPA 40 mg/mL inventory written off by Sandoz. Offsetting these decreases in product revenue in 2018, was the $10.0 million commercial milestone, included in research and development revenue, for which Sandoz was entitled to reduce contractual net profit by a corresponding amount, which reduced our product revenue by $5.0 million in 2017.

2017 vs 2016

The decrease in product revenue of $7.8 million, or 11%, from 2016 to 2017 was primarily due to lower net sales from price adjustments relating to Mylan N.V.'s entry into the COPAXONE market and higher Medicaid deductions as well as the $10.0 million commercial milestone, included in research and development revenue, earned on July 1, 2017, for which Sandoz was entitled to reduce contractual net profit by a corresponding amount, which reduced our product revenue by $5.0 million in 2017.

Enoxaparin Sodium Injection—Generic LOVENOX®

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

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

Table of Contents

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 $5.7 million from Mylan's $45 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.

2018 vs 2017

The decrease in research and development revenue of $36.2 million, or 50%, from the 2017 period to the 2018 period was primarily due to the $50.0 million upfront payment from CSL and the $10.0 million commercial milestone from Sandoz, both recognized in 2017, that were non-recurring in 2018. The Sandoz commercial milestone payment was earned in July 2017 in connection with GLATOPA being the sole FDA-approved generic of COPAXONE and achieving a certain level of contractually defined profits in the United States. The decrease in research and development revenue from 2017 to 2018 was were partially offset by an increase in revenue recognized of $28.4 million in 2018 from Mylan's $45 million upfront payment due to the partial termination of the Mylan Collaboration Agreement and the resulting determination that certain performance obligations under the agreement have been partially satisfied. Additional details concerning the accounting for the Mylan Collaboration Agreement is contained in Note 9, "Collaboration and License Agreements" included in the consolidated financial statements.

2017 vs 2016

The increase in research and development revenue of $37.1 million, or 106%, from 2016 to 2017 was primarily due to the $50.0 million upfront payment from CSL and the $10.0 million commercial milestone from Sandoz recognized in 2017. The increase was partially offset by a decrease of $22.0 million due to the recognition of the remaining balance of upfront and license payments from Baxalta in 2016, which was non-recurring in 2017.

Operating Expenses

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

									Dollar Change	
	2018	% of Total Operating Expenses	2017	% of Total Operating Expenses	2016	% of Total Operating Expenses	2018 compared to 2017	2017 compared to 2016
Operating expenses:										
Research and development	$124,004	48 %	$149,226	64 %	$119,880	65 %	$(25,222)	$ 29,346
General and administrative	85,105	33 %	82,207	36 %	64,466	35 %	2,898	17,741
Other operating expense	30,000	12 %	—	— %	—	— %	30,000	—
Restructuring	17,807	7 %	—	— %	—	— %	17,807	—
Total operating expenses	$256,916	100 %	$231,433	100 %	$184,346	100 %	$25,483	$ 47,087

Research and Development Expense

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

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

Table of Contents

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

The following table sets forth 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 years ended December 31, 2018, 2017 and 2016. 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 December 31, 2018	Year Ended December 31,		
		2018	2017	2016
External Costs Incurred by Product Area:				
Novel Therapeutics	Various (1)	$39,461	$15,557	$30,501
Biosimilars	Various (2)	9,709	53,186	8,069
Complex Generics	(3)	826	3,724	2,603
Internal Costs		74,008	76,759	78,707
Total Research and Development Expenses		$124,004	$149,226	$119,880

Table of Contents

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

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

(3) Includes external costs for GLATOPA and Enoxaparin Sodium Injection. In July 2010, the first ANDA for Enoxaparin Sodium Injection was approved by the FDA, and Sandoz launched the product. In April 2015, the FDA approved the ANDA for once-daily GLATOPA 20 mg/mL. Sandoz launched GLATOPA 20 mg/mL in June 2015. In February 2018, the FDA approved the ANDA for three-times-weekly GLATOPA 40 mg/mL, and Sandoz launched the product. For more information on GLATOPA 40 mg/mL, see "-Overview-Complex Generics-GLATOPA® 40 mg/mL-Generic Three-times-weekly COPAXONE® (glatiramer acetate injection) 40 mg/mL."

2018 vs 2017

External costs of our novel therapeutic programs increased by $23.9 million, or 154%, from the 2017 period to the 2018 period, primarily driven by clinical trial activity for M230, M254 and M281 that is more fully described in note 3 in the above table. External expenditures for our biosimilars programs decreased by $43.5 million, or 82%, from the 2017 period to the 2018 period, which was primarily due to decreased spending on M923 of $35.9 million as we had substantially completed development in 2017 in preparation for the filing of the biologic license application with the FDA. External expenditures for complex generics decreased by $2.9 million, or 78%, from the 2017 period to the 2018 period as support for Sandoz' GLATOPA 40 mg/mL ANDA filing in 2017 was non-recurring for 2018. Internal costs decreased by $2.8 million, or 4% from the 2017 period to the 2018 period primarily due to decreased personnel costs due in part to the workforce reduction announced in October 2018.

2017 vs 2016

External costs of our novel therapeutic programs decreased by $14.9 million, or 49%, from the 2016 period to the 2017 period, primarily driven by a $8.4 million reduction in spend on our necuparanib program, which we discontinued in August 2016, and a $5.4 million reduction in spend on M230 as, beginning in August 2017, these costs are shared with CSL. External expenditures for our biosimilars programs increased by $45.1 million, or 559%, from the 2016 period to the 2017 period, primarily due to increased spend on M923 of $37.9 million as we assumed responsibility for the development and commercialization of that program effective December 31, 2016. External expenditures for complex generics increased by $1.1 million, or 43%, from the 2016 period to the 2017 period as we continued to support our GLATOPA 40 mg/mL ANDA filing. Internal costs decreased by $1.9 million, or 2%, from the 2016 period to the 2017 period primarily due to the reversal of share-based compensation expense associated with performance-based stock awards that were no longer probable of vesting.

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.

Table of Contents

2018 vs 2017

The increase of $2.9 million, or 4%, from the 2017 period to the 2018 period was driven by the net of increased rent expense of $3.3 million related to occupancy of new premises, corporate costs of $3.0 million related to our strategic review and depreciation of $3.0 million as we evaluate estimates of the useful lives of depreciable assets. The increases were partially offset by decreases of $4.6 million in legal costs relating to our ongoing litigation and personnel salaries of $2.1 million due in part to the recent workforce reduction.

2017 vs 2016

The increase of $17.7 million, or 27%, from the 2016 period to the 2017 period was driven by $15.5 million of increased legal costs primarily relating to our ongoing litigation and $2.8 million in rent and maintenance of facilities, partially offset by a $0.7 million decrease in other professional fees, driven mainly by consulting fees.

Other Operating Expense

We recorded an expense of $30.0 million in 2018 in connection with the renegotiation with Human Genome Sciences, Inc., or GSK, of certain contractual obligations under a manufacturing services agreement. On August 15, 2018, we paid GSK $15.0 million and an additional $15.0 million is due by July 1, 2019.

Restructuring

Restructuring charges consist of severance, bonus, share-based compensation, and impairment of equipment associated with our workforce reduction. See to Note 14 "Restructuring" in our consolidated financial statements for further discussion.

Interest Income

Interest income was $6.2 million, $4.4 million and $2.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. The increases from 2017 to 2018 and from 2016 to 2017 were due to higher invested balances arising from financing activities and the benefit of higher market yields on our investments.

Other Income, Net

Other income, net includes other items of non-operating income and expense. The 2016 period includes a one-time cash receipt of $51.2 million in connection with the termination of the Baxalta Collaboration Agreement.

Equity Financings

In April 2015, we entered into an At-the-Market Equity Offering Sales Agreement, or the 2015 ATM Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal. We were required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under the 2015 ATM Agreement. In the year ended December 31, 2017, we sold approximately 4.5 million shares of common stock, raising net proceeds of $64.1 million, and concluded sales under the 2015 ATM Agreement.

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 December 31, 2018, we had $449.4 million in cash, cash equivalents and marketable securities. In addition, we also held $37.9 million in restricted cash, of which $36.1 million serves as collateral for a security bond posted in the litigation against Amphastar. Our funds at December 31, 2018 were primarily invested in commercial paper, overnight repurchase agreements, asset-backed securities, corporate debt securities and United States money market funds, directly or through managed funds, with remaining average 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 December 31, 2018.

Table of Contents

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. Since our inception through December 31, 2018, we have received $920 million through private and public issuances of equity securities. As of December 31, 2018, we received $469 million in revenues from sales of Enoxaparin Sodium Injection and milestones, and $255 million in revenues from sales of GLATOPA and milestones. We received $139 million under our collaboration with Baxalta, including a one-time cash payment of $51.2 million in connection with the termination of the Baxalta Collaboration Agreement. In addition, we received a $45.0 million upfront payment from Mylan as well as $60.0 million in milestone payments from Mylan which are applied towards Mylan 50% share of development-related collaboration costs. Finally, in February 2017, we received a $50.0 million upfront payment from CSL under the CSL License and Option Agreement.

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.

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Net cash (used in) provided by operating activities	$(155,590)	$(29,085)	$8,989
Net cash provided by (used in) investing activities	$98,081	$(121,079)	$80,048
Net cash provided by financing activities	$247,058	$74,348	$1,341
Net increase (decrease) in cash and cash equivalents	$189,549	$(75,816)	$90,378

Cash (used in) provided by operating activities

The cash used for 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 $155.6 million for the year ended December 31, 2018 reflecting a net loss of $176.1 million, which was partially offset by non-cash charges of $9.9 million for depreciation of property and equipment, $1.2 million amortization of intangible assets, $21.2 million in share-based compensation, $33.4 million for research and development revenue associated with the Mylan Collaboration Arrangement and $0.4 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of $15.5 million and is primarily due to the remaining $15.0 million amount due to GSK under our manufacturing services agreement entered into in 2018.

Cash used in operating activities was $29.1 million for the year ended December 31, 2017 reflecting a net loss of $88.1 million, which was partially offset by non-cash charges of $9.2 million for depreciation and amortization of property, equipment and intangible assets, $16.1 million in share-based compensation and $0.2 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of $32.2 million and is primarily due to a one-time cash payment of $51.2 million in connection with the termination of the Baxalta Collaboration Agreement, which was included in collaboration receivable at December 31, 2016, and reimbursement of tenant improvements by our landlord of $4.1 million, partially offset by the recovery of $24.7 million from Mylan for its 50% share of development-related collaboration expenses under the cost-sharing provisions of the Mylan Collaboration Agreement.

Cash provided by operating activities was $9.0 million for the year ended December 31, 2016 reflecting a net loss of $21.0 million, which was partially offset by non-cash charges of $9.1 million for depreciation and amortization of property, equipment and intangible assets, $18.3 million for share-based compensation and $0.6 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of $0.9 million, primarily due to: a $51.2 million receivable due from Baxalta in connection with the termination of the collaboration agreement; the collection of $2.1 million in contractual profit on Sandoz'

fourth quarter 2015 sales of Enoxaparin Sodium Injection; the receipt of $60.0 million in milestone payments from Mylan where $27.1 million was used to fund Mylan's 50% share of development-related 2016 collaboration expenses and $32.9 million will be applied towards the funding of Mylan's 50% share of future development-related collaboration expenses; and the receipt of a $45.0 million upfront payment from

Table of Contents

Mylan of which $6.4 million was recorded as research and development revenue in 2016. In addition, in 2016 we recorded research and development revenue of $22.0 million representing the remaining unamortized balance of the $40.0 million upfront and license payments from Baxalta.

Cash provided (used in) by investing activities

Cash provided by investing activities of $98.1 million for the year ended December 31, 2018 includes cash inflows of $308.2 million from maturities of marketable securities and proceeds from the sale of assets of $1.4 million, partially offset by cash outflows of $202.5 million for purchases of marketable securities and $9.0 million for capital equipment and leasehold improvements.

Cash used in investing activities of $121.1 million for the year ended December 31, 2017 includes cash outflows of $524.9 million for purchases of marketable securities and $17.1 million for capital equipment and leasehold improvements, partially offset by cash inflows of $420.7 million from maturities of marketable securities and proceeds from the sale of assets of $0.3 million.

Cash provided by investing activities of $80.0 million for the year ended December 31, 2016 includes cash inflows of $445.7 million from maturities of marketable securities, partially offset by cash outflows of $360.0 million for purchases of marketable securities and $5.6 million for capital equipment and leasehold improvements.

Cash provided by financing activities

Cash provided by financing activities of $247.1 million for the year ended December 31, 2018 includes $217.8 million of net proceeds from shares sold in our public offering of common stock and $29.3 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Cash provided by financing activities of $74.3 million for the year ended December 31, 2017 includes $64.1 million net proceeds from our issuance of common stock under the 2015 ATM facility and $10.3 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Cash provided by financing activities of $1.3 million for the year ended December 31, 2016 includes $2.4 million from stock option exercises and purchases of our common stock through our employee stock purchase plan, partially offset by $1.1 million of cash paid to tax authorities in connection with the vesting of performance-based restricted stock.

Contractual Obligations

Our major outstanding contractual obligations relate to operating lease obligations as well as license maintenance obligations including royalties payable to third parties.

The following table summarizes our contractual obligations at December 31, 2018 (in thousands):

Contractual Obligations	Total	2019	2020 through 2021	2022 through 2023	After 2023
License maintenance obligations	$1,163	$233	$465	$465	*
Operating lease obligations	125,096	15,418	32,138	33,427	$44,113
Purchase obligations**	50,820	—	22,500	28,320	—
Total contractual obligations	$177,079	$15,651	$55,103	$62,212	$44,113

* After 2023, the annual obligations, which extend through the life of the patents are approximately $0.2 million per year.

** Reflects minimum purchase obligations under a manufacturing services agreement with GSK.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the

62

Table of Contents

circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Collaboration and License Arrangements

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method as permissible for all contracts not yet completed as of January 1, 2018. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

License Agreements

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

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

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

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

The Company may earn a contractual percentage of a licensor’s revenues or profits after the successful development and commercialization of a licensed product. A sales or usage-based royalty on a license of intellectual property where the license is the predominant item to which the royalty relates is eligible for an exception to the standard revenue

recognition model under Topic 606. Under this exception, an entity is permitted to (i) exclude such amounts from the initial determination of the transaction price (hence no amounts to allocate amongst the performance obligations) and (ii) defer recognition until underlying sales occur. The amount of net sales and contractual profit is determined based on information provided by the licensor and involves the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations

Table of Contents

fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. Net sales and contractual profit may also include or exclude other amounts as defined in an agreement. The Company is highly dependent on the licensor for timely and accurate information regarding any net revenues realized from sales of the licensed products in order to accurately report its results of operations. Sales-based milestones and profit share revenues are recognized as revenue when sales thresholds are met under the sales or usage-based royalty exception under Topic 606.

Collaborative Arrangements

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

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

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

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves the following:

- communicating with appropriate internal personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our consolidated financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with process development and manufacturing activities;
- fees paid to CROs in connection with nonclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

64

Table of Contents

Share-Based Compensation

For performance-based restricted stock and restricted unit awards, at each reporting period we assess the probability that the performance condition(s) will be achieved. We use the accelerated attribution method to expense the awards over the implicit service period based on the probability of achieving the performance conditions. We estimate an award's implicit service period based on our best estimate of the period over which an award's vesting condition(s) will be achieved. We review and evaluate these estimates on a quarterly basis and will recognize any remaining unrecognized compensation as of the date of an estimate revision over the revised remaining implicit service period.

New Accounting Standards

Please see Note 2 "Summary of Significant Accounting Policies" to our consolidated financial statements, for a discussion of new accounting standards. The notes to our consolidated financial statements are contained in Part II, Item 8 of this Annual Report on Form 10-K.

Item 7A. 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 December 31, 2018, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

Table of Contents

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of Momenta Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Momenta Pharmaceuticals, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 22, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606)

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standard Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

Boston, Massachusetts

February 22, 2019

Table of Contents

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$248,334	$73,651
Marketable securities	174,076	269,017
Collaboration receivable	11,371	15,048
Prepaid expenses and other current assets	6,318	6,798
Assets held-for-sale	1,324	—
Restricted cash	—	2,412
Total current assets	441,423	366,926
Marketable securities, long-term	27,001	37,222
Property and equipment, net	20,944	29,916
Restricted cash	37,898	20,620
Intangible assets, net	2,883	4,036
Other long-term assets	1,414	711
Total assets	$531,563	$459,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$9,352	$11,456
Accrued expenses	14,060	20,528
Accrued restructuring	3,235	—
Collaboration liabilities	4,721	9,258
Deferred revenue	3,916	2,866
Other current liabilities	16,227	379
Total current liabilities	51,511	44,487
Deferred revenue, net of current portion	1,774	30,751
Other long-term liabilities	17,270	10,039
Total liabilities	70,555	85,277
Commitments and contingencies (Note 15)		
Stockholders' Equity:		
Common stock, $0.0001 par value per share; 100,000 shares authorized, 98,694 shares issued and 98,464 shares outstanding at December 31, 2018 and 76,584 shares issued and 76,355 shares outstanding at December 31, 2017	10	8
Additional paid-in capital	1,208,025	939,654
Accumulated other comprehensive loss	(87)	(140)
Accumulated deficit	(743,826)	(562,254)
Treasury stock, at cost, 229 shares	(3,114)	(3,114)
Total stockholders' equity	461,008	374,154
Total liabilities and stockholders' equity	$531,563	$459,431

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

Table of Contents

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

	Year Ended December 31,		
	2018	2017	2016
Collaboration revenues:			
Product revenue	$39,684	$66,803	$74,648
Research and development revenue	35,905	72,079	34,971
Total collaboration revenue	75,589	138,882	109,619
Operating expenses:			
Research and development	124,004	149,226	119,880
General and administrative	85,105	82,207	64,466
Other operating expense	30,000	—	—
Restructuring	17,807	—	—
Total operating expenses	256,916	231,433	184,346
Operating loss	(181,327)	(92,551)	(74,727)
Other income (expense):			
Interest income	6,194	4,427	2,226
Other income (expense), net	(928)	28	51,498
Total other income	5,266	4,455	53,724
Net loss	$(176,061)	$(88,096)	$(21,003)
Net loss per share:			
Basic and diluted	$(2.26)	$(1.20)	$(0.31)
Weighted average shares outstanding:			
Basic and diluted	77,845	73,136	68,656
Comprehensive loss:			
Net loss	$(176,061)	$(88,096)	$(21,003)
Net unrealized holding gains (losses) on available-for-sale marketable securities	53	(226)	82
Comprehensive loss	$(176,008)	$(88,322)	$(20,921)

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

Table of Contents

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

	Common Stock					Treasury Stock		
	Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Shares	Amount	Total Stockholders' Equity
Balances at December 31, 2015	69,077	$ 7	$824,385	$ 4	$(452,372)	(119)	$(2,048)	$ 369,976
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	211	—	2,407	—	—	—	—	2,407
Common shares issued to Parivid to settle milestone payment	266	—	3,190	—	—	—	—	3,190
Repurchase of common stock pursuant to share surrender	—	—	—	—	—	(110)	(1,066)	(1,066)
Issuance of restricted stock	2,081	—	—	—	—	—	—	—
Cancellation/forfeiture of restricted stock	(330)	—	—	—	—	—	—	—
Share-based compensation expense for employees	—	—	18,142	—	—	—	—	18,142
Share-based compensation expense for non-employees	—	—	180	—	—	—	—	180
Unrealized gain on marketable securities	—	—	—	82	—	—	—	82
Net loss	—	—	—		(21,003)	—	—	(21,003)
Balances at December 31, 2016	71,305	$ 7	$848,304	$ 86	$(473,375)	(229)	$(3,114)	$ 371,908
Impact of adopting ASU 2016-09	—	—	783	—	(783)			—
Net proceeds from issuance of common stock pursuant to the ATM facilities	4,537	1	64,089	—	—	—	—	64,090
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	903	—	10,351	—	—	—	—	10,351
Issuance of restricted stock	145	—	—	—	—	—	—	—
Cancellation/forfeiture of restricted stock	(306)	—	—	—	—	—	—	—
Share-based compensation expense	—	—	16,127	—	—	—	—	16,127
Unrealized loss on marketable securities	—	—	—	(226)	—	—	—	(226)
Net loss	—	—	—	—	(88,096)	—	—	(88,096)

Balances at December 31, 2017	76,584	$ 8	$939,654	$ (140)	$(562,254)	(229)	$(3,114)	$ 374,154
Impact of adopting ASC 606	—	—	—	—	(5,511)	—	—	(5,511)
Net proceeds from issuance of common stock	20,000	2	217,784	—	—	—	—	217,786
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	2,080	—	29,365	—	—	—	—	29,365
Issuance of restricted stock	445	—	—	—	—	—	—	—
Cancellation/forfeiture of restricted stock	(414)	—	—	—	—	—	—	—
Share-based compensation expense	—	—	21,222	—	—	—	—	21,222
Unrealized gain on marketable securities	—	—	—	53	—	—	—	53
Net loss	—	—	—	—	(176,061)	—	—	(176,061)
Balances at December 31, 2018	98,695	$ 10	$1,208,025	$ (87)	$(743,826)	(229)	$(3,114)	$ 461,008

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

Table of Contents

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

	Year Ended December 31,		
	2018	2017	2016
Cash Flows from Operating Activities:			
Net loss	$(176,061)	$(88,096)	$(21,003)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization of property and equipment	9,917	8,023	7,593
Impairment of equipment	3,608	—	—
Share-based compensation expense	21,222	16,127	18,322
Amortization of premium on investments	(438)	167	595
Amortization of intangibles	1,153	1,153	1,529
Loss on disposal of assets	510	61	—
Changes in operating assets and liabilities:			
Collaboration receivable	3,677	55,194	(49,057)
Prepaid expenses and other current assets	573	(2,098)	(1,128)
Other long-term assets	(703)	1,229	(1,692)
Accounts payable	(1,158)	7,446	(1,032)
Accrued expenses	(6,229)	(6,253)	2,043
Accrued restructuring	3,235	—	—
Collaboration liabilities	(4,537)	(23,637)	32,895
Deferred revenue	(33,438)	(5,015)	16,649
Lease incentive	5,860	4,051	—
Other current liabilities	15,182	(66)	(449)
Other long-term liabilities	2,037	2,629	3,724
Net cash (used in) provided by operating activities	(155,590)	(29,085)	8,989
Cash Flows from Investing Activities:			
Purchases of property and equipment	(9,019)	(17,127)	(5,609)
Proceeds from disposal of equipment	1,447	267	—
Purchases of marketable securities	(202,525)	(524,888)	(360,008)
Proceeds from maturities of marketable securities	308,178	420,669	445,665
Net cash provided by (used in) investing activities	98,081	(121,079)	80,048
Cash Flows from Financing Activities:			
Proceeds from public offering of common stock, net of issuance costs	217,786	—	—
Net proceeds from issuance of common stock under ATM facility	—	64,090	—
Proceeds from issuance of common stock under stock plans	29,272	10,258	2,407
Repurchase of common stock pursuant to share surrender	—	—	(1,066)
Net cash provided by financing activities	247,058	74,348	1,341
Net increase (decrease) in cash, cash equivalents and restricted cash	189,549	(75,816)	90,378
Cash, cash equivalents, and restricted cash, beginning of period	96,683	172,499	82,121
Cash, cash equivalents, and restricted cash, end of period	$286,232	$96,683	$172,499
Non-Cash Activities:			
Common shares issued to Parivid to settle milestone payment	$—	$—	$3,190
Purchases of property and equipment included in accounts payable and accrued expenses	$43	$1,228	$935
Receivable due from stock option exercises	$—	$93	$—

Impact of adopting ASU 2016-09	$—	$783	$—
Impact of adopting ASC 606	$5,511	$—	$—

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

Table of Contents

MOMENTA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. The Company

Business Overview

Momenta Pharmaceuticals, Inc., referred to as Momenta or the Company, was incorporated in the state of Delaware in May 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company focused on developing novel therapeutics for autoimmune diseases and other legacy products including complex generics and biosimilars. The Company presently derives all of its revenue from its collaborations.

2. Summary of Significant Accounting Policies

Consolidation

The accompanying 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 generally accepted accounting principles in the United States, or U.S. GAAP, requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and judgments, including those related to revenue recognition, accrued expenses, and share-based payments. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method as permissible for all contracts not yet completed as of January 1, 2018. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

License Agreements

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

If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. The Company evaluates all other promised goods or services in the license agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services that reflect their standalone selling prices do not provide the

Table of Contents

customer with a material right and, therefore, are not considered performance obligations. If optional future services reflect a significant or incremental discount, they are material rights, and are accounted for as performance obligations.

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

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

The Company may earn a contractual percentage of a licensor’s revenues or profits after the successful development and commercialization of a licensed product. A sales or usage-based royalty on a license of intellectual property where the license is the predominant item to which the royalty relates is eligible for an exception to the standard revenue recognition model under Topic 606. Under this exception, an entity is permitted to (i) exclude such amounts from the initial determination of the transaction price (hence no amounts to allocate amongst the performance obligations) and (ii) defer recognition until underlying sales occur. The amount of net sales and contractual profit is determined based on information provided by the licensor and involves the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. Net sales and contractual profit may also include or exclude other amounts as defined in an agreement. The Company is highly dependent on the licensor for timely and accurate information regarding any net revenues realized from sales of the licensed products in order to accurately report its results of operations. Sales-based milestones and profit share revenues are recognized as revenue when sales thresholds are met under the sales or usage-based royalty exception under Topic 606.

Collaborative Arrangements

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

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

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

Impact of Adoption

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

As more fully discussed in Note 9, "Collaboration and License Agreements", only the arrangement with Mylan Ireland Limited, or Mylan, a wholly owned indirect subsidiary of Myland N.V., was determined to have unsatisfied performance

Table of Contents

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

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

Condensed Consolidated Statement of Operations and Comprehensive Loss

	For the Year Ended December 31, 2018		
	Topic 606	Topic 605	Change
Research and development revenue	$35,905	$27,457	$8,448
Loss from operations	$181,327	$189,775	$(8,448)
Net loss	$176,061	$184,509	$(8,448)
Comprehensive loss	$176,008	$184,456	$(8,448)

Condensed Consolidated Balance Sheet

	Balance as of December 31, 2018		
	Topic 606	Topic 605	Change
Deferred revenue, current	$3,916	$6,186	$(2,270)
Deferred revenue, non-current	$1,774	$2,442	$(668)
Accumulated deficit	$743,826	$746,764	$(2,938)

Condensed Consolidated Statement of Cash Flows

	For the Year Ended December 31, 2018		
	Topic 606	Topic 605	Change
Net loss	$176,061	$184,509	$(8,448)
Adjustments to reconcile net loss to net cash used in operating activities:			
Deferred revenue	$33,438	$24,990	$8,448

Collaboration Receivable

Collaboration receivable includes:

- Amounts due to the Company for its contractual profit share on Sandoz Inc.’s, or Sandoz', and sales of GLATOPA;
- Amounts due to the Company for reimbursement of research and development services and certain external costs primarily under the collaborations with Sandoz; and
- Amounts due from Mylan for its 50% share of certain collaboration expenses under the cost-sharing provisions of the agreement with Mylan, as described in Note 9, "Collaboration and License Agreements", that are not funded through the continuation payments.

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

Table of Contents

Collaboration Liability

Collaboration liability includes:

- Advance payments received from Mylan that will be applied to amounts due from Mylan in future periods for the funding of Mylan's 50% share of certain collaboration expenses under the cost-sharing provisions of the agreement with Mylan; and
- Net payable to CSL Behring Recombinant AG, or CSL, for the Company's 50% share of collaboration expenses under the cost-sharing provisions of the agreement with CSL.

Cash, Cash Equivalents and Marketable Securities

The Company invests its cash in bank deposits, money market accounts, corporate debt securities, United States treasury obligations, commercial paper, asset-backed securities, overnight repurchase agreements and United States government-sponsored enterprise securities in accordance with its investment policy. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk.

The Company invests its excess cash balances in short-term and long-term marketable debt securities. The Company classifies its investments in marketable debt securities as available-for-sale based on facts and circumstances present at the time it purchased the securities. Purchased premiums or discounts on marketable debt securities are amortized to interest income through the stated maturities of the debt securities. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in interest income. To determine whether an other-than-temporary impairment exists, the Company considers whether it intends to sell the debt security and, if it does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. The Company reviewed its investments with unrealized losses and concluded that no other-than-temporary impairment existed at December 31, 2018 as it has the ability and intent to hold these investments to maturity and it is not more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. The Company did not record any impairment charges related to its marketable securities during the years ended December 31, 2018, 2017 and 2016. Realized gains or losses on marketable securities for each of the years ended December 31, 2018, 2017, and 2016 were immaterial. The Company's marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is 90 days or less, and as marketable securities if the original maturity, from the date of purchase, is in excess of 90 days. The Company's cash equivalents are primarily composed of money market funds and repurchase agreements carried at fair value, which approximates cost at December 31, 2018 and 2017.

Fair Value Measurements

The Company measures certain financial assets including cash equivalents and marketable securities at fair value on a recurring basis. These financial assets are generally classified as Level 1 or 2 within the fair value hierarchy. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices (adjusted), interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The fair value hierarchy level is determined by the lowest level of significant input.

The Company's financial assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period, typically utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. The Company did not adjust or override any fair value measurements provided by its pricing services as of December 31, 2018 and December 31, 2017.

Concentration of Credit Risk

The Company's primary exposure to credit risk is derived from its cash, cash equivalents, marketable securities and collaboration receivable.

Table of Contents

Property and Equipment

Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs which do not improve or extend the life of the respective assets are charged to expense. Upon disposal, the related cost and accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leased assets meeting certain capital lease criteria are capitalized and the present value of the related lease payments is recorded as a liability. Assets under capital lease arrangements are depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter. When the Company disposes of property and equipment, it removes the associated cost and accumulated depreciation from the related accounts on its consolidated balance sheet and includes any resulting gain or loss in its consolidated statements of operations and comprehensive loss.

Assets Held-for-Sale

The Company classifies assets as held-for-sale when the following conditions are met: (1) management has committed to a plan to sell, (2) the assets are available for immediate sale in their present condition, (3) the Company has initiated an active program to identify a buyer, (4) it is probable that a sale will occur within one year, (5) the assets are actively marketed for sale at a reasonable price in relation to their current fair value, and (6) there is a low likelihood of significant changes to the plan or that the plan will be withdrawn. If all of the criteria are met as of the balance sheet date, the assets are presented separately in the balance sheet as held-for-sale at the lower of the carrying amount or fair value less costs to sell. The assets are then no longer depreciated or amortized while classified as held-for-sale.

Long-Lived Assets

The Company evaluates the recoverability of its property, equipment and intangible assets when circumstances indicate that an event of impairment may have occurred. The Company recognizes an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the fair value of such assets or businesses.

Research and Development

Research and development expenses consist of costs incurred to conduct research, such as the discovery and development of the Company's product candidates. Research and development costs are expensed as incurred. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, nonclinical and clinical trial costs, contract research and manufacturing costs, and the costs of laboratory equipment and facilities. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are received.

Accounting for Share-Based Compensation

The Company grants awards under its share-based compensation programs, which awards have included stock options, time-based restricted stock awards, performance-based restricted stock awards, time-based restricted stock units and shares issued under its employee stock purchase plan (ESPP). The Company charges the estimated fair value of such awards to operating expense in its consolidated statements of operations and comprehensive loss over the requisite service period, which is generally the vesting period.

The fair values of stock option grants are estimated as of the date of grant using the Black-Scholes Merton option pricing model. The estimated fair values of the stock options are then expensed over the requisite service period. The Company uses its own historical data to estimate volatility and expected term, which includes an assessment of option exercise patterns and post-vesting employee termination behavior to arrive at the estimated expected life of an option. The Company reviews and evaluates these assumptions regularly to reflect recent historical data. The risk-free interest rate for periods within the expected term of the option is based on the United States Treasury yield curve in effect at the time of grant.

The fair values of restricted stock and restricted stock units are based on the market value of our stock on the date of grant. Compensation expense for time-based restricted stock and restricted stock units is recognized on a straight-line

basis over the applicable service period.

For performance-based restricted stock and restricted stock units, at each reporting period the Company assesses the probability that the performance condition(s) will be achieved. The Company uses the accelerated attribution method to

Table of Contents

expense the awards over the implicit service period based on the probability of achieving the performance conditions. The Company estimates the implicit service period based on its best estimate of the period over which an award's vesting condition(s) will be achieved. The Company reviews and evaluates these estimates on a quarterly basis and will recognize any remaining unrecognized compensation expense as of the date of an estimate revision over the revised remaining implicit service period.

Prior to 2017, the Company applied an estimated forfeiture rate to period expense to recognize share-based compensation expense only for those stock and option awards expected to vest. The Company estimated forfeitures based upon historical data, adjusted for known trends, and adjusted its estimate of forfeitures if actual forfeitures differed. Subsequent changes in estimated forfeitures were recognized through a cumulative adjustment in the period of change. In 2017, the Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting and made an entity-wide accounting policy election to account for award forfeitures as they occur. As a result, the Company recorded a cumulative opening adjustment to accumulated deficit and additional paid-in capital of $0.8 million.

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 restricted stock 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.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company was profitable and generated taxable income in 2010 and 2011. Since 2011, the Company has generated operating losses and expects to continue to incur future losses, therefore the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions that are more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had accrued no amounts for interest and penalties in the Company's consolidated balance sheets at December 31, 2018 and 2017.

The Company files income tax returns in the United States federal jurisdiction and multiple state jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination for years before 2015, except to the extent that in the future it utilizes net operating losses or tax credit carry forwards that originated before 2015. As of December 31, 2018, the Company was not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

Comprehensive Loss

Comprehensive income (loss) is the change in equity of a company during a period from transactions and other events and circumstances, excluding transactions resulting from investments by owners and distributions to owners. Comprehensive income (loss) includes net income (loss) and the change in accumulated other comprehensive income (loss) for the period. Accumulated other comprehensive income (loss) consists entirely of unrealized gains and losses on available-for-sale marketable securities for all periods presented.

Segment Reporting

Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance.

Momenta is a biotechnology company focused on discovering and developing novel therapeutics and its legacy products, which include complex generics and biosimilars. The product areas correspond with their respective

regulatory pathways. However, the Company's portfolio has similar development risk and market characteristics. The Company does not operate separate lines of business with respect to any of its products or product candidates and the Company does not prepare discrete financial information with respect to these product areas. Accordingly, the Company views its business as one reportable operating segment—the discovery, development and commercialization of pharmaceutical products.

Table of Contents

Accounting Pronouncements Adopted

In November 2016, the FASB issued ASU No. 2016-18, Restricted Cash, or ASU 2016-18. The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The retrospective adoption of ASU 2016-18 resulted in $23.0 million and $21.7 million of restricted cash being included in cash, cash equivalents and restricted cash balances on the statement of cash flows for the period ended December 31, 2017 and 2016, respectively. The Company includes the necessary reconciliation in Note 4, "Cash, Cash Equivalents, and Marketable Securities".

New Accounting Pronouncements

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

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. 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 has elected this transition method at the adoption date of January 1, 2019. The Company has also elected a 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 Company is in the process of finalizing the impact of adoption.

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 became effective for the Company on January 1, 2019. The Company does not believe the guidance will have a material impact on its financial statements.

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 believe the guidance will have a material impact on its 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 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 the 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 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.

Table of Contents

3. Fair Value Measurements

The tables below present information about the Company's assets that are regularly measured and carried at fair value on a recurring basis at December 31, 2018 and 2017, and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, which is described further within Note 2, Summary of Significant Accounting Policies.

Financial assets measured at fair value on a recurring basis at December 31, 2018 and 2017 are summarized as follows (in thousands):

Description	Balance as of December 31, 2018	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 119,955	$ 119,955	$ —	$ —
Marketable securities:				
U.S. government-sponsored enterprise securities	12,424	—	12,424	—
Corporate debt securities	129,308	—	129,308	—
Certificates of deposit	3,003	—	3,003	—
Commercial paper obligations	30,935	—	30,935	—
Asset-backed securities	25,407	—	25,407	—
Total	$ 321,032	$ 119,955	$ 201,077	$ —

Description	Balance as of December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 49,204	$ 49,204	$ —	$ —
Overnight repurchase agreements	11,250	—	11,250	—
Marketable securities:				
U.S. government-sponsored enterprise securities	18,181	—	18,181	—
Corporate debt securities	148,874	—	148,874	—
Certificates of deposit	7,794	—	7,794	—
Commercial paper obligations	108,630	—	108,630	—
Asset-backed securities	22,760	—	22,760	—
Total	$ 366,693	$ 49,204	$ 317,489	$ —

There have been no impairments of the Company’s assets measured and carried at fair value during the years ended December 31, 2018 and 2017. In addition, there were no changes in valuation techniques or transfers between Level 1 and Level 2 financial assets during the years ended December 31, 2018 and 2017. The fair value of Level 2 instruments classified as marketable securities was determined through third party pricing services. The carrying amounts reflected in the Company’s consolidated balance sheets for cash, collaboration receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities. Other than assets held-for-sale discussed in Note 5, the Company did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2018 and 2017.

78

Table of Contents

4. Cash, Cash Equivalents and Marketable Securities

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

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 more than one year	25,416	2	(11)	25,407
Total	$449,498	$ 44	$ (131)	$449,411
Reported as:				
Cash and cash equivalents	$248,334	$ —	$ —	$248,334
Marketable securities	201,164	45	(132)	201,077
Total	$449,498	$ 45	$ (132)	$449,411

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

Cash, Cash Equivalents, and Restricted Cash

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

	As of December 31, 2018	As of December 31, 2017
Cash and cash equivalents	$ 248,334	$ 73,651
Restricted cash, current portion	—	2,412
Restricted cash, long-term	37,898	20,620
Total	$ 286,232	$ 96,683

Table of Contents

5. Property and Equipment and Assets Held-for-Sale

As of December 31, 2018 and 2017, property and equipment, net and assets held-for-sale consists of the following (in thousands):

	2018	2017	Depreciable Lives
Computer equipment	$3,189	$3,061	3 years
Software	11,076	11,062	3 years
Office furniture and equipment	873	2,530	5 to 6 years
Laboratory equipment	18,348	51,315	7 years
Leasehold improvements	23,932	25,356	Shorter of asset life or lease term
Less: accumulated depreciation	(36,474)	(63,408)	
	$20,944	$29,916	
Assets held-for-sale	$1,324	$—	

During 2018, the Company disposed of property and equipment with a gross carrying amount of $19.0 million and accumulated depreciation of $17.0 million. The Company did not dispose of any property and equipment during 2017. Depreciation and amortization expense amounted to $9.9 million, $8.0 million, and $7.6 million in the years ended December 31, 2018, 2017 and 2016, respectively.

The estimated useful life of certain leasehold improvements was re-evaluated and adjusted to reflect the remaining period the Company would expect to have use of those leasehold improvements. As a result of this change in estimate, depreciation expense increased approximately $2.4 million, or $0.03 per share, for the year ended December 31, 2018 as compared to the amount of depreciation expense otherwise calculated based on prior estimates of useful life.

The Company initially recorded certain laboratory equipment asset impairments in the third quarter of 2018 in accordance with ASC 360 Property, Plant and Equipment for assets held-and-used, as the criteria to classify the laboratory equipment as held-for-sale had not been met. The Company identified an indicator of impairment related to this held-and-used laboratory equipment as it was more likely than not that some of its laboratory equipment would be sold or otherwise disposed of significantly before the end of its previously estimated useful life primarily as a result of the restructuring described in Note 14. For the laboratory equipment where its fair value did not exceed its carrying amount, an impairment was recognized. Fair value was estimated utilizing sales of similar equipment, a level 2 fair value measurement. In the fourth quarter of 2018, the Company committed to a plan to actively sell certain of its laboratory equipment. Having met all other criteria, the laboratory equipment met the criteria to classify that equipment as held-for-sale. At December 31, 2018, $1.3 million of laboratory equipment was classified as held-for-sale as reflected in the consolidated balance sheet. The sale is expected to be complete by the end of the first quarter of 2019. Laboratory equipment held-for-sale is reflected at the lower of its carrying amount or fair value less the cost to sell, with any excess recorded as an impairment. In aggregate, impairment losses recognized in connection with laboratory equipment was $3.6 million and included in restructuring costs in the consolidated statement of operations for the year ended December 31, 2018.

6. Intangible Assets

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

triggering the final milestone payment under the amended asset purchase agreement. In connection with the final milestone, on August 10, 2016, the Company issued 265,605 shares of its common stock to Parivid to satisfy the GLATOPA 20

Table of Contents

mg/mL milestone. The Company recorded $3.2 million as an intangible asset based on the number of shares issued and the closing price of the Company's common stock on the date the shares were issued to Parivid.

Intangible assets consist solely of the core developed technology assets acquired from Parivid. The intangible assets are being amortized using the straight-line method over the estimated useful life of GLATOPA 20 mg/mL of approximately six years through June 2021. As of December 31, 2018 and 2017, intangible assets, net of accumulated amortization, are as follows (in thousands):

	2018 Gross Carrying Amount	Accumulated Amortization	2017 Gross Carrying Amount	Accumulated Amortization
Total intangible assets for core and developed technology	$13,617	$ (10,734)	$13,617	$ (9,581)

Amortization expense was approximately $1.2 million, $1.2 million, and $1.5 million in the years ended December 31, 2018, 2017 and 2016, respectively.

The Company expects to incur amortization expense of approximately $1.2 million per year from 2019 to 2020 and $0.6 million in the final year (2021).

7. Restricted Cash

The Company designated $36.1 million as collateral for a letter of credit that is security for a bond posted in the litigation against Amphastar and International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. Additional information regarding the litigation is discussed within Note 15, Commitments and Contingencies. The $36.1 million is held on deposit with a bank. The Company classified this restricted cash as long-term as the timing of a final decision in the Enoxaparin Sodium Injection patent litigation is not known.

The following table summarizes the amounts designated as collateral for letters of credit related to the lease of office and laboratory space in Cambridge, Massachusetts (collateral amounts are presented in thousands).

Property Location	Approximate Square Footage	Lease Expiration Date	Letter of Credit Amount	Balance Sheet Classification
320 Bent Street	105,000	2/28/2027	$ 748	Non-Current Asset
301 Binney Street, Fifth Floor	80,000	6/29/2025	1,101	Non-Current Asset
Total			$ 1,849	

8. Accrued Expenses and Other Liabilities

Accrued Expenses

As of December 31, 2018 and 2017, accrued expenses consisted of the following (in thousands):

	2018	2017
Accrued compensation	$8,106	$8,743
Accrued contract research and manufacturing costs	2,944	8,843
Accrued professional fees	2,372	2,429
Other	638	513
Total accrued expenses	$14,060	$20,528

Other Liabilities

As of December 31, 2018 and 2017, other current and long-term liabilities consisted of the following (in thousands):

Table of Contents

Current

	2018	2017
Contract liability, current portion	$15,000	$—
Lease incentive, current	1,052	379
Lease liability, current	128	—
Deferred rent, current	47	—
Total other current liabilities	$16,227	$379

Long-Term

	2018	2017
Deferred rent, long-term	$8,477	$6,498
Lease incentive, long-term	7,877	3,541
Lease liability, long-term	916	—
Total other long-term liabilities	$17,270	$10,039

As of December 31, 2018, the Company included $15.0 million in other current liabilities in connection with the renegotiation with Human Genome Sciences, Inc. ("GSK") of certain remaining contractual obligations under a manufacturing services agreement.

9. Collaboration and License Agreements

Contracts with Customers

2003 Sandoz Collaboration 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 year ended December 31, 2018 and 2017, and therefore the Company did not record product revenue for the licensed product in those periods. The Company is no longer eligible to receive milestones under the agreement.

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

Table of Contents

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 million in future post-launch commercial milestones payments. The Company is still eligible to receive up to $30 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 first quarter of 2018, representing 50% of potential GLATOPA 40 mg/mL pre-launch inventory costs. In the first quarter of 2018, the Company's product revenue was reduced by $9.8 million for the Company's 50% share of GLATOPA 40 mg/mL written off by Sandoz.

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

Baxalta Agreement

The Company and Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated, collectively referred to as Baxalta, entered into a global collaboration and license agreement, or the Baxalta Agreement, effective February 2012, to develop and commercialize biosimilars, including M923, the Company's biosimilar HUMIRA® (adalimumab) candidate.

On September 27, 2016, Baxalta gave the Company twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Agreement. On December 31, 2016, the Company and Baxalta entered into the Baxalta Termination Agreement, amending certain termination provisions of the Baxalta Agreement. The termination of the Baxalta Agreement was made effective December 31, 2016. Baxalta was relieved of its obligations to continue to perform activities for M923 after December 31, 2016, except for certain on-going clinical and regulatory activities that were completed in 2017, and in January 2017, Baxalta paid the Company a one-time cash payment of $51.2 million representing the costs

Table of Contents

Baxalta would have incurred in performing the activities it would have performed under Baxalta Agreement through the original termination date.

As a result of termination, the Company's performance period for M923 ended on December 31, 2016; therefore, the Company recognized the remaining balance of deferred revenue of $22.0 million as research and development revenue in the year ended December 31, 2016. In addition, the Company recorded the $51.2 million asset return payment in other income in the fourth quarter of 2016.

Collaborative Agreements

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. As a result, the Company will only continue to advance its late-stage biosimilar candidate M710, our 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 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 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 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 for a given product candidate in a given country, unless earlier terminated by either party pursuant to the terms of the Mylan Collaboration Agreement.

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

Table of Contents

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 the M834, $7.1 million was allocated to M710, and between $5.7 million and $9.0 million 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 measure of proportionate performance. The pattern of recognition differs from the Company's previous accounting policy. Refer to Note 2, "Summary of Significant Accounting Policies", for disclosure of the quantification and impact of this change as a result of adopting Topic 606.

As a result of providing a notice of partial termination of the Mylan Collaboration Agreement in November 2018, specifically 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. Since 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. Accordingly, the Company updated its calculation of proportional performance in the fourth quarter of 2018, which resulted in revenue recognition of $31.5 million. As a result, as of December 31, 2018, $5.7 million of the transaction price remains allocated to unsatisfied performance obligations and is included in deferred revenue in the 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 of up to $200.0 million across the six product candidates, while other shared collaboration costs are reconciled by the parties with the owing party reimbursing the other party by making quarterly payments. The Company records a contract asset to reflect a receivable

Table of Contents

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

CSL License and Option Agreement

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

Pursuant to the 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.

Unless earlier terminated, the term of the agreement commences on February 17, 2017, and continues until the later of (i) the expiration of all payment obligations with respect to products under the agreement, (ii) the Company is no longer co-funding development or commercialization of any products and (iii) the Company and CSL are not otherwise collaborating on the development and commercialization of products or product candidates. CSL may terminate the agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. The Company may terminate the agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the agreement. Either party may terminate the agreement (i) on a product-by-product basis if certain patent challenges are made, (ii) on a product-by-product basis for material breaches, or (iii) due to the other party’s bankruptcy.

Upon termination of the agreement, subject to certain exceptions, the licenses granted under the agreement terminate. In addition, dependent upon the circumstances under which the agreement is terminated, the Company or CSL has the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

After the Company exercised its co-funding option for s 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

Table of Contents

obligation was delivered in 2017. As the $50 million upfront payment reflected the transaction price at contract inception, all revenue related to the single performance obligation was recognized prior to the date of adoption of Topic 606. Development milestones, sales-based milestones, and profit share related to the license of intellectual property will be recognized by analogy to the Company's revenue accounting policies. No transition adjustment was recognized as a result of adopting Topic 606.

Co-funding Costs and Reimbursements

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

Summary

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

	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	CSL Collaboration Agreement	Total
Contract assets					
Collaboration receivables:					
Opening - January 1, 2018	$ 406	$ 14,219	$ 423	$ —	$15,048
Revenue / cost recovery	7	42,145	550	—	$42,702
Receipts	(413)	(45,083)	(883)	—	$(46,379)
Ending - December 31, 2018	—	11,281	90	—	11,371
Contract liabilities					
Deferred revenue:					
Opening - January 1, 2018	—	—	39,128	—	39,128
Recognition of deferred revenue	—	—	(33,438)	—	(33,438)
Ending - December 31, 2018	—	—	5,690	—	5,690
Less: current portion	—	—	(3,916)	—	(3,916)
Deferred revenue, net of current portion - December 31, 2018	—	—	1,774	—	1,774
Collaboration liabilities:					
Opening - January 1, 2018	—	—	8,245	1,013	9,258
Payments	—	—	—	(7,369)	(7,369)
Net collaboration costs incurred in the period	—	—	(6,833)	9,665	2,832
Ending - December 31, 2018	$ —	$ —	$ 1,412	$ 3,309	$4,721

Table of Contents

	For the Year Ended December 31, 2018				
	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	CSL Collaboration Agreement	Total
Product revenue	$—	$ 39,684	$ —	$ —	$39,684
Research and development revenue	$7	$ 2,461	$ 33,437	$ —	$35,905
Total collaboration revenue	$7	$ 42,145	$ 33,437	$ —	$75,589
Operating expenses:					
Research and development expense	$—	$ 826	$ 25,932	$ 875	$27,633
General and administrative expense	$13,709	$ 152	$ 1,978	$ 31	$15,870
Net amount (recovered from) / payable to collaborators	$—	$ —	$ (7,383)	$ 9,665	$2,282
Total operating expenses	$13,709	$ 978	$ 20,527	$ 10,571	$45,785

	For the Year Ended December 31, 2017				
	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	CSL Collaboration Agreement	Total
Product revenue	$313	$ 66,490	$ —	$ —	$66,803
Research and development revenue	$2,856	$ 12,142	$ 5,015	$ 52,066	$72,079
Total collaboration revenue	$3,169	$ 78,632	$ 5,015	$ 52,066	$138,882
Operating expenses:					
Research and development expense	$1,958	$ 1,766	$ 62,049	$ 8,179	$73,952
General and administrative expense	$15,426	$ 494	$ 3,617	$ 124	$19,661
Net amount (recovered from) collaborators	$—	$ —	$ (25,835)	$ (3,320)	$(29,155)
Total operating expenses	$17,384	$ 2,260	$ 39,831	$ 4,983	$64,458

	For the Year Ended December 31, 2016				
	2003 Sandoz Agreement	2006 Sandoz Agreement	Mylan Collaboration Agreement	Baxalta Agreement	Total
Product revenue	$—	$ 74,648	$ —	$ —	$74,648
Research and development revenue	$345	$ 2,545	$ 6,368	$ 25,713	$34,971
Total collaboration revenue	$345	$ 77,193	$ 6,368	$ 25,713	$109,619
Operating expenses:					
Research and development expense	$692	$ 1,911	$ 55,147	$ 1,196	$58,946
General and administrative expense	$7	$ 470	$ 3,009	$ 187	$3,673
Net amount (recovered from) collaborators	$—	$ —	$ (27,770)	$ —	$(27,770)
Total operating expenses	$699	$ 2,381	$ 30,386	$ 1,383	$34,849

10. Preferred, Common and Treasury Stock

Preferred Stock

The Company is authorized to issue 5 million shares of preferred stock in one or more series and to fix the powers, designations, preferences and relative participating, option or other rights thereof, including dividend rights, conversion rights, voting rights, redemption terms, liquidation preferences and the number of shares constituting any series, without any further vote or action by the Company's stockholders. As of December 31, 2018 and 2017, the Company had no shares of preferred stock issued or outstanding.

Table of Contents

Common Stock

Holders of common stock are entitled to receive dividends, if and when declared by the Board of Directors, and to share ratably in the Company's assets legally available for distribution to the Company's stockholders in the event of liquidation. Holders of common stock have no preemptive, subscription, redemption, or conversion rights. The holders of common stock do not have cumulative voting rights. The holders of a majority of the shares of common stock can elect all of the directors and can control the Company's management and affairs. Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

Treasury Stock

Treasury stock represents common stock currently owned by the Company as a result of shares withheld from the vesting of performance-based restricted common stock to satisfy minimum tax withholding requirements.

11. Share-Based Payments

Incentive Award Plans

The 2013 Incentive Award Plan, or the 2013 Plan, initially became effective on June 11, 2013. Also on June 11, 2013, the 2004 Stock Incentive Plan terminated except with respect to awards previously granted under that plan. No further awards will be granted under the 2004 Stock Incentive Plan.

The 2013 Plan allows for the granting of stock options (both incentive stock options and nonstatutory stock options), restricted stock, stock appreciation rights, performance awards, dividend equivalents, stock payments and restricted stock units to employees, consultants and members of the Company's board of directors.

On March 7, 2018, the Company's Board of Directors approved the amendment and restatement of the Company’s 2013 Plan. At the Company’s 2018 Annual Meeting of Stockholders, held on June 20, 2018, stockholders approved the amended and restated 2013 Plan. The amended and restated 2013 Plan, among other things, increased the number of shares of common stock available for issuances under the plan by 1,000,000 shares.

Incentive stock options are granted only to employees of the Company. Incentive stock options granted to employees who own more than 10% of the total combined voting power of all classes of stock are granted with exercise prices no less than 110% of the fair market value of the Company's common stock on the date of grant. Incentive stock options generally vest ratably over four years. Non-statutory stock options, restricted stock and restricted stock units may be granted to employees, consultants, and members of the Company's board of directors. Non-statutory stock options granted have varying vesting schedules. Time-based restricted stock awards and restricted stock units have been granted to employees and generally vest ratably over four years. Time-based restricted stock and restricted stock units have been granted to board members and generally vest on the one year anniversary of the grant date.

Performance-based restricted stock or restricted stock units are granted to employees and vest in connection with the attainment of certain company milestones as described in more detail below. Incentive and non-statutory stock options generally expire ten years after the date of grant. As of December 31, 2018, there were 5,320,929 shares available for issuance under the 2013 Plan.

Equity Award Retirement Policy

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

As the policy amended the terms of certain existing grants of time-based options effective January 11, 2017, the Company recorded incremental compensation expense of $0.4 million related to the modification of those options in the consolidated statement of operations for the year ended December 31, 2017. Of that expense, $0.3 million was included in the general administrative expense and $0.1 million was included in research and development expense.

89

Table of Contents

Share-Based Compensation

The Company records compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock, and restricted stock units and the employee stock purchase plan.

The table below presents share-based compensation expense for research and development as well as general and administrative expense, both of which are included in operating expenses, in the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Research and development	$6,383	$5,699	$7,558
General and administrative	11,031	10,428	10,764
Restructuring	3,808	—	—
Total share-based compensation expense	$21,222	$16,127	$18,322

The following table summarizes share-based compensation expense recorded in each of the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Stock options	$7,081	$10,036	$9,831
Restricted stock awards and restricted stock units	10,032	5,608	8,064
Employee stock purchase plan	301	483	427
Restructuring	3,808	—	—
Total share-based compensation expense	$21,222	$16,127	$18,322

Stock Options

During the year ended December 31, 2018, the Company granted 372,690 stock options to its employees and board members. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions are noted in the table below.

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

	Weighted Average Assumptions					
	Stock Options			Employee Stock Purchase Plan		
	2018	2017	2016	2018	2017	2016
Expected volatility	48 %	53 %	58 %	49 %	55 %	57 %
Expected dividends	—	—	—	—	—	—
Expected life (years)	6.1	5.9	6.1	0.5	0.5	0.5
Risk-free interest rate	2.8%	2.1%	1.6%	1.6%	0.7%	0.4%

Table of Contents

The following table presents stock option activity for the year ended December 31, 2018:

	Number of Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	7,117	$ 14.71		
Granted	373	19.63		
Exercised	(1,995)	14.12		
Forfeited	(476)	15.53		
Expired	(61)	16.39		
Outstanding at December 31, 2018	4,958	$ 15.22	4.86	$ 407,629
Exercisable at December 31, 2018	3,662	$ 14.65	4.03	$ 339,688
Vested or expected to vest at December 31, 2018	4,837	$ 15.16	4.76	$ 404,503

The weighted average grant date fair value of option awards granted during 2018, 2017 and 2016 was $9.66, $9.05, and $6.04 per option, respectively. The total intrinsic value of options exercised during 2018, 2017 and 2016 was $13.9 million, $4.6 million, and $0.2 million, respectively. At December 31, 2018, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $8.0 million, which will be recognized over the weighted average remaining requisite service period of 2.18 years. The total fair value of options vested during 2018, 2017 and 2016 was $10.5 million, $9.3 million, and $9.9 million, respectively.

Cash received from option exercises for 2018, 2017 and 2016 was $28.2 million, $9.2 million, and $1.4 million, respectively.

Restricted Stock and Restricted Stock Units

The Company has also made awards of time-based restricted stock and restricted stock units and performance-based restricted stock to its employees and time-based restricted stock and restricted stock units to board members.

As of December 31, 2018, the total remaining unrecognized compensation cost related to all nonvested restricted stock and restricted stock unit awards amounted to $13.7 million, which is expected to be recognized over the weighted average remaining requisite service period of approximately 3.0 years.

Time-based Restricted Stock and Restricted Stock Units

During the year ended December 31, 2018, the Company awarded 1,357,505 shares of time-based restricted stock units to its employees and board members. The time-based restricted stock units awarded to employees vest as to 25% on the one year anniversary of the grant date and as to 6.25% quarterly over three years that follow the grant date while the restricted stock units awarded to board members vest as to 100% on the one year anniversary of the grant date. Time-based awards are generally forfeited if the employment or service relationship terminates with the Company prior to vesting, except as provided in the Retirement Policy.

2011 Performance-Based Restricted Stock

Between 2011 and through early 2013, the Company awarded 949,620 shares of performance-based restricted stock to its employees. The performance-based restricted stock was scheduled to vest upon FDA approval of the GLATOPA 20 mg/mL Abbreviated New Drug Application, or ANDA, on or before the performance deadline date of March 28, 2015 according to the following schedule: 50% of the shares vest upon FDA approval and 50% vest upon the one year anniversary of FDA approval. The Company had modified the awards to extend the performance deadline in periods prior to the earliest period presented in these financial statements. FDA approval was attained on April 16, 2015. On that date the first 50% of the awards vested. The remaining 50% vested on April 16, 2016, whereby compensation expense associated with this portion of the award was recognized through the vesting date.

2016 Performance-Based Restricted Stock

Since April 2016, the Company has awarded 1,785,600 shares of performance-based restricted stock to its employees. The vesting of these shares is subject to the Company achieving up to two of three possible performance milestones on or before April 13, 2019. Upon achieving each of the first and second milestones, 25% of the shares will vest on

the later of the milestone achievement date and the first anniversary of the grant date, and an additional 25% of the shares will vest on the one

Table of Contents

year anniversary of such achievement date. Each quarter, the Company evaluates the probability of achieving the milestones on or before April 13, 2019, and its estimate of the implicit service period over which the fair value of the awards will be recognized and expensed. At December 31, 2017 and through December 31, 2018, the Company concluded that two of the performance milestones were not probable of achievement by April 13, 2019. One performance milestone had been achieved in February 2018. For the year ended December 31, 2018, the Company recognized approximately $1.1 million of stock compensation costs related to these awards.

2018 Performance-Based Restricted Stock Units

Since October 2018, the Company has awarded 1,812,758 shares of performance-based restricted stock units to its employees. The vesting of these units are subject to the Company for achieving three possible milestones related to the Company's active novel programs. One sixth of the units will vest upon achievement of each milestone and one sixth shall vest on the one year anniversary of that date. At December 31, 2018, the Company concluded that all of the performance milestones were not probable of achievement. For the year ended December 31, 2018, the Company recognized no stock compensation costs related to these awards.

A summary of the status of nonvested shares of restricted stock and restricted stock units as of December 31, 2018 and the changes during the year then ended are presented below (in thousands, except fair values):

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2018	1,995	$ 12.60
Granted	3,170	14.83
Vested	(959)	14.03
Forfeited	(707)	13.25
Nonvested at December 31, 2018	3,499	$ 14.10

Nonvested shares of restricted stock and restricted stock units that have time-based vesting schedules and restricted stock that have performance-based vesting schedules as of December 31, 2018 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	1,142
Performance-based	2,357
Nonvested at December 31, 2018	3,499

The total fair value of shares of restricted stock and restricted stock units vested during 2018, 2017 and 2016 was $13.6 million, $3.7 million, and $7.6 million, respectively.

Employee Stock Purchase Plan

In 2004, the Company's Board of Directors adopted the 2004 Employee Stock Purchase Plan, or ESPP. An aggregate of 2,424,652 shares of common stock have been reserved for issuance under the ESPP.

The ESPP is generally available to all employees who work more than 20 hours per week and five months per year. Under the ESPP, eligible participants purchase shares of the Company's common stock at a price equal to 85% of the lesser of the closing price of the Company's common stock on the first business day and the final business day of the applicable plan purchase period. Plan purchase periods begin on February 1 and August 1 of each year, with purchase dates occurring on the final business day of the given purchase period. To pay for the shares, each participant authorizes periodic payroll deductions of up to 15% of his or her eligible cash compensation. All payroll deductions collected from the participant during a purchase period are automatically applied to the purchase of common stock on that period's purchase date provided the participant remains an eligible employee and has not withdrawn from the ESPP prior to that date and subject to certain limitations imposed by the ESPP and the Internal Revenue Code.

The Company issued 85,374 shares of common stock to employees under the ESPP during the year ended December 31, 2018. As of December 31, 2018, 927,612 shares of common stock have been issued to the Company's employees under the ESPP, and 1,497,040 shares remain available for future issuance.

92

Table of Contents

The fair value of each ESPP award is estimated on the first day of the offering period using the Black-Scholes-Merton option-pricing model. The weighted average assumptions the Company used in its fair value calculations and the expense recorded are noted in the table above under the heading Share-Based Compensation. The Company recognizes share-based compensation expense equal to the fair value of the ESPP awards on a straight-line basis over the offering period. At December 31, 2018, subscriptions were outstanding for an estimated 38,694 shares at a fair value of approximately $8.22 per share. The weighted average grant date fair value of the offerings during 2018, 2017 and 2016 was $5.80, $4.62, and $4.32 per share, respectively. Cash received from the ESPP for 2018, 2017 and 2016 was approximately $1.2 million, $1.2 million, and $1.1 million, respectively.

12. Net Loss Per Common Share

Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per share is the same in those periods. The weighted-average anti-dilutive shares shown in the foregoing table were not included in the computation of diluted net loss per share. Anti-dilutive shares comprise the impact of the number of shares that would have been dilutive had the Company had net income plus the number of common stock equivalents that would be anti-dilutive had the Company had net income.

The following table presents anti-dilutive shares for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	2,975	5,671	6,569
Restricted stock awards	868	1,064	1,202

13. Income Taxes

In 2018, the Company adopted ASC 606, using the modified retrospective transition method as permissible for all contracts not yet completed as of January 1, 2018. This created approximately $1.5 million of deferred tax liabilities relating to federal and state deferred revenue temporary differences that are fully offset by a corresponding decrease in the valuation allowance. As a result, there was no cumulative adjustment for income taxes to accumulated deficit upon adoption of ASC 606.

The Tax Cuts and Jobs Act of 2017 (the 2017 Tax Act), which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory tax rate reduction from 35% to 21%, which reduced the Company's deferred tax assets and corresponding valuation allowance.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118, or SAB 118, to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. The Company had recognized the provisional tax impacts related to the revaluation of the deferred tax assets and liabilities in the financial statements of prior periods. The accounting was completed in the year ended December 31, 2018, with the finalization and filing of the Company's 2017 U.S. corporate income tax return, with no adjustment to provisional amounts.

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. The Company reevaluates the positive and negative evidence bearing upon the realizability of its deferred tax assets on an annual basis. Since the Company has generated operating losses and expects to continue to incur future losses, the Company has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of all of its deferred tax assets.

Components of the net deferred tax assets at December 31, 2018 and 2017 are as follows (in thousands):

Table of Contents

	2018	2017
Deferred tax assets:		
Federal and state net operating losses	$154,164	$99,252
Research credits	39,222	36,819
Deferred compensation	7,605	8,274
Deferred revenue	1,555	9,184
Accrued expenses	6,960	4,977
Intangibles	1,800	2,020
Unrealized loss on marketable securities	24	13
Total deferred tax assets	211,330	160,539
Deferred tax liabilities:		
Depreciation	$(1,470)	$(802)
Total deferred tax liabilities	(1,470)	(802)
Valuation allowance	$(209,860)	$(159,737)
Net deferred tax assets	$—	$—

A reconciliation of the federal statutory income tax benefit to the Company's actual provision for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	2018	2017	2016
Benefit at federal statutory tax rate	$(36,967)	$(29,941)	$(7,137)
State taxes, net of federal benefit	(11,720)	(4,713)	(1,108)
Share-based compensation	(613)	1,370	5,148
Tax credits	(2,321)	(2,733)	(4,120)
Other	3	492	272
Change in valuation allowance	51,618	(17,817)	6,945
Federal statutory rate change	—	53,342	—
Income tax provision	$—	$—	$—

At December 31, 2018, the Company had federal and state net operating loss carryforwards of $569.0 million and $548.5 million, respectively, available to reduce future taxable income that will expire at various dates through 2038. At December 31, 2018, the Company had federal and state research and development and other credit carryforwards, including the orphan drug credit, of $37.9 million and $12.2 million, respectively, available to reduce future tax liabilities. Federal and state research and development and other credit carryforwards expire at various dates through 2038, while the orphan drug credit does not expire. Ownership changes, as defined in the Internal Revenue Code, may limit the amount of net operating loss that can be utilized to offset future taxable income or tax liability.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for the years ended December 31, 2018 2017 and 2016 is as follows (in thousands):

	2018	2017	2016
Balance, beginning of year	$7,940	$6,678	$5,116
Additions for tax positions related to the current year	639	1,262	1,602
Reductions of tax positions of prior years	—	—	(40)
Balance, end of year	$8,579	$7,940	$6,678

As of December 31, 2018 and 2017, the Company had $8.6 million and $7.9 million of gross unrecognized tax benefits, respectively, of which $8.4 million and $7.8 million, respectively, if recognized, would not impact the Company's effective tax rate as there is a full valuation allowance on these credits.

The Company does not anticipate that it is reasonably possible that the uncertain tax positions will significantly increase or decrease within the next twelve months.

Table of Contents

The Company files income tax returns in the United States federal jurisdiction and in the Massachusetts state jurisdiction. The Company is no longer subject to any tax assessment from an income tax examination for years before 2015, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2015.

14. 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%. As of December 31, 2018, the Company has substantially completed executing the Workforce Reduction. 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 of 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 recorded restructuring expense of $8.6 million pursuant to ASC 712 and $1.8 million pursuant to ASC 420 for the year ended December 31, 2018. The Company also recorded incremental stock-based compensation charges of $3.8 million associated with the accelerated vesting of certain awards and extended exercisability of options previously issued to the Company’s executives that were part of the Workforce Reduction. In addition, the Company recorded certain asset impairment charges of $3.6 million in accordance with ASC 360 Property, Plant and Equipment, associated with certain laboratory equipment. The Company classified $1.3 million of such laboratory equipment as held-for-sale at December 31, 2018. 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 for the year ended December 31, 2018 included in the consolidated statement of operations, and the ending liability recorded in accrued restructuring in the balance sheet as at December 31, 2018:

	Restructuring charges in the year ended December 31, 2018	Amount paid through December 31, 2018	Less: non-cash charges in the year ended December 31, 2018	Remaining liability at December 31, 2018
Employee severance, bonus and other	$ 10,391	$ (7,156)	$ —	$ 3,235
Acceleration of stock-based compensation	$ 3,808	$ —	$ (3,808)	$ —
Impairment of equipment	$ 3,608	$ —	$ (3,608)	$ —
Total restructuring charges	$ 17,807	$ (7,156)	$ (7,416)	$ 3,235

15. Commitments and Contingencies

Operating Leases

The Company leases office space and equipment under various operating lease agreements. Rent expense for office space under operating leases amounted to $26.8 million, $19.3 million and $18.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

The Company leased approximately 78,500 square feet of office and laboratory space at 675 West Kendall Street in Cambridge, Massachusetts. The lease expired on April 30, 2018.

In February 2013, the Company entered into a lease agreement to lease approximately 105,000 square feet of office and laboratory space at 320 Bent Street in Cambridge, Massachusetts. Annual rental payments are approximately $8.1 million and are subject to annual rent escalation. The lease expires on February 28, 2027.

In July 2017, the Company entered into a lease agreement to lease approximately 52,000 square feet of office and laboratory space on the fourth floor of 301 Binney Street in Cambridge, Massachusetts. On August 2, 2018, the Company amended its lease agreement terminate the lease with respect to the premises, effective August 6, 2018. The Company incurred a $1.1 million termination fee.

In September 2016, the Company leased approximately 80,000 square feet of office and laboratory space on the fifth floor of 301 Binney Street in Cambridge, Massachusetts. Annual rental payments are approximately $6.1 million and are subject to annual rent escalations. The lease expires on June 29, 2025.

Table of Contents

The Company was provided allowances from the landlord totaling approximately $9.9 million as reimbursement of certain laboratory and office improvements that could be spent among the premises.

The Company records rent expense, inclusive of the escalating rent payments and free rent periods, on a straight-line basis over the terms of the lease. Tenant reimbursement amounts are recorded upon payment as deferred rent on the consolidated balance sheets and are amortized as a reduction to rent expense over the lease term. The Company capitalizes the cost of normal tenant improvements as leasehold improvements as the costs are incurred.

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

Operating lease commitments	Total
2019	$15,418
2020	15,872
2021	16,266
2022	16,644
2023	16,783
2024 and beyond	44,113
Total future minimum lease payments	$125,096

Purchase Obligations

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

Legal Contingencies

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

GLATOPA 40 mg/mL-Related Litigation

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz in the United States District Court for the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, and sought declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015 and November 2015, Teva and Yeda filed additional suits against us and Sandoz in the United States District Court for the District of Delaware alleging infringement related to additional Orange Book-listed patents for COPAXONE 40 mg/mL, which were consolidated with the initial suit. Teva and Yeda sought declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of the patents at issue. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. In February 2017, Teva and Yeda appealed the District Court's January 30, 2017 decision to the U.S. Court of Appeals for the Federal Circuit, or CAFC. On October 12, 2018, the CAFC affirmed the District Court's decision that the four patents were invalid. The time period for appeal by Teva and Yeda has expired so the CAFC decision is binding.

On January 31, 2017, Teva filed a suit against us and Sandoz in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775. 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 is scheduled to commence before the United States District Court for the District of Delaware on May 6, 2019.

Table of Contents

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

M834-Related Proceedings

On July 2, 2015, the Company filed a petition for Inter Partes Review, or IPR, with the Patent Trial and Appeal Board, or PTAB, to challenge the validity of U.S. Patent No. 8,476,239, a patent for ORENCIA owned by Bristol-Myers Squibb, or BMS. The PTAB issued a decision instituting the IPR proceedings in January 2016, and BMS filed for a rehearing by the full PTAB. Oral arguments took place in September 2016. On December 22, 2016, the PTAB issued a decision upholding the validity of the patent. The Company filed a notice of appeal in the CAFC, on February 22, 2017. The parties have each briefed the CAFC on the question of whether a non-patent owner challenging a patented claim in IPR has constitutional standing to appeal by the PTAB that the challenged patented claim is valid. Oral argument before the Federal Circuit was held on December 5, 2017. On February 7, 2019 the CAFC dismissed the appeal of the IPR for lack of standing. The Company is in the process of evaluating its options with respect to the IPR.

Enoxaparin Sodium Injection-related Litigation

On September 21, 2011, the Company and Sandoz sued Amphastar and Actavis in the United States District Court for the District of Massachusetts for patent infringement. Also in September 2011, the Company filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar and Actavis from selling their Enoxaparin product in the United States. In October 2011, the District Court granted the Company's motion for a preliminary injunction and entered an order enjoining Amphastar and Actavis from advertising, offering for sale or selling their Enoxaparin product in the United States until the conclusion of a trial on the merits and required the Company and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded the case to the District Court.

In April 2017, the Company, Sandoz and Actavis, or the Settling Parties, settled and signed reciprocal releases of all claims, and filed a voluntary stipulation with the District Court, pursuant to which the Settling Parties stipulated and agreed to dismiss with prejudice all claims and counterclaims among the Settling Parties, without fees or costs to any party, and with the Settling Parties waiving any and all right of appeal. The District Court trial was held in July 2017, and the jury verdict found the Company's patent to be infringed, but invalid and unenforceable. In February 2018, the District Court confirmed the jury’s opinion that the patent was infringed but invalid, and narrowed the jury’s recommendation on unenforceability by finding the patent to be unenforceable against only one of the two infringing methods used by Amphastar. On March 20, 2018, the District Court entered its final judgment affirming its February 2018 rulings. On March 27, 2018, the Company and Sandoz filed a notice of appeal of the final judgment with the CAFC. The appeal has been docketed and briefing was completed on November 19, 2018. On February 20, 2019, the Company and Sandoz filed with the District Court a motion for relief from judgment with respect to its final judgment.In the event that the Company is not successful in further appeal or prosecution or settlement of this action against Amphastar, and Amphastar is able to prove they suffered damages as a result of the preliminary injunction, the Company could be liable for damages for up to $35.0 million of the security bond. The Company posted $36.1 million as collateral for the security bond and classified the collateral as restricted cash in its consolidated balance sheet. On March 23, 2018, Amphastar filed a motion to enforce liability on the security bond with the District Court. On April 3, 2018, the Company and Sandoz filed an emergency motion to defer consideration of Amphastar's motion to enforce liability on the security bond pending exhaustion of appeals. On July 16, 2018, the District Court denied Amphastar's motion to enforce liability on the security bond and allowed the Company's and Sandoz' motion to defer consideration. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against the Company and Sandoz in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is

seeking unspecified damages and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that the court reverse and review the District Court's grant of transfer and in May 2016, the writ requested by Amphastar was denied. On July 27, 2016, the Company's and Sandoz' motion to dismiss was granted by the District Court, and the case was dismissed. On August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court

Table of Contents

of Appeals for the First Circuit reversed the District Court's dismissal and remanded the case to the District Court for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, the Company and Sandoz filed a renewed motion to dismiss which was denied by the District Court on March 20, 2018. A trial is scheduled for September 2019. On February 19, 2019, Amphastar filed with the District Court a motion for partial summary judgment on issues previously litigated in the patent action.
On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against the Company and Sandoz in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic Enoxaparin Sodium Injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. On March 21, 2017, the United States District Court for the Middle District of Tennessee dismissed NGH's claim for damages against the Company and Sandoz, but allowed the case to move forward, in part, for NGH's claims for injunctive and declaratory relief. In the same opinion, the United States District Court for the Middle District of Tennessee denied the Company's motion to transfer. On June 9, 2017, NGH filed a motion to amend its complaint to add a new named plaintiff, the American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan, or DC37. NGH and DC37 seek to assert claims for damages under the laws of more than 30 different states, on behalf of a putative class of indirect purchasers of LOVENOX or generic Enoxaparin. On June 30, 2017, the Company and Sandoz filed a brief opposing the motion to amend the complaint. On December 14, 2017, the District Court granted NGH's motion to amend. In January 2018, the Company and Sandoz filed three motions to dismiss the amended complaint. On December 6, 2018 the District Court granted one of the motions, granted one in part and denied one. As a result the suit will continue pursuant to the surviving portions of the amended complaint. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and intends to vigorously defend itself in this litigation.

16. 401(k) Plan

The Company has a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company has discretion to make contributions to the plan. The Company matches 50% of the first 6% contributed by employees. The Company recorded $0.9 million, $1.1 million and $1.0 million of such match expense in the years ended December 31, 2018, 2017 and 2016, respectively.

17. Equity Financings

In April 2015, the Company entered into an ATM Agreement, or the 2015 ATM Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which the Company was authorized to issue and sell shares of its common stock having aggregate sales proceeds of up to $75.0 million from time to time through Stifel, acting as sales agent and/or principal. The Company paid Stifel a commission of 2.0% of the gross proceeds from the sale of shares of its common stock under the 2015 ATM Agreement. The Company concluded sales under the 2015 ATM Agreement in May 2017. In the year ended December 31, 2017, the Company sold approximately 4.5 million shares of common stock pursuant to an effective shelf registration statement filed with the SEC (Reg. No. 333-209813) and a related prospectus supplement, raising net proceeds of $64.1 million.

In December 2018, the Company sold an aggregate of 20 million shares of its 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, the Company received aggregate net proceeds of approximately $217.8 million, after deducting underwriting discounts and commissions and other offering expenses.

Table of Contents

18. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
(in thousands, except per share data)	March 31	June 30	September 30	December 31
2018				
Product revenue	$3,521	$11,779	$ 13,621	$ 10,763
Research and development revenue	$1,331	$1,252	$ 1,263	$ 32,059
Total collaboration revenue	$4,852	$13,031	$ 14,884	$ 42,822
Operating loss	$(49,002)	$(70,840)	$ (51,815)	$ (9,670)
Net loss	$(47,631)	$(69,885)	$ (50,300)	$ (8,245)
Comprehensive loss	$(48,066)	$(69,611)	$ (50,163)	$ (8,168)
Net loss per share:				
Basic	$(0.63)	$(0.91)	$ (0.65)	$ (0.10)
Diluted	$(0.63)	$(0.91)	$ (0.65)	$ (0.10)
Shares used in calculating net loss per share:				
Basic	75,454	76,543	77,229	82,087
Diluted	75,454	76,543	77,229	82,087
2017				
Product revenue	$23,404	$19,140	$ 10,890	$ 13,369
Research and development revenue	$3,210	$4,430	$ 13,200	$ 51,239
Total collaboration revenue	$26,614	$23,570	$ 24,090	$ 64,608
Operating (loss) income	$(32,592)	$(38,065)	$ (34,527)	$ 12,633
Net (loss) income	$(31,759)	$(36,908)	$ (33,188)	$ 13,759
Comprehensive (loss) income	$(31,825)	$(36,933)	$ (33,136)	$ 13,572
Net (loss) income per share:				
Basic	$(0.46)	$(0.50)	$ (0.44)	$ 0.18
Diluted	$(0.46)	$(0.50)	$ (0.44)	$ 0.18
Shares used in calculating net (loss) income per share:				
Basic	69,711	73,379	74,611	74,770
Diluted	69,711	73,379	74,611	75,033

Basic and diluted net loss per common share amounts for the quarters and full years have been calculated separately. Accordingly, quarterly amounts may not add to the annual amount because of differences in the weighted-average common shares outstanding during each period principally due to the effect of the Company issuing shares of its common stock during the year.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure 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 Exchange Act, as of December 31, 2018. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive

Table of Contents

Officer and Chief Financial Officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act.

Our management, including the supervision and participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018, based on the criteria set forth in the Committee of Sponsoring Organizations of the Treadway Commission's (COSO) updated 2013 framework entitled "Internal Control—Integrated Framework." Based on its assessment, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

The independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K has issued its report on the effectiveness of our internal control over financial reporting. This report appears below.

Changes in Internal Control Over Financial Reporting

We use a cloud-based enterprise resource management system provided by an outside service provider for which a service auditor has issued a System and Organization Controls Report (SOC-1) report concerning certain internal controls at the service provider. Upon issuance of the SOC-1 report in January 2019, we learned that the service provider had ineffective information technology change management controls during the period from April 1, 2018 to September 30, 2018, which would have permitted unauthorized changes to be made to production application systems by certain employees of the service provider (the “Deficiency”). After the issuance of the initial SOC-1 report, the service auditor issued a general use attestation report that determined that certain compensating controls that had not previously been tested by the service auditor operated effectively from October 1, 2018 to December 31, 2018, and therefore the Deficiency was remediated and the service provider’s change management controls were operating effectively as of December 31, 2018. The subsequent report indicated that no unauthorized changes were made to data or systems.

As a result of the Deficiency at the service provider, and due to the extent that our own internal controls and financial reporting processes are impacted by the service provider’s enterprise resource management system, in the first quarter of 2019 we determined that we had an interim material weakness in our internal control over financial reporting, which was remediated as of October 1, 2018 due to compensating controls with respect to change management that operated effectively. Apart from the foregoing, there was no change in our internal control over financial reporting during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of Momenta Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Momenta Pharmaceuticals, Inc.’s (the “Company”) internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Momenta Pharmaceuticals, Inc. (the “Company”) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 22, 2019 expressed an unqualified opinion thereon.

Table of Contents

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 22, 2019

Item 9B. OTHER INFORMATION

None.

Table of Contents

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information relating to our directors, nominees for election as directors and executive officers under the headings "Election of Directors," "Momenta's Corporate Governance—Our Executive Officers," "Momenta's Corporate Governance—Board Committees" and "Security Ownership of Certain Beneficial Owners and Management—Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2019 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We make available our code of business conduct and ethics free of charge through our website which is located at www.momentapharma.com. We intend to disclose any amendment to, or waiver from, our code of business conduct and ethics that is required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and The NASDAQ Global Select Market by posting it on our website.

Item 11. EXECUTIVE COMPENSATION

The information under the headings or subheadings "Executive Compensation," "Compensation of Directors," "Compensation Committee Report" and "Compensation Committee Interlocks and Insider Participation" in our definitive proxy statement for our 2019 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information under the heading "Security Ownership of Certain Beneficial Owners and Management" in our definitive proxy statement for our 2019 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. Information required by this Item relating to securities authorized for issuance under equity compensation plans is contained in our definitive proxy statement for our 2019 Annual Meeting of Stockholders under the subheading "Equity Compensation Plan Information" and is incorporated herein by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The discussion under the headings "Certain Relationships and Related Transactions" and "Momenta's Corporate Governance—Board Determination of Independence" in our definitive proxy statement for our 2019 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The discussion under the heading "Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement for our 2019 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Table of Contents

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are included as part of this Annual Report on Form 10-K.

1. Financial Statements:

2. All schedules are omitted as the information required is either inapplicable or is presented in the financial statements and/or the related notes.

3. The exhibits listed on the Exhibit Index beginning on the page that follows, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
	Articles of Incorporation and By-Laws				
3.1	Third Amended and Restated Certificate of Incorporation.	S-3	3.1	4/30/2013	333-188227
3.2	Certificate of Amendment to Third Amended and Restated Certificate of Incorporation	8-K	3.1	1/30/2019	000-50797
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of the Registrant.	8-K	3.1	11/8/2005	000-50797
3.4	Fourth Amended and Restated By-Laws of the Registrant, adopted on March 14, 2017.	8-K	3.1	3/17/2017	000-50797
	Instrument Defining the Rights of Security Holders				
4.1	Specimen Certificate evidencing shares of common stock.	S-1/A	4.1	6/15/2004	333-113522
	Material Contracts—Collaboration and License Agreements				
10.1	Letter Agreement dated January 29, 2007 between Sandoz AG and the Registrant.	10-K	10.16	3/15/2007	000-50797
10.2	Letter Agreement dated February 1, 2007 between Sandoz AG and the Registrant.	10-Q	10.2	5/10/2007	000-50797
10.3†	Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant.	10-Q/A	10.1	12/16/2016	000-50797
10.3.1	Amendment No. 1, dated April 25, 2008, to the Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant.	10-Q	10.1	5/9/2008	000-50797
10.3.2†	Amendment No. 2, dated December 14, 2009, to the Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant.	10-K	10.18	3/12/2010	000-50797
10.3.3	Amendment No. 3, dated April 1, 2011, to the Collaboration and License Agreement dated June 13, 2007 by and between Sandoz AG and the Registrant.	10-Q	10.1	8/5/2011	000-50797
10.3.4†	Amendment No. 4, dated May 26, 2016, to the Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant, as amended.	10-Q	10.1	8/5/2016	000-50797
10.3.5†	Amendment No. 5, dated November 30, 2017, to the Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant, as amended.	10-K	10.3.5	2/26/2018	000-50797
10.4	Letter Agreement dated November 8, 2011 by and between the Registrant, Sandoz AG and Sandoz Inc.	10-K	10.20	2/28/2012	000-50797
10.5†	Letter agreement by and between Sandoz AG and the Registrant, executed as of October 4, 2017.	10-Q	10.2	11/1/2017	000-50797

10.6†	Collaboration Agreement, by and between Momenta Pharmaceuticals, Inc. and Mylan Ireland Limited, executed as of January 8, 2016.	10-Q/A	10.2	2/3/2017	000-50797
10.7†	License and Option Agreement, by and between the Registrant and CSL Behring Recombinant Facility AG, dated as of January 4, 2017.	10-Q	10.1	5/5/2017	000-50797
10.8†	Letter to the Registrant from CSL Limited, dated as of January 4, 2017.	10-Q	10.2	5/5/2017	000-50797

Table of Contents

10.9†	Letter Amendment, dated as of June 27, 2017, to License and Option Agreement, by and between the Registrant and CSL Behring Recombinant Facility AG, dated as of January 4, 2017.	10-Q	10.1	8/4/2017	000-50797
10.10†	Asset Return and Termination Agreement, effective as of December 31, 2016, by and between the Registrant and Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH.	10-K	10.7	2/24/2017	000-50797
10.10.1†	Amendment No. 1 to Asset Return and Termination Agreement, effective as of March 20, 2017, to Asset Return and Termination Agreement, effective as of December 31, 2016, by and between the Registrant and Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH.	10-Q	10.3	5/5/2017	000-50797
	Material Contracts—Management Contracts and Compensation Plans				
10.11#	Amended and Restated 2002 Stock Incentive Plan.	10-K	10.17	3/15/2007	000-50797
10.12#	2004 Stock Incentive Plan, as amended.	10-K	10.18	3/15/2007	000-50797
10.13#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan.	10-Q	10.1	8/16/2004	000-50797
10.14#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan.	10-Q	10.2	8/16/2004	000-50797
10.15#	Form of Restricted Stock Agreement Under 2004 Stock Incentive Plan.	8-K	10.2	2/28/2008	000-50797
10.16#	Momenta Pharmaceuticals, Inc. 2004 Employee Stock Purchase Plan (as amended and restated).	10-Q	10.6	8/4/2017	000-50797
10.17#	Non-Employee Director Compensation Policy.	10-Q	10.4	8/4/2017	000-50797
10.18#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant.	10-Q	10.7	11/8/2006	000-50797
10.18.1#	Amendment effective December 16, 2010 to the Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant.	10-K	10.28	3/10/2011	000-50797
10.19#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant.	10-Q	10.8	11/8/2006	000-50797
10.19.1#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant.	10-Q	10.9	11/8/2006	000-50797
10.20#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant.	10-Q	10.10	11/8/2006	000-50797
10.21#	Form of Employment Agreement for executive officers.	10-Q	10.3	5/9/2008	000-50797
10.22#	Second Amended and Restated Employment Agreement, dated April 28, 2008, by the Registrant and Ganesh Venkataraman.	10-Q	10.4	5/9/2008	000-50797
10.23#	Form of Amendment to the Employment Agreement for executive officers dated December 15, 2010.	10-K	10.39	3/10/2011	000-50797
10.24#	Amendment No. 1 to the Restricted Stock Agreement made on January 17, 2007 between the Registrant and Craig A. Wheeler dated November 4, 2009.	10-Q	10.1	11/5/2009	000-50797
10.25#	Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan (as amended and restated).	10-Q	10.1	8/9/2018	000-50797

10.26#	Form of Stock Option Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan.	8-K	10.1	6/13/2013	000-50797
10.27#	Form of Restricted Stock Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan.	8-K	10.2	6/13/2013	000-50797
10.28#	Form of Restricted Stock Unit Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan.	10-K	10.27	2/24/2017	000-50797
10.29#	Executive Employment Agreement, effective as of October 27, 2016, by and between the Registrant and Scott M. Storer.	10-K	10.29	2/24/2017	000-50797

Table of Contents

10.30#	Industry Consulting Agreement, dated as of December 30, 2016, by and between the Registrant and Richard P. Shea.	10-K	10.30	2/24/2017	000-50797
10.31#	Momenta Pharmaceuticals, Inc. Equity Award Retirement Policy.	10-Q	10.4	5/5/2017	000-50797
10.32#	Agreement and General Release, by and between the Registrant and Matthew Ottmer, dated as of May 4, 2017.	10-Q	10.2	8/4/2017	000-50797
10.33#	Form of Amendment to the Executive Employment Agreements between the Registrant and each of Scott M. Storer, Ganesh V. Kaundinya and Bruce A. Leicher, effective as of June 21, 2017.	10-Q	10.3	8/4/2017	000-50797
10.34#	Form of Amendment to the Executive Employment Agreements between the Registrant and each of Young Kwon, Anthony Manning, Jo-Ann Beltramello, Ian Fier and Santiago Arroyo, effective as of June 29, 2017.	10-Q	10.3	8/4/2017	000-50797
*10.35#	Separation and Release Agreement between the Registrant and Scott M. Storer, dated November 5, 2018.				
*10.36#	Separation and Release Agreement between the Registrant and Ganesh V. Kaundinya, dated October 5, 2018.				
*10.37#	Separation and Release Agreement between the Registrant and Bruce A. Leicher, dated October 5, 2018.				
*10.38#	Employment Agreement, as amended, effective as of May 29, 2017, by and between the Registrant and Michelle Robertson.				
*10.39#	Employment Agreement, as amended, effective as of August 10, 2017, by and between the Registrant and Alejandra Carvajal.				
	Material Contracts—Leases				
10.40†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant.	10-Q	10.9	11/12/2004	000-50797
10.40.1	First Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004), dated September 7, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant.	10-Q	10.3	11/14/2005	000-50797
10.40.2	Second Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of November 21, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant.	10-K	10.47	3/16/2006	000-50797
10.40.3	Third Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of January 27, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant.	10-K	10.48	3/16/2006	000-50797
10.40.4	Letter Agreement (regarding Sublease Agreement, dated September 14, 2004, as amended), dated June 29, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant.	10-Q	10.1	8/9/2006	000-50797
10.40.5	Fourth Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of July 14, 2014, between Vertex Pharmaceuticals Incorporated and the Registrant.	8-K	10.1	7/18/2014	000-50797
10.41	Lease, dated February 5, 2013, by and between BMR-Rogers Street LLC and the Registrant.	10-Q	10.1	5/10/2013	000-50797
10.41.1	First Amendment dated March 21, 2013 to the Lease dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant.	10-Q	10.2	5/10/2013	000-50797
10.41.2	Second Amendment to the Lease, dated May 24, 2013, by and between BMR-Rogers Street LLC and the Registrant.	10-Q	10.4	8/6/2013	000-50797

10.41.3	Third Amendment to the Lease, dated December 30, 2015, by and between BMR-Rogers Street LLC and the Registrant.	8-K	10.1	1/5/2016	000-50797

Table of Contents

10.41.4	Fourth Amendment dated July 24, 2017 to the Lease dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant.	10-Q	10.1	11/1/2017	000-50797
10.41.5	Letter agreement dated November 15, 2017 to the Lease dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant.	10-K	10.37.5	2/26/2018	000-50797
*10.41.6	Fifth Amendment dated April 24, 2018 to the Lease dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant.				
10.41.7	Sixth Amendment dated August 2, 2018 to the Lease dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant.	10-Q	10.2	8/9/2018	000-50797
10.42	Sublease, between Biogen MA Inc. and the Registrant, dated September 14, 2016.	10-Q	10.1	11/4/2016	000-50797
	Additional Exhibits				
*21	List of Subsidiaries				
*23.1	Consent of Independent Registered Public Accounting Firm				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
**32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				
*101.INS	XBRL Instance Document.				
*101.SCH	XBRL Taxonomy Extension Schema Document.				
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
*101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
*101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

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*Filed herewith.

**Furnished herewith

+Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

#Management contract or compensatory plan or arrangement.

The following financial information from Momenta Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2018, filed with the SEC on February 22, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018, 2017 and 2016, (ii) the Consolidated Balance Sheets as of December 31, 2018 and 2017, (iii) the Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016 and (v) Notes to Consolidated Financial Statements.

Table of Contents

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ CRAIG A. WHEELER
Craig A. Wheeler
President and Chief Executive Officer

Date: February 22, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CRAIG A. WHEELER Craig A. Wheeler	President, Chief Executive Officer and Director (Principal Executive Officer)	February 22, 2019
/s/ MICHELLE ROBERTSON Michelle Robertson	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 22, 2019
/s/ BRUCE DOWNEY Bruce Downey	Chairman of the Board of Directors	February 22, 2019
/s/ GEORGES GEMAYEL, Ph.D. Georges Gemayel, Ph.D.	Director	February 22, 2019
/s/ JAMES SULAT James Sulat	Director	February 22, 2019
/s/ THOMAS KOESTLER, Ph.D. Thomas Koestler, Ph.D.	Director	February 22, 2019
/s/ COREY N. FISHMAN Corey N. Fishman	Director	February 22, 2019
/s/ ELIZABETH STONER, M.D. Elizabeth Stoner, M.D.	Director	February 22, 2019

/s/ STEVEN C. GILMAN, Ph.D. Steven C. Gilman, Ph.D.	Director	February 22, 2019
/s/ JOSE-CARLOS GUTIERREZ-RAMOS, Ph.D. Jose-Carlos Gutierrez-Ramos, Ph.D.	Director	February 22, 2019