

# MOMENTA PHARMACEUTICALS INC

## **FORM 10-K** (Annual Report)

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The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 30, 2016, based on \$10.80 per share, the last reported sale price of Common Stock on The NASDAQ Global Select Market on that date, was \$744,539,278 .

As of February 1, 2017 , the registrant had 71,853,002 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 2017 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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## 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," "believe," "continue," "could," "hope," "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 expectations regarding the development and utility of our products and product candidates; development, manufacture and commercialization of our products and product candidates; efforts to seek and manage relationships with collaboration partners, including without limitation for our biosimilar and novel therapeutic programs; the timing of clinical trials and the availability of results; the timing of launch of products and product candidates, including GLATOPA<sup>®</sup> (glatiramer acetate injection) 40 mg/mL; GLATOPA market share, market potential and product revenues; the timing, merits, strategy, impact and outcome of litigation and legal proceedings; collaboration revenues and research and development revenues; manufacturing, including statements regarding Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; timing of regulatory filings, reviews and approvals, including the timing of the regulatory review and approval of the GLATOPA 40 mg/mL ANDA; the sufficiency of our current capital resources and projected milestone payments and product revenues for future operations; our future financial position, including but not limited to our future operating losses, our potential future profitability, our future expenses, the composition and mix of our cash, cash equivalents and marketable securities, our future revenues and our future liabilities; our funding transactions and our intended uses of proceeds thereof; Enoxaparin Sodium Injection product revenues and market potential; product candidate development costs; receipt of contingent milestone payments; accounting policies, estimates and judgments; our estimates regarding the fair value of our investment portfolio; the market risk of our cash equivalents, marketable securities, and derivative, foreign currency and other financial instruments; rights, obligations, terms, conditions and allocation of responsibilities and decision making under our collaboration agreements; the regulatory pathway for biosimilars; our strategy, including but not limited to our regulatory strategy, and scientific approach; the importance of key customer distribution arrangements; market potential and acceptance of our products and product candidates; future capital requirements; reliance on our collaboration partners and other third parties, including Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; the competitive landscape; changes in, impact of and compliance with laws, rules and regulations; product reimbursement policies and trends; pricing of pharmaceutical products, including our products and product candidates; our stock price; our intellectual property strategy and position; sufficiency of insurance; attracting and retaining qualified personnel; our internal controls and procedures; acquisitions or investments in companies, products and technologies; entering into collaboration and/or license arrangements; marketing plans; financing our planned operating and capital expenditure; leasing additional facilities; materials used in our research and development; transfer of regulatory, development, manufacturing and commercialization activities and related records for M923; Baxalta's performance of transitional development and manufacturing activities for M923; 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.*

**PART I**

**Item 1. BUSINESS**

**Our Company**

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

Our approach to drug discovery and development is built around a complex systems analysis platform that we use to obtain a detailed understanding of complex chemical and biologic systems, design product candidates, evaluate the biological function of products and product candidates, and develop reliable and scalable manufacturing processes. The core objective of our platform is to resolve the complexity of molecular structures and related biologic systems. We first map the key measurements needed to obtain comprehensive data on a targeted molecular structure and related biology and then develop a set of analytic tools and methods, including standard, modified and proprietary analytics, to generate the data, including multiple related and complementary, or orthogonal, measures. We also utilize proprietary data analytics software. Applying our approach, we developed the first generic version of LOVENOX® (enoxaparin sodium injection), which was approved by the United States Food and Drug Administration, or FDA, in July 2010, and GLATOPA® 20 mg/mL, which was approved by the FDA in April 2015 and is, to date, the only generic version of once-daily COPAXONE® (glatiramer acetate injection) 20 mg/mL. Both products were approved without the need for clinical safety and efficacy data.

Today we are developing biosimilar and novel drug candidates using some of the structural and process insights gained from our work on complex generics. We believe our complex systems analysis platform and our biological protein engineering capabilities gives us a competitive advantage in developing biosimilars and novel therapeutics. The analytic tools and methods, models and data sets, and the knowledge and insights developed in one area further expand the platform and can direct, inform and advance efforts in other areas. For example, in our biosimilars program, the analytics aimed at fully characterizing monoclonal antibodies and fusion proteins were adapted from the physicochemical analytics we developed in our complex generics programs. The biocharacterization efforts for our complex generics and biosimilar programs provide a core set of models and biologic data sets that can form the basis of inquiries in our novel therapeutic research. Our understanding of the impact of sialylation patterns on antibodies derived in our biosimilars program has informed our research on our novel autoimmune product candidates. In selecting our current development programs and in the evaluation of any potentially new programs, we look for those opportunities where we believe we can best leverage our platform to realize a competitive advantage to bring new medicines to patients and create value for our stockholders.

We have three product areas: Complex Generics, Biosimilars and Novel Therapeutics. A summary of our programs in each area is set forth below.



## Complex Generics

### Our Approach

We have developed generic versions of two complex drugs. Generics are therapeutic equivalents of chemically synthesized brand name drugs that were approved by the FDA under New Drug Applications, or NDAs. While most chemically synthesized brand name drugs are simple small molecules that are relatively easy to duplicate, we have focused on developing generic versions of LOVENOX and COPAXONE, which are complex molecular mixtures that are difficult to analyze and reproduce.

### Our Programs

#### **GLATOPA® 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 on April 16, 2015 and was launched on June 18, 2015. GLATOPA 20 mg/mL is the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. GLATOPA 20 mg/mL was developed and is being commercialized in collaboration with Sandoz AG, or 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, Licenses and Asset Purchases—Sandoz*."

On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States.

For the year ended December 31, 2016, we recorded \$74.6 million in product revenues from Sandoz' profits on sales of GLATOPA 20 mg/mL.

GLATOPA 20 mg/mL was formerly referred to as "GLATOPA." GLATOPA now refers to GLATOPA 20 mg/mL and our generic product candidate for three-times-weekly COPAXONE 40 mg/mL, GLATOPA 40 mg/mL, collectively.

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

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

The ANDA seeking approval of GLATOPA 40 mg/mL was filed by Sandoz in February 2014 and remains under review by the FDA. Our GLATOPA 40 mg/mL formulation contains the same active pharmaceutical ingredient, or API, as GLATOPA 20 mg/mL, which we believe should help streamline the FDA review of the ANDA. To date, we are the only ANDA applicant for the three-times-weekly COPAXONE 40 mg/mL with an FDA-approved API. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. We therefore believe that an approval of the GLATOPA 40 mg/mL ANDA in the first quarter of 2017 is unlikely.

The ANDA approval process and related patent challenge process are described below under "*Regulatory and Legal Matters—United States Government Regulation—'ANDA Approval Process for Generics' and 'Patent Challenge Process ANDAs*." Legal proceedings related to GLATOPA 40 mg/mL are described below under "*Item 3. Legal Proceedings -- GLATOPA 40 mg/mL-Related Proceedings*."

Teva reported \$3.5 billion and \$3.2 billion in U.S. sales of COPAXONE (combined 20 mg/mL and 40 mg/mL) in 2016 and 2015, respectively.

GLATOPA 40 mg/mL was formerly referred to as "M356."

## ***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 the collaboration agreement, Sandoz is responsible for commercialization of Enoxaparin Sodium Injection and we earn 50% of contractually-defined profits on Enoxaparin Sodium Injection sales.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, we do not anticipate significant Enoxaparin Sodium Injection product revenue in the near future.

## **Biosimilars**

### **Our Approach**

Biosimilars are biologics that are highly similar to therapeutic biologic products, referred to as reference products, approved by the FDA under Biologics License Applications, or BLAs. Biologics are produced using living cells. Biosimilars have no clinically meaningful differences from their respective reference products in terms of safety, purity and potency. Our approach to biosimilars has three parts:

1. *Build a broad and diverse product portfolio .*

We are advancing a broad portfolio of biosimilar candidates. We believe having a broad portfolio can help diversify risk, reduce reliance on single source revenue and allow us to capture the scale, technology, and regulatory synergies that are possible in biologic product development. Our portfolio consists of over half a dozen complex biosimilar candidates such as monoclonal antibodies and fusion proteins at various stages of development. We select biosimilar candidates with development and litigation timelines that we believe provide us the opportunity to have the first, or among the first, biosimilars on the market for each targeted reference product.

2. *Gain competitive advantage through our scientific approach and regulatory strategies .*

We believe our approach to biosimilars is capable of providing the FDA with robust and compelling analytical evidence of biosimilarity so that the FDA, under its totality-of-the-evidence approach to biosimilars, could designate our products as interchangeable and grant extrapolation across indications with reduced clinical trial requirements. We believe the realization of potentially reduced clinical and marketing costs would give our products an advantage over competing biosimilars. The biosimilar regulatory pathway is discussed in more detail below under "*Regulatory and Legal Matters—United States Government Regulation—Biosimilars.*"

3. *Ensure product candidates are positioned to capture the global opportunity through collaborations with leading pharmaceutical companies.*

We are developing and commercializing M834 and five other programs in collaboration with Mylan Ireland Limited, or Mylan. Mylan provides financial resources, manufacturing expertise and extensive commercial reach to better position our product candidates for future commercial success. We are identifying and exploring possible collaboration partners for M923 who similarly possess global commercial capabilities and can help secure high quality, low cost manufacturing and distribution.

Biologics represent an important advance in the treatment of disease and continue to have a transformative impact on the lives of patients with difficult to treat conditions like cancer and autoimmune disease. The market for biologics is significant and growing. In 2016, the global biologics market represented approximately \$225 billion in sales, with virtually the entire market comprised of brand products. In 2020, global sales of biologics are expected to be approximately \$306 billion. Many currently commercially successful biologics are expected to face loss of patent exclusivity in the next five to ten years. While therapeutically beneficial, biologics can be extremely costly to patients, costing upwards of thousands, or even hundreds of thousands, of dollars a year. They can also be costly to governments, insurers and other payers of healthcare benefits. Biosimilars are expected to generally be more affordable than their reference products. As a result, we believe there is a significant market potential for biosimilars.

### **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.

In February 2015, a randomized, double-blind, single-dose study was commenced in healthy volunteers to compare the pharmacokinetics, safety, tolerability and immunogenicity of M923 versus EU-sourced and US-sourced HUMIRA. A total of 324 healthy volunteers were enrolled in the study. The volunteers were randomized 1:1:1 to receive a single 40 mg injection of M923, US-sourced HUMIRA, or EU-sourced HUMIRA. The volunteers were followed for 71 days. In December 2015, we announced that M923 met its primary endpoint in the study as the data demonstrated pharmacokinetic bioequivalence to the reference products. In October 2015, a pivotal confirmatory clinical trial of M923 was initiated in patients with moderate-to-severe chronic plaque psoriasis. The trial is a randomized, double blind, active control, multi-center, global study in patients with moderate-to-severe chronic plaque psoriasis to compare the safety, efficacy and immunogenicity of M923 with HUMIRA. In April 2016, enrollment in the pivotal clinical trial for M923 was completed, and in November 2016, following an interim analysis, we announced that M923 met its primary endpoint in the study. The proportion of subjects in the study who achieved the primary endpoint, at least 75% reduction in the Psoriasis Area and Severity Index, or PASI-75, following 16 weeks of treatment, was equivalent between M923 and HUMIRA. The estimated difference in responders was well within the pre-specified confidence interval, confirming equivalence. Equivalence was also achieved for all secondary efficacy endpoints, including the achievement of PASI-50, PASI-90, proportion achieving clear or near-clear skin, and change from baseline in absolute PASI score. Adverse events were comparable in terms of type, frequency, and severity, and were consistent with the published safety data for HUMIRA. Due to unexpectedly high enrollment rates, additional patients to those included in the interim analysis were enrolled in the study. We expect to present final analysis of the full dataset for the study at a future conference or in a future publication. The first regulatory submission for marketing approval for M923 is planned for mid-2017 and, subject to marketing approval and patent considerations, we are planning for the first commercial launch to be as early as the 2020 timeframe.

M923 was previously developed in collaboration with Baxalta. In June 2016, Baxalta became a wholly-owned subsidiary of Shire plc. In September 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience our collaboration agreement. On December 31, 2016, we and Baxalta entered into an asset return and termination agreement pursuant to which the collaboration agreement was terminated effective December 31, 2016. Baxalta was relieved of its obligations to perform activities for M923 after that date, except for certain clinical and regulatory activities expected to be completed by April 2017, and in January 2017, Baxalta paid us a one-time payment of \$51.2 million, representing the costs Baxalta would have incurred in performing the activities it would have performed under the collaboration agreement through the original termination effective date. The terms of the collaboration agreement and the asset return and termination agreement are described below under "*Collaborations, Licenses and Asset Purchases - Baxalta*."

AbbVie reported approximately \$16.1 billion in worldwide sales of HUMIRA in 2016, including approximately \$10.4 billion in the United States. Total worldwide sales of HUMIRA are expected to be approximately \$18.2 billion in 2020, including approximately \$13.1 billion in the United States.

#### ***M834—Biosimilar ORENCIA® (abatacept) Candidate***

M834 is being developed as a biosimilar of ORENCIA. ORENCIA is a complex fusion protein composed of the Fc region of the immunoglobulin IgG1 fused to the extracellular domain of CTLA-4 that inhibits an immune response by blocking certain T cell signals. ORENCIA is the only CTLA-4Ig fusion protein approved for autoimmune diseases. ORENCIA is approved for use in treating patients with rheumatoid arthritis and juvenile idiopathic arthritis and is in development for several high unmet need indications. Analysts estimate that worldwide ORENCIA sales could increase to \$2.5 billion by 2020. ORENCIA is marketed globally by Bristol-Myers Squibb and co-promoted by Ono Pharmaceutical in Japan.

M834 is being developed and commercialized in collaboration with Mylan. Under our collaboration agreement, we and Mylan share equally costs and profits (losses) for M834. We and Mylan share development and manufacturing responsibilities, and Mylan will lead commercialization of M834, if approved. The terms of our Mylan collaboration are further discussed below under "*Collaborations, Licenses and Asset Purchases—Mylan*."

In November 2016, we initiated a randomized, double-blind, three-arm, parallel group, single-dose Phase 1 clinical trial in normal healthy volunteers to compare the pharmacokinetics, safety and immunogenicity of M834 to US-sourced and EU-sourced ORENCIA. We plan to report top-line data from the trial in the second half of 2017. We believe there is currently limited biosimilar competition for M834. Subject to development, marketing approval and patent considerations, we expect to be able to launch M834 in the 2020 timeframe to be able to be among the first biosimilars of ORENCIA on the market.

ORENCIA's composition of matter patents expire in the United States in 2019. In December 2016, the U.S. PTAB in an Inter Partes Review we filed upheld the validity of Bristol-Myers Squibb's formulation patent '239 on ORENCIA. We are considering our options to appeal. Information about this proceeding is further discussed below under " *Item 3. Legal Proceedings -- M834-Related Proceedings* ."

Bristol-Myers Squibb reported approximately \$2.3 billion in worldwide sales of ORENCIA in 2016 , including approximately \$1.5 billion in the United States.

### ***Other Biosimilar Programs in Collaboration with Mylan***

In addition to M834, we are also developing five other biosimilar candidates from our portfolio with Mylan, including our undisclosed biosimilar candidate, M710. We and Mylan will share equally costs and profits (losses) related to these earlier stage product candidates. We and Mylan will share development and manufacturing responsibilities across product candidates, and Mylan will lead commercialization of the products, if approved. The terms of our Mylan collaboration are further discussed below under " *Collaborations, Licenses and Asset Purchases—Mylan* ."

Total worldwide sales of the reference products that we are targeting in these biosimilar programs were approximately \$17.8 billion in 2016 , including approximately \$11.1 billion in the United States, and are projected to be approximately \$25.3 billion in 2020, including approximately \$15.5 billion in the United States. Taking into account the timing of reference product loss of regulatory exclusivity and key reference product patent expirations, we plan to launch each of these products as early as the 2020-2025 timeframe to be among the first biosimilars on the market for each reference product.

## **Novel Therapeutics**

### **Our Approach**

We seek to develop novel therapeutics and novel combinations of therapeutics that may positively modulate key disease pathways and meet significant unmet patient need. The majority of human diseases result from the interaction of a complex web of biologic systems. We believe that applying our complex systems analysis and biological protein engineering platforms may enable new insights into the complex biology underlying diseases and the optimal design of therapeutics. Currently we are applying these platforms to development of novel therapeutics for autoimmune disease.

### ***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, thereby presenting a common pathological mechanism across multiple autoimmune diseases. However, few therapeutic agents exist that interfere directly with these autoantibodies or immune complex-immune cell activation processes. Today, intravenous immunoglobulin, or IVIg, and plasmapheresis represent the most common approaches to treat autoantibody-driven disease. IVIg is 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, or ITP, Kawasaki disease, and chronic inflammatory demyelinating polyneuropathy, or CIDP. We estimate that the global market for immunoglobulin products currently approved for use in the treatment of autoimmune disease is approximately \$3.2 billion. The manufacture of IVIg, which requires large amounts of human plasma sourced from donated blood, is expensive, subject to donated blood shortages and often involves high batch-to-batch variation.

We are developing therapeutics for patients with autoimmune diseases, and in particular, those with autoantibody-driven disease. Initially we have applied our complex systems analysis and biological protein engineering platforms in an effort to improve IVIg. We utilized our proprietary sialylation technology, a method to add sialic acid to protein, to create a high potency version of IVIg. By gaining a deeper understanding of IVIg and immune complex driven autoimmune disease, we have designed two novel recombinant therapeutic candidates to leverage what we believe are key biologies associated with autoimmune disease. The design of these candidates was based on our analysis of the complex mechanism of action of IVIg and our insights into biological protein engineering.

We believe our novel product candidates could be capable of treating a large number of immunological disorders driven by antibodies, immune complexes, and Fc receptor biology. Such disorders include systemic lupus erythematosus, autoimmune neurologic diseases such as Guillain-Barre syndrome, chronic inflammatory demyelinating neuropathy and myasthenia gravis, autoimmune blood disorders such as immune thrombocytopenic purpura, systemic autoimmune diseases such as dermatomyositis, and antiphospholipid syndrome, antibody-mediated transplant rejection, and autoimmune blistering diseases, several of which have few treatment options.

## **Our Programs**

### ***M254 - hsIVIg Candidate***

M254 is a hyper-sialylated version of IVIg. Using our proprietary sialylation technology, we have developed a robust, controlled sialylation process to generate tetra-Fc-sialylated immunoglobulins, or hsIVIg, with consistent enhanced anti-inflammatory activity. In nonclinical trials, hsIVIg 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.

Our hsIVIg product is currently in nonclinical development and has the potential to be developed as a high-potency alternative to IVIg. We plan to initiate a toxicology study in 2017 that will enable an Investigational New Drug application, or IND, with the FDA. We continue to identify and explore potential collaboration opportunities to further develop and commercialize this product candidate.

### ***M281 - Anti-FcRn Candidate***

M281 is a fully-human monoclonal antibody that blocks the neonatal Fc receptor, or FcRn. This receptor recycles IgG antibodies, enabling a long half-life. M281 blocks this receptor, effectively inhibiting the binding of IgGs and leading to the rapid clearance of IgGs, similar to what occurs in plasmapheresis. M281 exhibits high affinity to human and non-human FcRn in nonclinical studies and shows selective induction of human and non-human IgG clearance. Based on this data, we believe M281 has the potential for use as acute and chronic/intermittent therapies in a broad range of autoantibody driven disease.

A Phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 was initiated in June 2016. In January 2017, we announced that we had successfully completed five cohorts in the Phase 1 single ascending dose, or SAD, study in healthy volunteers. In the SAD portion of the study, a single dose of 30 mg/kg achieved up to 80% reduction in circulating IgG antibodies, and M281 was well-tolerated with no serious adverse events observed. The multiple ascending portion of the study was initiated in January 2017. We plan to report the full data from the single and multiple ascending dose portions of the study in the second half of 2017.

### ***M230 - Selective Immunomodulator of Fc receptors (SIF3) Candidate***

M230, a selective immunomodulator of Fc receptors, or SIF3, is a novel homogenous recombinant Fc multimer containing three IgG Fc regions joined carefully to maximize activity. The multiple Fc domains of immune complexes aggregate Fc $\gamma$  receptors, or Fc $\gamma$ Rs, triggering cellular activation processes that play critical roles in inflammation and tissue damage. The development of therapeutics that broadly antagonize Fc $\gamma$ Rs has been hampered by a limited understanding of the molecular determinants directing Fc $\gamma$ Rs activation. Through the engineering and characterization of oligomeric Fc structures we believe we have novel insights into Fc $\gamma$ Rs modulation for the development of M230. Nonclinical data has shown that M230 enhances the molecules' avidity and affinity for the Fc receptors matching the potency and efficacy of IVIg at significantly lower doses.

On January 5, 2017, we entered into a License and Option Agreement, which became effective on February 17, 2017, with CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited, pursuant to which we have granted CSL an exclusive worldwide license to research, develop, and commercialize M230. We and CSL plan to advance this candidate with a goal of beginning clinical development in 2017. The terms of our CSL collaboration are further discussed below under "*Collaborations, Licenses and Asset Purchases-CSL.*"

### ***Necuparanib— Former Oncology Product Candidate***

In August 2016, following the outcome of a planned futility analysis, we discontinued development of necuparanib, an oncology product candidate then being studied in a Phase 2 clinical trial.

## **Collaborations, Licenses and Asset Purchases**

### **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 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, we are generally responsible for all of the development costs in the United States. For GLATOPA outside of the United States, we share development costs in proportion to our profit sharing interest. 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 will be borne by Sandoz as they are incurred for all products.

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. Under the 2006 Sandoz Collaboration Agreement, we earn 50% of contractually-defined profits on Sandoz' worldwide net sales of GLATOPA 20 mg/mL. We are entitled to earn 50% of contractually-defined profits on Sandoz' worldwide net sales of GLATOPA 40 mg/mL, if and when GLATOPA 40 mg/mL is commercialized. Profits on net sales of GLATOPA are calculated by deducting from net sales the costs of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. With respect to GLATOPA, Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement, except for 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 the year ended December 31, 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. We are eligible to receive up to \$120 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA in the United States. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. Sandoz 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.

Under the 2006 Sandoz Collaboration Agreement, each party has granted the other an exclusive license under its intellectual property 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 2006 Sandoz Collaboration Agreement. The 2006 Sandoz Collaboration Agreement may be terminated if either party breaches the 2006 Sandoz Collaboration Agreement or files for bankruptcy. In addition, either we or Sandoz may terminate the 2006 Sandoz Collaboration Agreement with respect to GLATOPA 40 mg/mL, if clinical trials are required for regulatory approval of GLATOPA 40 mg/mL.

Under the stock purchase agreement, we sold approximately 4.7 million shares of our common stock to Novartis for an aggregate purchase price of \$75 million, representing a premium of \$13.6 million based on the closing price of our common stock on The NASDAQ Global Select Market on the date of purchase. As of December 31, 2016, Novartis had sold all of its shares of our common stock.

## **Mylan**

We and Mylan, a wholly-owned indirect subsidiary of Mylan N.V., entered into a collaboration agreement, or the Mylan Collaboration Agreement, which became effective on 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.

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, in part, through up to six contingent early development milestone payments, totaling up to \$200 million across the six product candidates.

For each product candidate other than M834, at a specified stage of early development, we and Mylan will each decide, based on the product candidate's development progress and commercial considerations, whether to continue the development, manufacture and commercialization of such product candidate under the collaboration or to terminate the collaboration with respect to such product candidate. If one party decides not to continue development, manufacture and commercialization of a 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.

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 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; additional (pivotal or phase 3 equivalent) clinical development activities for M834; 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 other than M834; regulatory activities for the product candidates outside the United States; and regulatory activities for products in the United States after regulatory approval, when all marketing authorizations for the products in the United States will be transferred to Mylan. Mylan will commercialize any approved products, with 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 the product candidates, on a product-by-product and 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 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 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, manufacture 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.

## 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, which became effective on February 17, 2017, or the Effective Date, pursuant to which we granted CSL an exclusive worldwide license to research, develop, and commercialize our 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 and commercialize these additional research products globally.

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

Under the CSL License Agreement, 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 will form 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.

Unless earlier terminated, the term of the CSL License Agreement commenced on the Effective Date and will continue until the later of (i) the expiration of all payment obligations with respect to products under the CSL License Agreement, (ii) we are no longer co-funding development or commercialization of any products and (iii) 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 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 or country-by-country 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.

## **Baxalta**

We and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (or collectively referred to as Baxter) entered into a global collaboration and license agreement, or the Baxter Collaboration Agreement, effective February 2012, to develop and commercialize biosimilars, including M923. In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned the Baxter Collaboration Agreement to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated (or collectively referred to as Baxalta). Subsequent to the assignment, we refer to "Baxter" as "Baxalta" and the "Baxter Collaboration Agreement" as the "Baxalta Collaboration Agreement." On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement. On December 31, 2016, we and Baxalta entered into an asset return and termination agreement, or the Baxalta Termination Agreement, which made the termination of the Baxalta Collaboration Agreement effective as of December 31, 2016.

Under the Baxalta Collaboration Agreement, we and Baxalta agreed to collaborate, on a worldwide basis, on the development and commercialization of M923 and M834, and Baxalta had the right to select four additional reference products to target for biosimilar development under the collaboration. In July 2012, Baxalta selected an additional product candidate and in December 2013, following an internal portfolio review, terminated its option to license the product candidate. In February 2015, Baxalta's right to select additional programs expired without further exercise. Also, in February 2015, Baxalta terminated in part the Baxalta Collaboration Agreement as it related to M834 and all worldwide development and commercialization rights for M834 reverted to us.

Under the Baxalta Collaboration Agreement, each party granted the other an exclusive license under its intellectual property rights to develop and commercialize M923 for all therapeutic indications. We agreed to provide development and related services on a commercially reasonable basis through the filing of an IND or equivalent application in the European Union for M923. Development and related services included high-resolution analytics, characterization, and product and process development. Baxalta was responsible for clinical development, manufacturing and commercialization activities for M923. We had the right to participate in a joint steering committee, consisting of an equal number of members from us and Baxalta, to oversee and manage the development and commercialization of M923 under the collaboration. Costs, including development costs, payments to third parties for intellectual property licenses, and expenses for legal proceedings, including the patent exchange process pursuant to the Biologics Price Competition and Innovation Act of 2009, was to be borne by the parties in varying proportions, depending on the type of expense and the stage of development. We were generally responsible for research and process development costs prior to filing an IND or equivalent application in the European Union, and the cost of in-human clinical trials, manufacturing in accordance with current good manufacturing practices and commercialization was borne by Baxalta.

Under the terms of the Baxalta Collaboration Agreement, we received an initial cash payment of \$33 million, a \$7 million license payment for achieving pre-defined "minimum development criteria" for M834, and \$12 million in technical and development milestone payments in connection with the UK Medicines and Healthcare Products Regulatory Agency's acceptance of Baxalta's clinical trial application to initiate a pharmacokinetic clinical trial for M923. We were reimbursed at a contractual FTE rate for any FTE employee expenses and external development costs for reimbursable activities related to M923. Had M923 been successfully developed and launched under the Baxalta Collaboration Agreement, Baxalta would have been required to pay us royalties on net sales of licensed products worldwide, with a base royalty rate in the high single digits



with the potential for significant tiered increases based on the number of competitors, the interchangeability of the product, and the sales tier for the product. The maximum royalty with all potential increases would have been slightly more than double the base royalty.

On June 3, 2016, Baxalta Incorporated and Shire plc, or Shire, announced the completion of the combination of Baxalta Incorporated and Shire. As a result of the combination, Baxalta Incorporated, of which Baxalta US Inc. and Baxalta GmbH are wholly-owned subsidiaries, is a wholly-owned subsidiary of Shire. On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement. Under the terms of the Baxalta Collaboration Agreement, the effective date of the termination was twelve months following the date Baxalta gave the termination notice, as more particularly set forth in the Baxalta Collaboration Agreement. As of the termination effective date, (i) Baxalta was obligated to transfer to us all ongoing regulatory, development, manufacturing and commercialization activities and related records for M923 and, at our request, assign to us any third party agreements reasonably necessary for and primarily related to the development, manufacture, and commercialization of M923 to the extent permitted by the agreements' terms, (ii) the licenses granted pursuant to the Baxalta Collaboration Agreement by us to Baxalta under our intellectual property rights relating to M923 would terminate, the licenses granted pursuant to the Baxalta Collaboration Agreement by Baxalta to us under Baxalta's intellectual property rights relating to M923 would survive, and Baxalta was obligated to grant to us additional licenses under Baxalta's intellectual property rights relating to M923 existing as of the termination effective date, and (iii) we were obligated to pay to Baxalta a royalty of 5% of net sales, as such term is defined in the Baxalta Collaboration Agreement, until Baxalta's development expenses and commercialization costs, as such terms are defined in the Baxalta Collaboration Agreement, occurring through the termination effective date were reimbursed. Following receipt of the termination notice, we were no longer eligible to receive any regulatory milestone payments under the Baxalta Collaboration Agreement. Prior to the termination effective date, Baxalta was obligated to continue to perform development and manufacturing activities for M923.

On December 31, 2016, we and Baxalta entered into the Baxalta Termination Agreement, amending certain termination provisions of the Baxalta Collaboration Agreement. Under the terms of the Baxalta Termination Agreement, the termination of the Baxalta Collaboration Agreement was effective December 31, 2016. Baxalta was relieved of its obligations to continue to perform development, manufacturing or commercialization activities for M923 after December 31, 2016, except for certain clinical and regulatory activities that are expected to be completed by April 2017, which we refer to as the Transition Services. In order to fund the other activities that it would have been required to perform under the Baxalta Collaboration Agreement through the original termination effective date, in January 2017, Baxalta paid us a one-time cash payment of \$51.2 million. Under the termination provisions of the Baxalta Collaboration Agreement, following the commercialization of M923, we are obligated to pay to Baxalta a royalty of 5% of M923's net sales (as such term is defined in the Baxalta Collaboration Agreement) until the combined total amount of Baxalta's development expenses and commercialization costs (as such terms are defined in the Baxalta Collaboration Agreement) are reimbursed. Effective December 31, 2016, under the Baxalta Termination Agreement, this royalty obligation covers Baxalta's actual development expenses and commercialization costs incurred through December 31, 2016, plus Baxalta's costs incurred in providing the Transition Services and plus the \$51.2 million payment we received in January 2017. The licenses granted pursuant to the Baxalta Collaboration Agreement by us to Baxalta under our intellectual property rights relating to M923 terminated as of December 31, 2016, except solely to the extent reasonably necessary or useful for Baxalta to perform the Transition Services. The licenses granted by Baxalta to us under its intellectual property rights relating to M923 survive, and Baxalta has granted to us licenses under additional Baxalta intellectual property rights, if any, relating to M923 existing upon completion of the Transition Services. The Baxalta Termination Agreement also assigned to us certain third party agreements relating to the development, manufacture, and commercialization of M923.

## **Parivid**

In April 2007, we entered into an asset purchase agreement with Parivid, LLC, or Parivid, a provider of data integration and analysis services to us, and S. Raguram, the principal owner and Chief Technology Officer of Parivid. Pursuant to the purchase agreement, which was amended in August 2009 and July 2011, we 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 up to \$11.0 million in contingent milestone payments in a combination of cash and/or stock in the manner and on the terms and conditions set forth in the purchase agreement if certain milestones are achieved within 15 years of the date of the purchase agreement. In August 2016, we paid the final milestone payment under the purchase agreement by issuing 265,605 shares of our common stock to Parivid upon GLATOPA 20 mg/mL remaining the sole generic COPAXONE 20 mg/mL product on the U.S. market for one-year following its commercial launch in June 2016.

## **Patents and Proprietary 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.

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:

- methods and technologies for characterizing complex generics and biosimilars, including our biosimilar HUMIRA candidate and our biosimilar ORENCIA candidate;
- methods for manufacturing complex generics and biosimilars, including our biosimilar HUMIRA candidate and our biosimilar ORENCIA candidate;
- 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;
- 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, we and Mylan will jointly oversee manufacturing activities, with us having primary responsibility for contracting with contract manufacturers for clinical supply for products and Mylan having primary responsibility for contracting with contract manufacturers for commercial supply for products other than M834. 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 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.

### **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 NDA and 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. Beginning in 2010, with the enactment of the Biologics Price Competition and Innovation Act, or BPCI Act, a biosimilar may also be filed for approval under the abbreviated pathway under Section 351(k) of the Public Health Service Act.

#### ***ANDA Approval Process for Generics***

FDA approval is required before a generic equivalent of an existing brand name drug may be marketed. Such approval is typically obtained by submitting an ANDA to the FDA and demonstrating therapeutic equivalence. However, it is within the FDA's regulatory discretion to determine the kind and amount of evidence required to approve a product for marketing. An ANDA may be submitted for a drug on the basis that it is the same as a previously approved branded drug, also known as a reference listed drug. Specifically, the generic drug that is the subject of the ANDA must have the same active ingredient(s), route of administration, dosage form, and strength, as well as the same labeling, with certain exceptions, and the labeling must prescribe conditions of use that have been previously approved for the listed drug. If the generic drug product has a different route of administration, dosage form, or strength, the FDA must grant a suitability petition approving the differences(s) from the listed drug before the ANDA may be filed. The ANDA must also contain data and information demonstrating that the generic drug is bioequivalent to the listed drug (or alternatively seek a waiver as is requested for most injectable products), or if the application is submitted pursuant to an approved suitability petition, information to show that the listed drug and the generic drug can be expected to have the same therapeutic effect when administered to patients for a proposed condition of use.

Generic drug applications are termed "abbreviated" because they are not required to duplicate the clinical (human) testing or, generally, nonclinical testing necessary to establish the underlying safety and effectiveness of the branded product, other than the requirement for bioequivalence testing. However, the FDA may refuse to approve an ANDA if there is insufficient information to show that the active ingredients are the same and to demonstrate that any impurities or differences in active ingredients do not affect the safety or efficacy of the generic product. In addition, like NDAs, an ANDA will not be approved

unless the product is manufactured in current Good Manufacturing Practices, or cGMP, compliant facilities to assure and preserve the drug's identity, strength, quality and purity. As is the case for NDAs and BLAs, the FDA may refuse to accept and review insufficiently complete ANDAs.

Generally, in an ANDA submission, determination of the "sameness" of the active ingredients to those in the reference listed drug is based on the demonstration of the chemical equivalence of the components of the generic version to those of the branded product. While the standard for demonstrating chemical equivalence is relatively straightforward for small molecule drugs, it is inherently more difficult to define sameness for the active ingredients of complex drugs. Under the NDA pathway, these types of drugs include products such as recombinant versions of certain hormones, among others. Due to the limited number of ANDA submissions for generic complex drugs, the FDA has not reached a final position for demonstrating chemical equivalence for many of these products specifically, nor provided broad guidance for achieving "sameness" for complex drugs in general. In many cases, the criteria the FDA may apply are evolving and are being determined on an application-by-application basis.

To demonstrate bioequivalence, ANDAs generally must also contain *in vivo* bioavailability data for the generic and branded drugs. "Bioavailability" indicates the rate and extent of absorption and levels of concentration of a drug product in the bloodstream needed to produce a therapeutic effect. "Bioequivalence" compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body are the same as the previously approved branded drug. The studies required to demonstrate *in vivo* bioequivalence are generally very small, quick to complete, and involve relatively few subjects. Under current regulations, the FDA may waive requirements for *in vivo* bioequivalence data for certain drug products, including products where bioequivalence is self-evident such as injectable solutions which have been shown to contain the same active and inactive ingredients as the reference listed drug. Although the FDA may waive requirements for *in vivo* bioequivalence data, it may still require the submission of alternative data on purity, such as immunogenicity and/or pharmacokinetics and pharmacodynamics data, to provide additional evidence of pharmaceutical equivalence. The FDA, however, does not always waive requirements for *in vivo* bioequivalence data.

Generic drug products that are found to be therapeutically equivalent by the FDA receive an "A" rating in FDA's Orange Book, which lists all approved drug products and therapeutic equivalence evaluations. Products that are therapeutically equivalent can be expected in the FDA's judgment to have equivalent clinical effect and no difference in their potential for adverse effects when used under the approved conditions of their approved labeling. Products with "A" ratings are generally substitutable for the innovator drug by both in-hospital and retail pharmacies. Many health insurance plans require automatic substitution for "A" rated generic versions of products when they are available, although physicians may still prescribe the branded drug for individual patients. On rare occasions in the past, generic products were approved that were not rated as therapeutically equivalent, and these products were generally not substitutable at retail pharmacies. Therapeutic equivalence ratings are used under Medicare to determine reimbursement for generic drugs and facilitate market uptake of generic drugs.

The timing of final FDA approval of a generic drug for commercial distribution depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and/or its use and whether the manufacturer of the branded product is entitled to one or more statutory periods of non-patent regulatory exclusivity, during which the FDA is prohibited from accepting or approving generic product applications. For example, submission of an ANDA for a drug that was approved under an NDA as a new chemical entity will be blocked for five years after the pioneer's approval or for four years after approval if the application includes a paragraph IV certification of non-infringement or invalidity against a patent applicable to the branded drug. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on or after the patent expiration date. For example, a three-year exclusivity period may be granted for new indications, dosage forms, routes of administration, or strengths of previously approved drugs, or for new uses, if approval of such changes required the sponsor to conduct new clinical studies. In addition, the FDA may extend the exclusivity of a product by six months past the date of patent expiry or other regulatory exclusivity if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric exclusivity.

The brand manufacturer may seek to delay or prevent the approval of an ANDA by filing a Citizen Petition or other forms of comments with the FDA. For example, a Citizen Petition may request the FDA to rule that a determination of "sameness" and/or therapeutic equivalence for a particular ANDA is not possible without extensive clinical testing, based on the characteristics of the brand product. Because relatively few ANDAs for complex mixture drugs have been reviewed by FDA, such a petition could substantially delay approval, or result in non-approval, of an ANDA for a complex mixture generic product. For example, Teva filed a Citizen Petition that argued that "sameness" could not be established by any applicant filing an ANDA for a generic COPAXONE on the grounds that COPAXONE was too complex to be thoroughly characterized. The FDA denied Teva's petition in connection with the approval of the ANDA for GLATOPA 20 mg/mL. The review of the Citizen Petition or other comments filed with the FDA and the preparation of the FDA response, however, can involve significant legal and regulatory resources that may extend the time for FDA review and approval of an ANDA.

### ***Patent Challenge Process Regarding ANDAs***

The Hatch-Waxman Act provides incentives for generic pharmaceutical manufacturers to challenge patents on branded pharmaceutical products and/or their methods of use, as well as to develop products comprising non-infringing forms of the patented drugs. The Hatch-Waxman legislation places significant burdens on the ANDA filer to ensure that such challenges are not frivolous, but also offers the opportunity for significant financial reward if the challenge is successful.

If there is a patent listed for the branded drug in the FDA's Approved Drug Products with Therapeutic Equivalence and Evaluations listing or "Orange Book" at the time of submission of the ANDA, or at any time before the ANDA is approved, the generic manufacturer's ANDA must include one of four types of patent certification with respect to each listed patent. If the applicant seeks approval to market the generic equivalent prior to the expiration of a listed patent, the generic company includes a certification asserting that the patent is invalid or unenforceable or will not be infringed, a so-called "paragraph IV certification." Within 20 days after receiving notice from the FDA that its application is acceptable for review, or immediately if the ANDA has been amended to include a paragraph IV certification after the application was submitted to the FDA, the generic applicant is required to send the patent owner and the holder of the NDA for the brand-name drug notice explaining why it believes that the listed patents in question are invalid, unenforceable or not infringed. If the patent holder commences a patent infringement lawsuit within 45 days of receipt of such notice, the Hatch-Waxman Act provides for an automatic stay on the FDA's ability to grant final approval of the ANDA for the generic product, generally for a period of 30 months. A 30-month stay may be shortened or lengthened by a court order if the district court finds that a party has failed to reasonably cooperate in expediting the action. Moreover, the district court may, before expiration of the stay, issue a preliminary injunction prohibiting the commercial sale of the generic drug until the court rules on the issues of validity, infringement, and enforceability. If the district court finds that the relevant patent is invalid, unenforceable, or not infringed, such ruling terminates the 30-month stay on the date of the judgment. If it is finally determined that the patent is valid, enforceable, and infringed, approval of the ANDA may not be granted prior to the expiration of the patent. In addition, if the challenged patent expires during the 30-month period, the FDA may grant final approval for the generic drug for marketing, if the FDA has determined that the application meets all technical and regulatory requirements for approval and there are no other obstacles to approval.

In most cases, patent holders may only obtain one 30-month stay with respect to patents listed in the Orange Book. Specifically, for ANDAs with paragraph IV certifications to a patent listed for the branded drug in the Orange Book on or after August 18, 2003, a single 30-month stay is available for litigation related to that patent only if the patent was submitted to the FDA before the date that the ANDA (excluding an amendment or supplement) was submitted. In other words, 30-month stays are not triggered by later listed patents submitted to the FDA on or after the date the ANDA application was submitted. Because of this limitation, in most cases ANDAs will be subject to no more than one 30-month stay.

Under the Hatch-Waxman Act, the first ANDA applicant to have submitted a substantially complete ANDA that includes a paragraph IV certification may be eligible to receive a 180-day period of generic market exclusivity during which the FDA may not approve any other ANDA for the same drug product. However, this exclusivity does not prevent the sponsor of the innovator drug from selling an unbranded "authorized generic" version of its own product during the 180-day exclusivity period. This period of market exclusivity may provide the patent challenger with the opportunity to earn a return on the risks taken and its legal and development costs and to build its market share before other generic competitors can enter the market. Under the Hatch-Waxman Act, as amended by the Medicare Modernization Act of 2003, or MMA, there are a number of ways an applicant who has filed an ANDA after the date of the MMA may forfeit its 180-day exclusivity, including if the ANDA is withdrawn or if the applicant fails to market its product within the specified statutory timeframe or achieve at least tentative approval within the specified timeframe. In addition, for ANDAs filed after the MMA was enacted, it is possible for more than one ANDA applicant to be eligible for 180-day exclusivity. This occurs when multiple "first" applicants submit substantially complete ANDAs with paragraph IV certifications on the same day.

### ***Approval Process for Biosimilars***

With the enactment of federal healthcare reform legislation in 2010, the Biologics Price Competition and Innovation Act, or BPCI Act, was enacted which created a new abbreviated approval pathway for biosimilars. The abbreviated pathway is codified in Section 351(k) of the Public Health Service Act. Under Section 351(k), the FDA must wait four years after approval of a 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. In addition, the new legislation redefines "biologic" versus "drug." There is a ten year transition period during which applicants can elect regulation as a drug or biologic when applications are filed.

The Section 351(k) pathway creates a regulatory and legal pathway to encourage the development of biosimilars. First, it authorizes the FDA to rely on the safety and efficacy of a reference product approved under a BLA to approve biosimilar products under the abbreviated pathway. Second, it establishes a process for negotiation and clearance of patents controlled by the reference product BLA holder. The law defines a biosimilar product 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
- 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 Section 351(k) pathway states that a biosimilar product that is determined to be interchangeable may be substituted for the reference product without the intervention of a health care provider who prescribed the reference product. The law states that the biosimilar must be for the same indication as the reference product, involve the same mechanism of action and that the manufacturing facility meets the standards necessary to assure that the product continues to be safe, pure and potent. The types of data that would ordinarily be required in an application to show similarity would include:

- analytical data and studies to demonstrate chemical similarity;
- 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 new approval pathway. It provides for pre-application meetings where the applicant can propose and submit analytic, 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. 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 an abbreviated application, an applicant may trigger the patent negotiation and clearance process. Under the 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 is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning will be subject to uncertainty for years to come.

### ***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 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.

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.

Upon approval of a new drug or a new indication based under an NDA or a supplement to an NDA, the holder of the approval receives the benefit of protection from generic competition. As discussed above, for example, the FDA must wait at least four years before accepting a filing for approval of a generic version of the brand product under an ANDA, and the FDA cannot approve a generic version of the brand product under an ANDA until five years after the brand product was approved under the NDA. In addition, in certain circumstances where a brand product files additional data as outlined above for a new indication or use of a brand based upon new clinical studies and receives an approval, the FDA is similarly precluded from approving a generic version of the brand product for such new indication or use until three years after the new use or indication was approved by the brand.

The BPCI Act added new exclusivity provisions for reference products along with the creation of a new approval pathway for biosimilars. Under the law, the FDA must wait four years after approval of a biologic under a BLA before accepting a filing for a biosimilar of that product, and the FDA cannot approve a biosimilar of the reference product until 12 years after the reference product was approved under a BLA. In addition, the new legislation redefines the definition of biologic versus drug and, as a result, a number of products that were previously regulated as drugs may now be regulated as biologics. There is a ten year transition period during which applicants can elect regulation as a drug or as a biologic when applications are filed. This could provide an applicant that elects regulation as a biologic with the longer twelve year period of exclusivity protection as compared to the five year period of exclusivity protection against generic drug competition.

### ***Manufacturing Requirements***

Before approving an NDA, BLA, ANDA or Section 351(a) 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(a) 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 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 products under development.

## **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 vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorizations 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.

## **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.

### *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. If the ANDA for GLATOPA 40 mg/mL is approved, GLATOPA 40 mg/mL would be a substitutable generic for, and would compete directly with, Teva's three-times-weekly COPAXONE 40 mg/mL. Teva's three-times-weekly COPAXONE 40 mg/mL, which launched in early 2014, accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL) based on volume prescribed. Teva's three-times-weekly COPAXONE 40 mg/mL share of the overall glatiramer acetate market may

continue to increase, which could continue to decrease the size of the 20 mg/mL glatiramer acetate market and the market potential for GLATOPA 20 mg/mL. Currently, GLATOPA 20 mg/mL is the sole approved generic for once-daily COPAXONE 20 mg/mL in the United States and, to date, there is no approved generic for three-times-weekly COPAXONE 40 mg/mL in the United States. However, we may be subject to competition from other generic versions of COPAXONE approved in the future by the FDA. ANDAs for generic versions of COPAXONE 20 mg/mL and/or 40 mg/mL have been submitted to the FDA by Mylan Inc., 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 competes (and GLATOPA 40 mg/mL, if approved, will 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), Plegridy (peginterferon beta-1a), and Zinbryta (daclizumab), 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; and Aubagio (teriflunomide), marketed by Sanofi.

### *Biosimilars*

If approved, our biosimilar candidates would compete with their applicable reference products, 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. Amgen's biosimilar to HUMIRA, Amjevita, received FDA approval in 2016 and a Committee for Medicinal Products for Human Use, or CHMP, positive opinion in January 2017. Currently, Sandoz, Samsung Bioepis, Fujifilm Kyowa Kirin Bio., Pfizer, Boehringer Ingelheim, Biocon/Mylan, Merck KGaA, LG Life Sciences, Coherus, Innovent Biologics, Oncobiologics, Biocad, Genor/Biocnd, and Bio-Thera have biosimilars to HUMIRA in clinical development. There are two biosimilars to HUMIRA approved in India, one from Torrent Pharmaceuticals and one from Zydus Cadila. Alphamab, bioXpress, Dr. Reddy's Laboratories, and Harvest Moon have announced they are developing a biosimilar to ORENCIA.

### *Novel Therapeutics*

Our novel product pipeline will also face substantial competition from major pharmaceutical and other biotechnology companies. Our development work focused on Fc biology, which has yielded three named product candidates: M230, an Fc multimer, M281, anti-FcRn, and M254, hyper-sialylated IVIg. These candidates face competition from a number of companies. Merck & Co. and Pfizer have compounds in development that are mechanistically similar to M230. Pfizer's compound is in nonclinical development, and Merck's compound completed a Phase I clinical trial in May 2015. Several companies, including UCB, HanAll, Shire, Syntimmune and Argenx are developing FcRn targeted agents. UCB's compound is in a phase II clinical trial in ITP. Argenx's compound is in a phase 2 trial in myasthenia gravis, and Syntimmune's compound is in a phase I clinical trial. HanAll and Shire are in nonclinical development. M254 would compete with currently marketed intravenous and subcutaneous IgG products, including Octagam 5% and Octagam 10% marketed by Octapharma, Gammagard S/D, Gammagard Liquid 10%, Cuvitru and HyQvia marketed by Shire, Carimune, Privigen Liquid 10%, Carimune NF, and Hizentra marketed by CSL Behring, Flebogamma 5% DIF, Gamunex-C, Flebogamma 10% DIF marketed by Grifols, Gammaplex marketed by BPL Holdings, Gammaked marketed by Kendrion Biopharma, and Bivigam Liquid 10% marketed by Biotest, as well as those that are currently in development.

## **Employees**

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2016, we had 290 employees, including 81 employees who hold Ph.D. degrees and one employee who holds 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.

## **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 2016 was \$119.9 million, compared with \$126.0 million in 2015 and \$106.5 million in 2014.



## 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, 2016 have come from our collaborators and are based solely on activities in the United States. Our long-lived assets were \$26.0 million, \$25.4 million and \$30.0 million at December 31, 2016, 2015, and 2014, 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 675 West Kendall 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. Such reports, proxy statements and other information can be read and copied at the public reference facilities maintained by the Securities and Exchange Commission at the Public Reference Room, 100 F Street, NE, Washington, D.C. 20549. Information regarding the operation of the Public Reference Room may be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. 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](http://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 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

***If we or our collaborative partners encounter difficulties in our supply or manufacturing arrangements, including an inability by third party manufacturers to satisfy FDA quality standards and related regulatory requirements, our development and commercialization efforts may be materially harmed.***

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborative partners and other third parties, including sole source suppliers, to provide raw materials meeting FDA quality standards and related regulatory requirements, manufacture the drug substance, produce the final drug product and provide certain analytical services with respect to our products and product candidates. The FDA and other regulatory authorities require that our products be manufactured according to current good manufacturing practices, or cGMP, regulations

and that proper procedures are implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborative partners or our third-party manufacturers to comply with cGMP and/or scale-up manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval. In addition, such failure could be the basis for action by the FDA to withdraw approvals for products previously granted to us and for other regulatory action, including product recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions. To the extent we rely on a third-party manufacturer, the risk of non-compliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed. For example, on February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States; however, the FDA may withhold approval of pending drug applications listing the facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. If the FDA delays an approval of the GLATOPA 40 mg/mL until satisfactory resolution of the compliance observations in the FDA warning letter, the greater the risk to us and Sandoz of prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL. Any prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

We have relied upon third parties, including sole source suppliers, to produce material for nonclinical and clinical studies and may continue to do so in the future. We cannot be certain that we will be able to obtain and/or maintain long-term supply and supply arrangements of those materials on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

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

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

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

Since the damages associated with a GLATOPA 40 mg/mL launch prior to final resolution of any product-related patent infringement litigation in our and Sandoz' favor can be substantial, Sandoz may delay or reduce the scope of a GLATOPA 40 mg/mL launch following any FDA approval. A delayed launch could occur as late as final resolution of all GLATOPA 40 mg/mL-related patent infringement litigation in our and Sandoz' favor or, if we and Sandoz are unsuccessful in such litigation, the expiration of the GLATOPA 40 mg/mL-related patents. A launch that is delayed or reduced in scope could delay or reduce any

future contractual profits due to us from sales of GLATOPA 40 mg/mL, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

***If other generic versions of the brand name drugs, or other biosimilars of the reference products, for which we have products or product candidates, including GLATOPA 20 mg/mL, GLATOPA 40 mg/mL, M923 and M834, are approved and successfully commercialized, our business would suffer.***

Pricing and market share of generic and biosimilar products may decline, often dramatically, as other generics or biosimilars of the same brand name drug or reference product, respectively, enter the market. Competing generics include brand name manufacturers' "authorized generics" of their own brand name products. Generally, earlier-to-market generics and biosimilars are better able to gain significantly greater market share than later-to-market competing generics and biosimilars, respectively. Accordingly, revenue and profits from GLATOPA 20 mg/mL and, if approved, our generic and biosimilar product candidates, may be significantly reduced based on the timing and number of competing generics and biosimilars, respectively. We expect GLATOPA 20 mg/mL and, if approved, certain of our generic and biosimilar product candidates may face intense and increasing competition from other generics and biosimilars. For example, Mylan and several other companies have submitted ANDAs to the FDA for generic versions of COPAXONE. A launch of an additional generic version of COPAXONE could significantly reduce anticipated revenue from GLATOPA 20 mg/mL and, if approved and launched, GLATOPA 40 mg/mL. The longer the period of time that it takes us and Sandoz to receive approval of the GLATOPA 40 mg/mL ANDA, the greater the risk of prior or contemporaneous competition from other generic versions of COPAXONE. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

In addition, the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that reference product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(1)(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(1)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first

interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). A determination that another company's product is interchangeable with HUMIRA, ORENCIA or another of the reference products for which we have a biosimilar product candidate prior to approval of M923, M834 or our other applicable biosimilar product candidates may therefore delay any determination that our product is interchangeable with the reference product, which may materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

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

Brand companies may develop alternative versions of a reference product as part of a life cycle extension strategy, and may obtain approval of the alternative version under a supplemental new drug application, for a drug, or biologics license application, for a biologic. The alternative version may offer patients added benefits such as a more convenient form of administration or dosing regimen. Should the brand company succeed in obtaining an approval of an alternative product, it may capture a significant share of the collective reference product market and significantly reduce the market for the original reference product and thereby the potential size of the market for our generic or biosimilar products. For example, Teva's three-times-weekly COPAXONE 40 mg/mL, which launched in early 2014, accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed. As a result, the market potential for GLATOPA 20 mg/mL has decreased, and may decrease further as additional patients are converted from once-daily COPAXONE to three-times-weekly COPAXONE. In addition, the alternative product may be protected by additional patent rights as well as have the benefit, in the case of drugs, of an additional three years of FDA marketing approval exclusivity, which would prohibit a generic version of the alternative product for some period of time. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

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

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

Current injectable treatments commonly used to treat multiple sclerosis, including COPAXONE, are competing with novel therapeutic products, including oral therapies. These oral therapies may offer patients a more convenient form of administration than COPAXONE and may provide increased efficacy.

If the market for the reference product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

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

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

Our near-term ability to generate GLATOPA product revenue also depends in large part on Sandoz' ability to maintain market share and the pricing levels for GLATOPA 20 mg/mL and, if approved, GLATOPA 40 mg/mL, as Sandoz competes with Teva's three-times-weekly COPAXONE 40 mg/mL, which currently accounts for approximately 81% of the overall U.S.

glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed. Because GLATOPA 20 mg/mL is only a substitutable generic version of the once-daily 20 mg/mL formulation of COPAXONE, the market potential of GLATOPA 20 mg/mL is negatively impacted by the conversion of patients from once-daily COPAXONE 20 mg/mL to three-times-weekly COPAXONE 40 mg/mL prior to the approval and launch of the GLATOPA 40 mg/mL product, which is currently pending FDA approval. Following any such approval and launch of the GLATOPA 40 mg/mL product, our near-term ability to generate GLATOPA product revenue will continue to depend on Sandoz' ability to compete with Teva's three-times-weekly COPAXONE 40 mg/mL product. In addition, other competitors may in the future receive approval to market generic versions of the 20 mg/mL or 40 mg/mL formulations of COPAXONE which would further impact our product revenue, which is based on a fifty-percent contractual profit share and, as a result, our business, including our near-term financial results and our ability to utilize GLATOPA revenue to fund future discovery and development programs, may suffer.

***Any future Enoxaparin Sodium Injection product revenue is dependent on the successful manufacture and commercialization of Enoxaparin Sodium Injection***

Our near-term ability to generate Enoxaparin Sodium Injection product revenue depends, in large part, on Sandoz' ability to manufacture and commercialize Enoxaparin Sodium Injection and compete with LOVENOX brand competition as well as authorized and other generic competition. Sandoz is facing increasing competition and pricing pressure from brand, authorized generic and other currently-approved generic competitors, which has and will continue to impact Sandoz' net sales and profits from Enoxaparin Sodium Injection, and therefore our product revenue. Furthermore, other competitors may in the future receive approval to market generic Enoxaparin products which would further impact our product revenue, which is based on a fifty-percent contractual profit share. Due to these circumstances, the resulting market price for our Enoxaparin Sodium Injection product has substantially decreased and may decrease further. Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the year ended December 31, 2016, and therefore we recorded no product revenue for Enoxaparin Sodium Injection in the same period. Accordingly, we do not anticipate significant Enoxaparin Sodium Injection revenue in the near term.

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

In the event that we are not successful in our continued prosecution of our suit against Amphastar and Amphastar is able to prove it suffered damages as a result of the preliminary injunction preventing it from selling its Enoxaparin product in the United States, we could be liable for up to \$35 million of the security bond for such damages. Moreover, if third parties are successful in antitrust litigation against us for asserting our Enoxaparin patent rights, they may be able to recover damages incurred as a result of enforcement of our patent rights, thereby negatively affecting our financial condition and results of operations.

***If efforts by manufacturers of reference products to delay or limit the use of generics or biosimilars are successful, our sales of generic and biosimilar products may suffer.***

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay regulatory approval and to seek to restrict competition from manufacturers of generic drugs and biosimilars. These efforts have included:

- settling patent lawsuits with generic or biosimilar companies, resulting in such patents remaining an obstacle for generic or biosimilar approval by others;
- seeking to restrict biosimilar commercialization options by making mandatory the optional right to adjudicate patent rights under Section 351(l) of the Biologics Price, Competition and Innovation Act or restricting access by biosimilar and generic applicants 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;

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- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of generic drug or biosimilar applications;
- restricting access to reference products for equivalence and biosimilarity testing that interfere with timely generic and biosimilar development plans, respectively;
- conducting medical education with physicians, payers and regulators that claim that generic or biosimilar products are too complex for generic or biosimilar approval and influence potential market share;
- seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking federal reimbursement policies that do not promote adoption of biosimilars and interchangeable biologics;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- pursuing new patents for existing products or processes which could extend patent protection for a number of years or otherwise delay the launch of generic drugs or biosimilars; and
- influencing legislatures so that they attach special regulatory exclusivity or patent extension amendments to unrelated federal legislation.

The FDA's practice is to rule within 150 days on Citizen Petitions that seek to prevent approval of an ANDA if the petition was filed after the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA. If, at the end of the 150-day period, the ANDA is not ready for approval or rejection, then the FDA has typically denied and dismissed the petition without acting on the petition. For example, Teva Neuroscience, Inc. filed eight Citizen Petitions regarding GLATOPA 20 mg/mL, all of which have been denied, dismissed or withdrawn. Teva also sought reversal of the denial of a Citizen Petition in federal court. Other third parties may also file Citizen Petitions requesting that the FDA adopt specific approval standards for generic or biosimilar products. Teva may seek to file additional Citizen Petitions pertaining to the GLATOPA 40 mg/mL ANDA or file other forms of comments to the FDA, and seek to delay or prevent the FDA approval of the GLATOPA 40 mg/mL ANDA, which could materially harm our business.

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

### ***Competition in the biotechnology and pharmaceutical industries is intense, and if we are unable to compete effectively, our financial results will suffer.***

The markets in which we intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. We expect competition to intensify as technological advances are made or new biotechnology products are introduced. New developments by competitors may render our current or future product candidates and/or technologies non-competitive, obsolete or not economical. Our competitors' products may be more efficacious or marketed and sold more effectively than any of our products.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process;
- more extensive experience in commercializing generic drugs, biosimilars and novel therapeutics, conducting nonclinical studies, conducting clinical trials, obtaining regulatory approvals, challenging patents and manufacturing and marketing pharmaceutical products;
- products that have been approved or are in late stages of development; and



- collaborative arrangements in our target markets with leading companies and/or research institutions.

We face, and will continue to face, competition with regard to our products and, if approved, our product candidates, based on many different factors, including:

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

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

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

Drug products and biologics are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. The distribution of such products is also managed by pharmacy benefit management firms, or PBMs, such as Express Scripts or CVS. These GPOs and PBMs rely on competitive bidding, discounts and rebates across their purchasing arrangements. We believe that we, in collaboration with commercial collaboration partners, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products to establish and maintain relationships with GPOs and PBMs. The GPOs, PBMs and other customers with whom we or our collaborators have established contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of products to certain market segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by, or offered to, GPOs, PBMs, and customers, including wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our or our competitors' products. For example, if PBMs, distributors and other customers contract with Teva for net price discounts or rebates on COPAXONE 20 mg/mL and 40 mg/mL in exchange for exclusivity or preferred status for COPAXONE prior to approval and launch of GLATOPA 40 mg/mL, our opportunity to capture market share would be significantly restricted for the term of these contracts even after a launch of GLATOPA 40 mg/mL. If we or our collaborators are unable to establish and maintain competitive distribution arrangements with all of these customers, sales of our products, our revenue and our profits would suffer.

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

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

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

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

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

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

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

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

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in a recall of our products or a change in the approved indications for which they may be used. We cannot be sure that the product liability insurance coverage we maintain will be adequate to cover any incident or all incidents. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

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

Our operations rely on the secure processing, storage and transmission of confidential and other information in our and our third party contractors' computer systems and networks. Our internal computer systems are vulnerable to breakdown or breach, including as a result of computer viruses, security breaches by individuals with authorized access, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The increased use of mobile and cloud technologies can heighten these and other operational risks. Moreover, systems breaches are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Any breakdown or breach by employees or others



may pose a risk that sensitive data, including clinical trial data, intellectual property, trade secrets or personal information belonging to us, our patients or our collaborators may be exposed to unauthorized persons or to the public. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture and commercialize our products and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our products and product candidates could be delayed, we could suffer reputational harm, we could be subject to regulatory action, and the trading price of our common stock could be adversely affected. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to breakdown or breach of our computer systems and other related breaches.

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

As we advance an increasing number of product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to lease additional or alternative facilities and manage additional relationships with various collaborative partners, suppliers and other organizations. The market for laboratory and office facilities is highly competitive near our current location. If we are not successful in leasing additional or alternative space in our current area and have to move our facilities, the timing of our development programs could be disrupted.

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

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

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

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

- we may find that the acquired company or assets does not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;
- difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;
- difficulty incorporating the acquired technologies;

- difficulties or failures with the performance of the acquired technologies or products;
- we may face product liability risks associated with the sale of the acquired company's products;
- disruption or diversion of management's attention by transition or integration issues and the complexity of managing diverse locations;
- difficulty maintaining uniform standards, internal controls, procedures and policies;
- the acquisition may result in litigation from terminated employees or third parties; and
- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

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

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

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

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

Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002, as amended. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

#### **Risks Relating to Our Financial Position and Need for Additional Capital**

***We have incurred a cumulative loss since inception. If we do not generate significant revenue, we may not return to profitability.***

We have incurred significant losses since our inception in May 2001. At December 31, 2016, our accumulated deficit was \$473 million. We may incur annual operating losses over the next several years as we expand our product development, commercialization and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our product candidates, and effectively manufacture, market and sell any products we successfully develop. Accordingly, we may not generate significant revenue in the longer term and, even if we do generate significant revenue, we may never achieve long-term profitability.

To be profitable, we and our collaborative partners must succeed in developing and commercializing products with significant market potential. This will require us and our collaborative partners to be successful in a range of challenging activities: developing product candidates; obtaining regulatory approval for product candidates through either existing or new

regulatory approval pathways; clearing allegedly infringing patent rights; enforcing our patent rights; and manufacturing, distributing, marketing and selling products. Our potential profitability will also be adversely impacted by the entry of competitive products and, if so, the degree of the impact could be affected by whether the entry is before or after the launch of our products. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other therapeutic candidates or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

***We will require substantial funds and may require additional capital to execute our business plan and, if additional capital is not available, we may need to delay, limit or cease our product development efforts or other operations. If we are unable to fund our obligations under our collaboration and license agreements, we may breach those agreements and our collaboration partners could terminate those agreements.***

As of December 31, 2016, we had cash, cash equivalents and marketable securities totaling approximately \$353.2 million. For the year ended December 31, 2016, we had a net loss of \$21.0 million and our operations provided cash of \$7.9 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, nonclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development and commercialization of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

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

- the level of sales of GLATOPA 20 mg/mL;
- the successful commercialization of GLATOPA 40 mg/mL and our other product candidates;
- the cost of advancing our product candidates and funding our development programs, including the costs of nonclinical and clinical studies and obtaining regulatory approvals;
- the receipt of continuation payments under our Mylan Collaboration Agreement;
- the receipt of milestone payments under our CSL License Agreement;
- the continuation without disruption of development and manufacturing activities of M923 following Baxalta's termination of the Baxalta Collaboration Agreement, which was effective on December 31, 2016;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar relating to Enoxaparin Sodium Injection, that is not otherwise covered by our collaboration agreements, or potential patent litigation with others, as well as any damages, including possibly treble damages, that may be owed to third parties should we be unsuccessful in such litigation;
- the ability to enter into additional strategic alliances for our non-partnered programs, such as M923, as well as the terms and timing of any milestone, royalty or profit share payments thereunder;
- the continued progress in our research and development programs, including completion of our nonclinical studies and clinical trials;
- the cost of acquiring and/or in-licensing other technologies, products or assets; and
- the cost of manufacturing, marketing and sales activities, if any.

We expect to finance and manage our planned operating and capital expenditure requirements principally through our current cash, cash equivalents and marketable securities, capital raised through our collaboration and license agreements and equity financings, including utilization of our At-the-Market financing facility, continuation and milestone payments and product revenues under existing collaboration and license agreements. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2018. We may seek additional funding in the future through third-party

collaborations and licensing arrangements, public or private debt financings or from other sources. Additional funds may not be available to us on acceptable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also may not be able to fund our obligations under one or more of our collaboration and license agreements, which could enable one or more of our collaborators to terminate their agreements with us, and therefore harm our business, financial condition and results of operations.

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

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

### **Risks Relating to Development and Regulatory Approval**

***The future success of our business is significantly dependent on the success of our GLATOPA 40 mg/mL product candidate. If we are not able to obtain regulatory approval for the commercial sale of our GLATOPA 40 mg/mL product candidate, our future results of operations will be adversely affected.***

Our future results of operations depend to a significant degree on our ability to obtain regulatory approval for and commercialize GLATOPA 40 mg/mL. Our application for GLATOPA 40 mg/mL has been under review with the FDA since February 2014. To receive approval, we will be required to demonstrate to the satisfaction of the FDA, among other things, that GLATOPA 40 mg/mL:

- contains the same active ingredients as COPAXONE 40 mg/mL;
- is of the same dosage form, strength and route of administration as COPAXONE 40 mg/mL, and has the same labeling as the approved labeling for COPAXONE 40 mg/mL, with certain exceptions; and
- meets compendia or other applicable standards for strength, quality, purity and identity, including potency.

In addition, approval of a generic product generally requires demonstrating that the generic drug is bioequivalent to the reference listed drug upon which it is based, meaning that there are no significant differences with respect to the rate and extent to which the active ingredients are absorbed and become available at the site of drug action. However, the FDA may or may not waive the requirements for certain bioequivalence data (including clinical data) for certain drug products, including injectable solutions that have been shown to contain the same active and inactive ingredients in the same concentration as the reference listed drug.

Determination of therapeutic equivalence of GLATOPA 40 mg/mL to COPAXONE 40 mg/mL will be based, in part, on our demonstration of the chemical equivalence of our version to its respective reference listed drugs. The FDA may not agree that we have adequately characterized GLATOPA 40 mg/mL or that GLATOPA 40 mg/mL and COPAXONE 40 mg/mL are chemical equivalents. In that case, the FDA may require additional information, including nonclinical or clinical trial results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product's safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. We cannot predict whether GLATOPA 40 mg/mL will receive FDA approval as therapeutically equivalent to COPAXONE 40 mg/mL.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of COPAXONE 40 mg/mL, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of GLATOPA 40 mg/mL could be delayed or prevented or become more expensive. Regulatory approval of this or any other product may also be significantly delayed where manufacturing inspections are pending or have unresolved pending compliance issues. Delays in any part of the process or our inability to obtain regulatory approval for GLATOPA 40 mg/mL could adversely affect our operating results by restricting or significantly delaying our introduction of GLATOPA 40 mg/mL.

Moreover, on February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the facility,

including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

***Although the BPCI Act establishes a regulatory pathway for the approval by the FDA of biosimilars, the standards for determining biosimilarity and interchangeability for biosimilars are only just being implemented by the FDA under recently developed and developing guidance. Therefore, substantial uncertainty remains about the potential value of our scientific approach and regulatory strategy for biosimilar development.***

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

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that our analytics, biocharacterization and protein engineering platform technology provides a level of scientific assurance that facilitates determinations of biosimilarity and/or interchangeability, reduces the need for large scale clinical trials or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a reference product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach within the context of the biosimilar meeting and application review process. In addition, the FDA will likely require significant new resources and expertise to review biosimilar applications, and the timeliness of the review and approval of our future applications could be adversely affected if there were a decline or even limited growth in FDA funding. Our strategy to reduce and target clinical requirements by relying on analytical and functional nonclinical data may not be successful or may take longer than strategies that rely more heavily on clinical trial data.

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

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

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

In addition, there is reconsideration and legislative debate that could lead to the repeal or amendment of the healthcare legislation. If the legislation is significantly amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected. Similarly, the legislative debate at the federal level regarding the federal government budget in 2013 restricted federal agency funding for the biosimilar pathway, including biosimilar user fee funding for fiscal year 2014, and has resulted in delays in hiring and in the conduct of meetings with biosimilar applicants and the review of

biosimilar meeting and application information. The scheduling and conduct of biosimilar meeting and applications review was also suspended during the U.S. Government shutdown in October 2013, and could be subject to future suspensions as a result of future deadlocks in passage of federal appropriations bills in 2017 or future years. In addition, the hiring and regulatory freeze implemented by the federal government in 2017 and other potential regulatory reform initiatives could also impact the future implementation of the biosimilar regulatory pathway. While proposals to repeal the Affordable Care Act do not appear to include proposals to repeal the BPCI Act, there is still some uncertainty about that possibility. Depending on the timing and the extent of these funding, meeting and review disruptions, our development of biosimilar products could be delayed.

***Our opportunity to realize value from the potential of the biosimilars market is difficult and challenging due to the significant scientific and development expertise required to develop and consistently manufacture complex protein biologics.***

The market potential of biosimilars may be difficult to realize, in large part due to the challenges of successfully developing and manufacturing biosimilars. Biologics are therapeutic proteins and are much more complex and much more difficult to characterize and replicate than small-molecule, chemically synthesized drugs. Proteins tend to be 100 to 1000 times larger than conventional drugs, and are more susceptible to physical factors such as light, heat and agitation. They also have greater structural complexity. Protein molecules differ from one another primarily in their sequence of amino acids, which results in folding of the protein into a specific three-dimensional structure that determines its activity. Although the sequence of amino acids in a protein is consistently replicated, there are a number of changes that can occur following synthesis that create inherent variability. Chief among these is the glycosylation, or the attachment of sugars at certain amino acids. Glycosylation is critical to protein structure and function, and thoroughly characterizing and matching the glycosylation profile of a targeted biologic is essential and poses significant scientific and technical challenges. Furthermore, it is often challenging to consistently manufacture proteins with complex glycosylation profiles, especially on a commercial scale. Protein-based therapeutics are inherently heterogeneous and their structure is highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots of the same product produced at the same facility. The physicochemical complexity and size of biologics creates significant technical and scientific challenges in their replication as biosimilar products. Accordingly, the technical complexity involved and expertise and technical skill required to successfully develop and manufacture biosimilars poses significant barriers to entry. Any difficulties encountered in developing and producing, or any inability to develop and produce, biosimilars could adversely affect our business, financial condition and results of operations.

***Even if we are able to obtain regulatory approval for our generic and biosimilar product candidates as therapeutically equivalent or interchangeable, state pharmacy boards or agencies may conclude that our products are not substitutable at the pharmacy level for the corresponding reference product. If our generic or biosimilar products are not substitutable at the pharmacy level for the corresponding reference product, this could materially reduce sales of our products and our business would suffer.***

Although the FDA may determine that a generic product is therapeutically equivalent to a reference product and provide it with an “A” rating in the FDA’s Orange Book, this designation is not binding on state pharmacy boards or agencies for generic drugs. As a result, in states that do not deem our generic drugs and product candidates therapeutically equivalent, physicians will be required to specifically prescribe a generic product alternative rather than have a routine substitution at the pharmacy level for the prescribed reference product. Should this occur with respect to one of our generic drugs or product candidates, it could materially reduce sales in those states which would substantially harm our business.

While a designation of interchangeability is a finding by the FDA that a biosimilar can be substituted at the pharmacy without physician intervention or prescription, reference product pharmaceutical companies are lobbying state legislatures and the FDA to enact physician prescription requirements, or in the absence of a prescription, physician and patient notification requirements, special labeling requirements and unique naming requirements for biosimilars which if enacted could create barriers to substitution and adoption rates of interchangeable biologics as well as non-interchangeable biosimilars. Should this occur with respect to one of our biosimilars or interchangeable biologic product candidates in a discriminatory manner, it could materially reduce sales in those states which would substantially harm our business. To date, the FDA has adopted a non-discriminatory policy that would apply the same non-proprietary naming requirements to reference products.

***If our nonclinical studies and clinical trials for our novel product candidates are not successful, we will not be able 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 the historical failure rate for novel product candidates is high.



A failure of one or more of our nonclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, nonclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our novel 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 novel product candidate and in initial human clinical studies of a novel product candidate may not predict the results that will be obtained in subsequent human clinical trials. If we are required by regulatory authorities to conduct additional clinical trials or other testing of our novel 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 novel 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 novel product candidates. If any of these events occur, our business will be materially harmed.

***Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.***

We intend in the future to market our products, if approved, outside of the United States, either directly or through collaborative partners. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with the numerous and varying regulatory requirements of each jurisdiction. The approval procedure and requirements vary among countries, and can require, among other things, conducting additional testing in each jurisdiction. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in any other foreign country or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside of the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition, and results of operations.

***Even if we obtain regulatory approvals, our marketed products will be subject to ongoing regulatory review. If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market products and our business would be seriously harmed.***

Even after approval, any pharmaceutical products we develop will be subject to ongoing regulatory review, including the review of clinical results that are reported after our products are made commercially available. Any regulatory approvals that

we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, the manufacturer and manufacturing facilities we use to produce any of our product candidates will be subject to periodic review and inspection by the FDA, or foreign equivalent, and other regulatory agencies. We will be required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Certain changes to an approved product, including in the way it is manufactured or promoted, often require prior FDA approval before the product as modified may be marketed. If we fail to comply with applicable FDA regulatory requirements, we may be subject to fines, warning letters, civil penalties, refusal by the FDA to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions, refusal to permit the import or export of products, and/or criminal prosecutions and penalties.

Similarly, our commercial activities will be subject to comprehensive compliance obligations under state and federal reimbursement, Sunshine Act, anti-kickback and government pricing regulations. If we make false price reports, fail to implement adequate compliance controls or our employees violate the laws and regulations governing relationships with health care providers, we could also be subject to substantial fines and penalties, criminal prosecution and debarment from participation in the Medicare, Medicaid, or other government reimbursement programs.

In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs, and to spur innovation, but its ultimate implementation remains unclear. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***If third-party payers do not adequately reimburse customers for any of our approved products, they might not be purchased or used, and our revenue and profits will not develop or increase.***

Our revenue and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payers, both in the United States and in foreign markets. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from each government or other third-party payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payer. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. There is substantial uncertainty whether any particular payer will reimburse the use of any product incorporating new technology. Even when a payer determines that a product is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable authority. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory



discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products. The Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payers may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payers, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

We also anticipate that application of the existing and evolving reimbursement regimes to biosimilar products will be somewhat uncertain. In the 2016 Physician Fee Schedule Final Rule, CMS made it clear that the payment amount for a biosimilar is based on the average sales price of all products included within the same billing and payment code. In general, this means that CMS will group biosimilar products that rely on a common reference product's biologics license application into the same payment calculation, and these products will share a common payment limit and billing code. Separate codes could reduce or significantly impair the value of interchangeability of the biosimilar. However, it is unclear what effect this will have on private payors. Reimbursement uncertainty could adversely impact market acceptance of biosimilar products.

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

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

The MMA changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for pharmaceutical products that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for pharmaceutical product purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered pharmaceutical products, and provides authority for limiting the number of pharmaceutical products that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered pharmaceutical products. As a result of the MMA and the expansion of federal coverage of pharmaceutical products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could materially adversely affect our operating results and overall financial condition. While the MMA generally applies only to pharmaceutical product benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payers.

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

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

prescription drugs, surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, the BPCI Act establishes an abbreviated regulatory pathway for the approval of biosimilars and provides that reference products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new approval pathway for biosimilars and adjusting reimbursement for biosimilars, the new law could promote the development and commercialization of biosimilars. However, given the uncertainty of how the law will be interpreted and implemented, the impact of the law on our strategy for biosimilars as well as novel biologics remains uncertain. Other provisions in the law, such as the comparative effectiveness provisions, may ultimately impact positively or negatively both brand and biosimilars products alike depending on an applicant's clinical data, effectiveness and cost profile. If a reference product cannot be shown to provide a benefit over other therapies, then it might receive reduced coverage and reimbursement. While this might increase market share for biosimilars based on cost savings, it could also have the effect of reducing biosimilars' market share.

The full effects of the U.S. healthcare reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the CMS and other federal and state health care agencies. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability. In addition, litigation may prevent some or all of the legislation from taking effect. In 2017 and beyond, we may face additional uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the U.S. healthcare reform legislation. There is no assurance that the U.S. healthcare reform legislation, as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

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

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

***The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in review and approval of applications. As a result, the review and potential approval of our application for GLATOPA 40 mg/mL may be significantly delayed.***

The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in the review and approval of ANDAs and amendments or supplements due to insufficient staffing and resources. Resource constraints have also resulted in significant delays in conducting ANDA-related pre-approval inspections. Until the backlog of ANDA filings is reduced, our application for GLATOPA 40 mg/mL and any supplements may be subject to significant delays during their review cycles, which may adversely affect our business and financial condition. In addition, the hiring freeze implemented by the federal government in 2017 could also impact the review and potential approval of our application for GLATOPA 40 mg/mL, which may adversely affect our business and financial condition.

### **Risks Relating to Intellectual Property**

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

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patent applications. As a result, we may be required to obtain licenses under third-party patents to market our proposed products. If licenses are not available to us on acceptable terms, or at all, we will not be able to market the affected products.

Assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or U.S. PTO, or become involved in opposition, derivation, reexamination, Inter Partes Review, or IPR, or interference proceedings challenging our patent rights or the patent rights of others. For example, several of our European patents are being challenged in opposition proceedings before the European Patent Office. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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

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

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

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

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

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

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

***If we remain involved in patent litigation or other proceedings to determine or enforce our intellectual property rights, we could incur substantial costs which 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, 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 of complex patent litigation more effectively than we can because they may have substantially greater resources. Moreover, the failure to obtain a favorable outcome in any litigation in a jurisdiction where there is a claim of patent infringement could significantly delay the marketing of our products in that particular jurisdiction. Counterclaims for damages and other relief may be triggered by such enforcement actions. The costs, uncertainties and counterclaims resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

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

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

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

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

Either we or Sandoz AG may terminate the 2006 Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. For some of the products, for any termination of the 2006 Sandoz Collaboration Agreement other than a termination by Sandoz AG due to our uncured breach or bankruptcy, or a termination by us alone due to the need for clinical trials, we will be granted an exclusive license under certain intellectual property of Sandoz AG to develop and commercialize the particular product. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. For some products, if Sandoz AG terminates the 2006 Sandoz Collaboration Agreement due to our uncured breach or bankruptcy, or if there is a termination by us alone due to the need for clinical trials, Sandoz AG

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

Under our collaboration agreement, we are dependent upon Sandoz AG to successfully continue to commercialize GLATOPA 20 mg/mL and are significantly dependent on Sandoz AG to successfully commercialize GLATOPA 40 mg/mL. We do not fully control Sandoz AG's commercialization activities or the resources it allocates to our products. While the 2006 Sandoz Collaboration Agreement contemplates joint decision making and alignment, our interests and Sandoz AG's interests may differ or conflict from time-to-time or we may disagree with Sandoz AG's level of effort or resource allocation. Sandoz AG may internally prioritize our products and product candidates differently than we do or it may fail to allocate sufficient resources to effectively or optimally commercialize our products and alignment may only be achieved through dispute resolution. If these events were to occur, our business would be adversely affected.

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

On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement, or the Baxalta Termination. On December 31, 2016, we and Baxalta entered into an Asset Return and Termination Agreement pursuant to which the effective date of the Baxalta Termination was December 31, 2016. Following the effective date of the Baxalta Termination, Baxalta is not obligated to continue to perform development, manufacturing or commercialization activities for M923 except for certain transitional clinical and regulatory activities that are expected to be completed by April 2017. If Baxalta does not allocate sufficient resources for the agreed upon transitional clinical and regulatory activities for M923, there could be significant delays in the M923 program. Furthermore, there could be changes or delays in the timing of the M923 program in connection with the transition of the M923 program back to us.

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

***The Mylan Collaboration Agreement is important to our business. If we or Mylan fail to adequately perform under the Agreement, or if we or Mylan terminate the Mylan Collaboration Agreement, the development and commercialization of one or more of our biosimilar candidates, including M834, could be delayed or terminated and our business would be adversely affected.***

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party shall have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries. In the case of a termination for convenience, the other party shall have the right to continue. If a termination occurs, the licenses granted to the non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that has the right to continue the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

If the Mylan Collaboration Agreement were terminated and we had the right to continue the development and commercialization of one or more terminated products, to fully exercise that right, we would need to expand our internal capabilities or enter into another collaboration, which, if we were able to do so, could cause significant delays that could prevent us from commercializing those products. Any alternative collaboration could be on less favorable terms to us. In addition, we may need to seek additional financing to support the development and commercialization of any terminated products, or alternatively we may decide to discontinue one or more terminated products, which could have a material adverse effect on our business. If the Mylan Collaboration Agreement were terminated and Mylan had the right to continue the development and commercialization of one or more terminated products, we would have no influence or input into those activities.

Under the Mylan Collaboration Agreement, we are dependent upon Mylan to successfully perform its responsibilities and activities, including conducting clinical trials for certain products and leading the commercialization of products. We do not control Mylan's execution of its responsibilities, including commercialization activities, or the resources it allocates to our products. Our interests and Mylan's interests may differ or conflict from time to time, or we may disagree with Mylan's level of effort or resource allocation. Mylan may internally prioritize our products and product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally execute its responsibilities or activities. If these events were to occur, our business would be adversely affected.

***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 or country-by-country basis for material breaches, or due to the other party's bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, we or CSL have the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

If the CSL License Agreement were terminated and we had the right to continue the research, development, and commercialization of one or more terminated products, to fully exercise that right, we would need to expand our internal capabilities or enter into another collaboration, which, if we were able to do so, could cause significant delays that could prevent us from commercializing those products. Any alternative collaboration could be on less favorable terms to us. In addition, we may need to seek additional financing to support the research, development and commercialization of any terminated products, or alternatively we may decide to discontinue one or more terminated products, which could have a material adverse effect on our business. If the CSL License Agreement were terminated and CSL had the right to continue the development and commercialization of one or more terminated products, we would have no influence or input into those activities.

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

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

Because we have limited internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we may need to enter into strategic alliances with other companies in addition to our current alliances with Sandoz, Mylan and CSL. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical



development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances as a result of many factors including the following:

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

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

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

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

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

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

Since many of our product candidates are developed under collaborations or licenses with third parties, we do not have sole decision making authority with respect to commercialization or development of those product candidates. We have built relationships and work collaboratively with our third-party collaborators and manufacturers to ensure the success of our development and commercialization efforts. A significant change in the senior management team, a change in the financial condition or a change in the business operations, including a change in control or internal corporate restructuring, of any of our collaboration partners or third-party manufacturers, could result in delayed timelines on our products. In addition, we may have to re-establish working relationships and familiarize new counterparts with our products and business. Any such change may result in the collaboration partner or third party manufacturer internally re-prioritizing our programs or decreasing resources or funding allocated to support our programs. For example, in June 2016, Baxalta Incorporated and Shire announced the completion of a combination of Baxalta Incorporated and Shire, as a result of which Baxalta Incorporated became a wholly-

owned subsidiary of Shire. On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement, and on December 31, 2016, we and Baxalta entered into an Asset Return and Termination Agreement pursuant to which the effective date of the Baxalta Termination was December 31, 2016. Baxalta is obligated to perform certain transitional clinical and regulatory activities that are expected to be completed by April 2017. As a result, we are dependent on Shire to allocate resources for the agreed upon transitional clinical and regulatory activities of M923, and there could be changes or delays in the timing of the M923 program in connection with the transition of the M923 program back to us. Similar changes with respect to any of our other collaborators may negatively impact our business operations.

### **General Company Related Risks**

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

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

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

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

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

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

- delays in achievement of, or failure to achieve, program milestones that are associated with the valuation of our company or significant milestone revenue;
- failure of GLATOPA 20 mg/mL to sustain profitable sales or market share that meet expectations of securities analysts;
- other adverse FDA decisions relating to our GLATOPA programs, including any FDA decision to delay approval of the GLATOPA 40 mg/mL ANDA until satisfactory resolution of the compliance observations in the FDA's February 2017 warning letter to Pfizer, Sandoz' third party fill/finish manufacturing partner for GLATOPA, and an FDA decision to require additional data, including requiring clinical trials, as a condition to GLATOPA 40 mg/mL ANDA approval;
- litigation involving our company or our general industry or both, including litigation pertaining to the launch of our collaborative partners' or our competitors' products, including without limitation, a decision in the GLATOPA 40 mg/mL patent litigation or a competitors' related patent litigation that prevents the launch or delays the launch of our GLATOPA 40 mg/mL product;
- 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;
- 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 therapeutic equivalence with respect to our technology-enabled generic product candidate, GLATOPA 40 mg/mL, or biosimilarity or interchangeability with respect to our biosimilar product candidates such as M923 or M834;
- demonstration of or failure to demonstrate the safety and efficacy for our novel product candidates;
- our inability to manufacture any products in conformance with cGMP or in sufficient quantities to meet the requirements for the commercial sale of the product or to meet market demand;
- failure of any of our product candidates, if approved, to achieve commercial success;
- the discovery of unexpected or increased incidence in patients' adverse reactions to the use of our products or product candidates or indications of other safety concerns;
- developments or disputes concerning our patents or other proprietary rights;
- changes in estimates of our financial results or recommendations by securities analysts;
- termination of any of our product development and commercialization collaborations;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- investors' general perception of our company, our products, the economy and general market conditions;
- rapid or disorderly sales of stock by holders of significant amounts of our stock; or
- significant fluctuations in the price of securities generally or biotechnology company securities specifically.

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

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

The stock market in general has recently experienced significant price and volume fluctuations. In addition, the market prices of securities of companies in the biotechnology industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of or other events at these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. We may be the target of similar litigation in the future. For example, we are aware that several law firms have announced investigations of potential claims against the Company concerning possible violations of federal securities laws in connection with our February 17, 2017, announcement of the FDA warning letter to Sandoz' third party fill/finish manufacturing partner for GLATOPA. 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, 2017, pursuant to our sublease agreements, we lease a total of approximately 263,500 square feet of office and laboratory space in Cambridge, Massachusetts:

<u>Property Location</u>	<u>Approximate Square Footage</u>	<u>Use</u>	<u>Lease Expiration Date</u>
675 West Kendall Street Cambridge, Massachusetts 02142	78,500	Laboratory and Office	04/30/2018
320 Bent Street Cambridge, Massachusetts 02141	105,000	Laboratory and Office	02/28/2027
301 Binney Street Cambridge, Massachusetts 02142	80,000	Laboratory and Office	06/29/2025
	<u>263,500</u>		

### Item 3. LEGAL PROCEEDINGS

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

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz Inc. in the United States District Court for the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and sought declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015, Teva and Yeda filed an additional suit against us and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit that was filed in September 2014. In November 2015, Teva and Yeda filed a suit against us and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. In December 2015, this suit was also consolidated with the initial suit that was filed in September 2014. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of these patents. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017, decision to the Court of Appeals for the Federal Circuit.

On December 19, 2016, Teva and Yeda filed suit against us and Sandoz Inc. in the United States District Court for the District of Delaware again in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL for alleged infringement of an Orange Book-listed patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,402,874. On January 31, 2017, Teva filed a suit against us and Sandoz Inc. in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, which issued in October 2015 and expires in October 2035. We and Sandoz Inc. filed a motion to dismiss and a motion to transfer the suit to the United States District Court for the District of Delaware. On January 31, 2017, Teva voluntarily dismissed us from the New Jersey suit, maintaining the suit against Sandoz Inc. 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. On February 17, 2017, Teva filed a motion for preliminary injunction against Sandoz Inc. in the New Jersey suit for U.S. Patent No. 9,155,775.

#### *M834-Related Proceedings*

On July 2, 2015, we filed a petition for Inter Partes Review, or IPR, with the PTAB to challenge the validity of U.S. Patent No 8,476,239, a patent for ORENCIA owned by Bristol-Myers Squibb, or BMS. The PTAB issued a decision instituting the IPR proceedings in January 2016, and BMS filed for a rehearing by the full PTAB. Oral arguments took place in

September 2016. On December 22, 2016, the PTAB issued a decision upholding the validity of the patent. We filed a notice of appeal in the United States Court of Appeals for the Federal Circuit on February 22, 2017.

#### *Enoxaparin Sodium Injection-Related Proceedings*

On September 21, 2011, we and Sandoz Inc. sued Amphastar and Actavis in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar and Actavis from selling their Enoxaparin product in the United States. In October 2011, the District Court granted our motion for a preliminary injunction and entered an order enjoining Amphastar and Actavis from advertising, offering for sale or selling their Enoxaparin product in the United States until the conclusion of a trial on the merits and required us and Sandoz Inc. to post a security bond of \$100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded the case to the District Court. In September 2012, we filed a petition with the CAFC for rehearing by the full court *en banc*, which was denied. In February 2013, we filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied in June 2013.

In July 2013, the District Court granted a motion by Amphastar and Actavis for summary judgment. We filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling, which the CAFC denied in May 2014. On November 10, 2015, the CAFC affirmed the District Court summary judgment decision with respect to Actavis, reversed the District Court summary judgment decision with respect to Amphastar, and remanded the case against Amphastar to the District Court. On January 11, 2016, Amphastar filed a petition for rehearing by the CAFC, which was denied on February 17, 2016. On May 17, 2016, Amphastar filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied on October 3, 2016. The District Court trial is scheduled to begin on July 10, 2017. In the event that we are not successful in further prosecution or settlement of this action against Amphastar, and Amphastar is able to prove it suffered damages as a result of the preliminary injunction, we could be liable for damages for up to \$35 million of the security bond. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz Inc. will prevail in this patent enforcement suit.

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

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against us and Sandoz Inc. in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic Enoxaparin Sodium Injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz Inc. sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, we and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. Hearings on the motions were held before a U.S. magistrate in April 2016 and February 2016, respectively. On September 29, 2016, the magistrate judge filed a Report and Recommendation to the District Court to deny the motions to dismiss and to transfer. These motions are subject to briefing and review by the District Court. 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.

**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." The following table sets forth the high and low sale prices of our common stock for the periods indicated, as reported on The NASDAQ Global Select Market:

<b>Quarter ended</b>	<b>High</b>	<b>Low</b>
March 31, 2015	\$ 15.98	\$ 10.22
June 30, 2015	25.56	14.58
September 30, 2015	23.89	15.61
December 31, 2015	18.85	14.55
March 31, 2016	\$ 15.15	\$ 7.86
June 30, 2016	13.30	8.82
September 30, 2016	14.24	10.50
December 31, 2016	15.90	10.75

***Holders***

On February 8, 2017, the approximate number of holders of record of our common stock was 33.

***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 in Item 12 below.

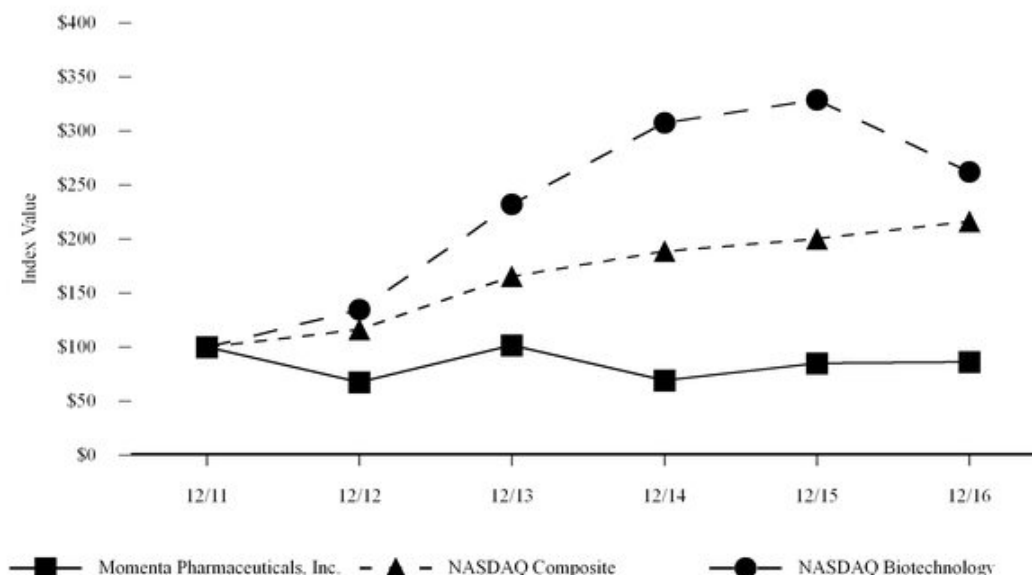
***Stock Performance Graph***

The comparative stock performance graph below compares the cumulative total stockholder return (assuming reinvestment of dividends, if any) from investing \$100 on December 31, 2011 through December 31, 2016, 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 12/31/11 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

	12/11	12/12	12/13	12/14	12/15	12/16
Momenta Pharmaceuticals, Inc.	100.00	67.80	69.24	86.54	101.67	85.34
NASDAQ Composite	100.00	116.41	188.69	216.54	165.47	200.32
NASDAQ Biotechnology	100.00	134.68	307.67	262.08	232.37	328.76

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, 2016, 2015 and 2014 and the balance sheet data as of December 31, 2016 and 2015 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, 2013 and 2012 and the balance sheet data as of December 31, 2014, 2013 and 2012 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 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**

	2016	2015	2014	2013	2012
(in thousands, except per share information)					
<b>Statements of Operations and Comprehensive Loss Data:</b>					
Collaboration revenues:					
Product revenue	\$ 74,648	\$ 48,503	\$ 19,963	\$ 16,701	\$ 54,772
Research and development revenue	34,971	41,147	32,287	18,764	9,149
Total collaboration revenue	109,619	89,650	52,250	35,465	63,921
Operating expenses:					
Research and development	119,880	126,033	106,482	103,999	80,345
General and administrative	64,466	48,051	45,164	41,057	43,682
Total operating expenses	184,346	174,084	151,646	145,056	124,027
Operating loss	(74,727)	(84,434)	(99,396)	(109,591)	(60,106)
Interest income	2,226	808	548	950	1,238
Other income	51,498	313	248	233	220
Net loss	\$ (21,003)	\$ (83,313)	\$ (98,600)	\$ (108,408)	\$ (58,648)
Basic and diluted net loss per share	\$ (0.31)	\$ (1.32)	\$ (1.91)	\$ (2.13)	\$ (1.16)
Shares used in calculating basic and diluted net loss per share	68,656	63,130	51,664	50,907	50,411
Comprehensive loss	\$ (20,921)	\$ (83,293)	\$ (98,641)	\$ (108,494)	\$ (58,456)

	As of December 31,				
	2016	2015	2014	2013	2012
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 150,738	\$ 61,461	\$ 61,349	\$ 29,766	\$ 52,990
Marketable securities	202,413	288,583	130,180	215,916	287,613
Working capital	357,324	335,926	181,541	243,649	339,006
Total assets	477,737	421,040	256,216	316,815	406,629
Deferred revenue	38,632	21,983	30,998	27,716	31,695
Other liabilities	67,197	29,081	18,850	19,262	14,447
Total liabilities	105,829	51,064	49,848	46,978	46,142
Accumulated deficit	(473,375)	(452,372)	(369,059)	(270,459)	(162,051)
Total stockholders' equity	371,908	369,976	206,368	269,837	360,487

**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 on developing generic versions of complex drugs, biosimilars and novel therapeutics for autoimmune disease.

To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. Although we were profitable in fiscal years 2010 and 2011, since that time we have been incurring operating losses and we expect to incur annual operating losses over the next several years as we advance our drug development portfolio. As of December 31, 2016, we had an accumulated deficit of approximately \$473 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.

### ***Recent Development—CSL License and Option Agreement***

On January 5, 2017, 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, which became effective on February 17, 2017, pursuant to which we have granted CSL an exclusive worldwide license to research, develop, and commercialize our M230 nonclinical 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 and commercialize these additional research products globally.

Under the terms of the CSL License Agreement, CSL has agreed to pay us a non-refundable upfront payment of \$50 million. For the development and commercialization of M230, we are eligible to receive up to \$550 million in contingent clinical, regulatory and sales milestone payments, and additional negotiated milestone payments for a named research stage product should that enter development.

## Complex Generics

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

On April 16, 2015, the FDA approved the ANDA for once-daily GLATOPA (glatiramer acetate injection) 20 mg/mL, a generic equivalent of once-daily COPAXONE® 20 mg/mL. GLATOPA 20 mg/mL is the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. Sandoz commenced sales of GLATOPA 20 mg/mL on June 18, 2015. Under our collaboration agreement with Sandoz, we earn 50% of contractually-defined profits on GLATOPA 20 mg/mL sales. For the year ended December 31, 2016, we recorded \$74.6 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting \$78.2 million in profit share net of a deduction of \$3.6 million for reimbursement to Sandoz of 50% of GLATOPA 40 mg/mL legal expenses incurred by Sandoz.

On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States.

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

An ANDA seeking approval for GLATOPA 40 mg/mL, our generic version of three-times-weekly COPAXONE 40 mg/mL, was filed in February 2014 and remains under review by the FDA. Our GLATOPA 40 mg/mL formulation contains the same drug substance as GLATOPA 20 mg/mL, which we believe should help streamline the FDA review of the ANDA. To date, we are the only ANDA applicants for the three-times-weekly COPAXONE 40 mg/mL with an FDA-approved active pharmaceutical ingredient. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. We therefore believe that an approval of the GLATOPA 40 mg/mL ANDA in the first quarter of 2017 is unlikely.

On January 30, 2017, the District Court for the District of Delaware found four Orange Book-listed patents related to COPAXONE 40 mg/mL that we were alleged to have infringed to be invalid. Three of these patents had previously been found invalid in August 2016 by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, in an Inter Partes Review filed by an unrelated third party. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017, decision to the Court of Appeals for the Federal Circuit. This and other legal proceedings related to GLATOPA 40 mg/mL are described under "*Item 3. Legal Proceedings - GLATOPA 40 mg/mL-Related Proceedings.*"

### ***Enoxaparin Sodium Injection—Generic LOVENOX®***

In June 2015, we and Sandoz amended our collaboration agreement relating to Enoxaparin Sodium Injection, replacing Sandoz' obligation to pay us a royalty on net sales with an obligation to pay us 50% of contractually-defined profits on sales. The amendment, which was effective April 1, 2015, better aligned our interests in an evolving market that has seen continued pricing pressure.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the year ended December 31, 2016, and therefore we recorded no product revenue for Enoxaparin Sodium Injection in the same period.

## **Biosimilars**

### ***M923—Biosimilar HUMIRA® (adalimumab) Candidate***

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

The first regulatory submission for marketing approval for M923 is planned for mid- 2017 and, subject to marketing approval and patent considerations, we are planning for the first commercial launch to be as early as the 2020 timeframe.

On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement, pursuant to which we and Baxalta had agreed to collaborate, on a worldwide basis, on the development and commercialization of M923. 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. Under the terms of the Baxalta Termination Agreement, the termination of the Baxalta Collaboration 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 clinical and regulatory activities that are expected to be completed by April 2017, and 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.

### ***M834—Biosimilar ORENCIA® (abatacept) Candidate***

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

We believe there is currently limited biosimilar competition for M834. Subject to development, marketing approval and patent considerations, we expect to be able to launch M834 in the 2020 timeframe to be able to be among the first biosimilars of ORENCIA on the market.

ORENCIA's composition of matter patents expire in the United States in 2019. In December 2016, the U.S. PTAB in an Inter Partes Review we filed upheld the validity of Bristol-Myers Squibb's formulation patent '239 on ORENCIA. We are considering our options to appeal. Information about this proceeding is further discussed below under " *Item 3. Legal Proceedings -- M834-Related Proceedings* ."

## ***Other Biosimilar Candidates***

Under our Mylan collaboration, we and Mylan are also developing five other biosimilar candidates from our portfolio in addition to M834, including our undisclosed biosimilar candidate, M710. We and Mylan will share equally costs and profits (losses) related to these earlier stage product candidates. We and Mylan will share development and manufacturing responsibilities across product candidates, and Mylan will lead commercialization of the products.

As of December 31, 2016, we had approximately 100 employees working on our biosimilars programs. We maintain a state-of-the-art development facility for bioprocess manufacturing development and scale-up and operations.

## **Novel Therapeutics**

We believe our novel programs discussed below could have the potential to produce product candidates capable of treating a large number of immunological disorders driven by antibodies, immune complexes, and Fc receptor biology. Such disorders include rheumatoid arthritis, autoimmune neurologic diseases such as Guillain-Barre syndrome, chronic inflammatory demyelinating neuropathy and myasthenia gravis, autoimmune blood disorders such as immune thrombocytopenic purpura, systemic autoimmune diseases such as dermatomyositis, lupus nephritis, and catastrophic antiphospholipid syndrome, antibody-mediated transplant rejection, and autoimmune blistering diseases, several of which have few treatment options.

### ***M281 - Anti-FcRn Candidate***

M281 is a fully-human monoclonal antibody that blocks the neonatal Fc receptor, or FcRn. A Phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 was initiated in June 2016. In January 2017, we announced that we had successfully completed five cohorts in the Phase 1 single ascending dose, or SAD, study in healthy volunteers. In the SAD portion of the study, a single dose of 30 mg/kg achieved up to 80% reduction in circulating IgG antibodies, and M281 was well-tolerated with no serious adverse events observed. The multiple ascending portion of the study was initiated in January 2017. We plan to report the full data from the single and multiple ascending dose portions of the study in the second half of 2017.

### ***M230 - Selective Immunomodulator of Fc receptors (SIF3) Candidate***

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

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

### ***M254 - hsIVIg Candidate***

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

### ***Necuparanib—Former Oncology Product Candidate***

In August 2016, following the results of a planned futility analysis, we discontinued development of necuparanib, which was then being studied in a Phase 2 clinical trial. The Phase 2 clinical trial was part of a Phase 1/2 clinical trial initiated in 2012 evaluating necuparanib in combination with ABRAXANE® (nab-paclitaxel) plus gemcitabine in patients with advanced metastatic pancreatic cancer.

## **Equity Financings**

In May 2015, we sold an aggregate of 8,337,500 shares of our common stock through an underwritten public offering at a price to the public of \$19.00 per share. As a result of the offering, which included the full exercise of the underwriters' option to purchase additional shares, we received aggregate net proceeds of approximately \$148.4 million, after deducting underwriting discounts and commissions and other offering expenses.

In May 2014, we entered into an At-the-Market Equity Offering Sales Agreement, or the 2014 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 paid Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under this facility. The offering was conducted by us pursuant to an effective shelf registration statement on Form S-3 previously filed with the Securities and Exchange Commission, or SEC, (Reg. No. 333-188227) and a related prospectus supplement. We intend to use the net proceeds from this facility to advance our development pipeline and for general corporate purposes, including

working capital. Between October 2014 and April 2015, we sold approximately 5.4 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately \$73.5 million. We concluded sales under the 2014 ATM Agreement in April 2015.

In April 2015, we entered into a new ATM Agreement, or the 2015 ATM Agreement, with Stifel, under which we are 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 are required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under the 2015 ATM Agreement. From April 2015 through December 2015, we sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement pursuant to an effective shelf registration statement previously filed with the SEC (Reg. No. 333-188227) and a related prospectus supplement, raising aggregate net proceeds of approximately \$9.3 million. We did not sell any shares of common stock under the 2015 ATM Agreement in the year ended December 31, 2016.

## Results of Operations

### Comparison of Years Ended December 31, 2016, 2015 and 2014

#### Collaboration Revenue

Collaboration revenue includes both product revenue and research and development revenue earned under our collaborative arrangements. Product revenue includes our contractually-defined profits and/or royalties earned on Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA.

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

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. We earn 50% of contractually-defined profits on Sandoz' sales of GLATOPA 20 mg/mL. A portion of certain legal expenses for GLATOPA, including any patent infringement damages, is deducted from our profits in proportion to our 50% profit sharing interest.

For the year ended December 31, 2016, we recorded \$74.6 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting \$78.2 million in profit share net of a deduction of \$3.6 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz. For the year ended December 31, 2015, we recorded \$43.4 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting \$52.5 million in profit share net of a deduction of \$9.1 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz since 2008. The increase in product revenues of \$31.2 million, or 72% from the 2015 period to the 2016 period was primarily due to a higher number of GLATOPA 20 mg/mL units sold. We expect that any future quarterly legal expense deductions will be lower as they will generally be incurred and reimbursed on a quarterly basis. We estimate that the number of prescriptions for GLATOPA 20 mg/mL represents approximately 42% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

We believe there is a meaningful market opportunity for GLATOPA 20 mg/mL. The price for once-daily COPAXONE 20 mg/mL has increased over 190% since 2009, and there is no other generic for relapsing forms of multiple sclerosis currently available in the United States. Teva received marketing approval of its three-times-weekly COPAXONE 40 mg/mL in January 2014. Teva's three-times-weekly COPAXONE 40 mg/mL accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on total prescriptions. Because GLATOPA 20 mg/mL is a substitutable generic version of the once-daily 20 mg/mL formulation of COPAXONE and not the three-times-weekly COPAXONE, the market potential of GLATOPA 20 mg/mL is negatively impacted by the conversion of patients from once-daily COPAXONE to three-times-weekly COPAXONE. Teva reported \$4.2 billion in worldwide sales of COPAXONE (20 mg/mL and 40 mg/mL) in 2016, \$3.5 billion of which was from the United States.

##### *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. Our contractual share of such development and legal expenses is subject to an annual claw-back adjustment at the end of each of the first five product years, with the product year beginning on July 1 and ending on June 30. The annual adjustment can only reduce our profits, royalties and milestones by up to 50% in a given calendar quarter and any excess amount due would be carried forward into future quarters and reduce any profits in those future periods until it is paid in full. Annual adjustments, including amounts carried forward into future periods, are recorded as a reduction in product revenue.

Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the year ended December 31, 2016, therefore we recorded no product revenue for Enoxaparin Sodium Injection in that period.



For the year ended December 31, 2015, we earned \$5.1 million in product revenue consisting of \$6.9 million in contractual profit share and royalties, net of an annual claw-back adjustment of \$1.8 million for the product year ended June 30, 2015, on Sandoz' sales of Enoxaparin Sodium Injection. As of December 31, 2015, the 2015 annual claw-back adjustment was fully paid.

For the year ended December 31, 2014, we earned \$19.9 million in product revenue, which consists of \$20.0 million in royalties on Sandoz' sales of Enoxaparin Sodium Injection, offset by \$2.2 million of our contractual share of development and other expenses for the product year ended June 30, 2014, and increased by \$2.1 million to reflect an adjustment to royalties earned in the product year ended June 30, 2012.

The decrease in our product revenue was \$5.1 million, or 100%, from the 2015 period to the 2016 period was attributed to the change in our collaboration economics (change from a royalty to a profit sharing arrangement) and lower unit sales driven by lower market share and lower prices in response to competitor pricing reductions on enoxaparin.

The decrease in our product revenue was \$14.8 million, or 74%, from the 2014 period to the 2015 period, and was attributed to the change in our collaboration economics and lower unit sales driven by lower market share and lower prices in response to competitor pricing reductions on enoxaparin.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, we do not anticipate significant Enoxaparin Sodium Injection product revenue in the near future.

### **Research and Development Revenue**

Research and development revenue generally consists of amounts earned by us under our collaborations for:

- Technical development, regulatory and commercial milestones under the Sandoz and Baxalta collaborations;
- Reimbursement of research and development services and reimbursement of development costs under our Sandoz and Baxalta collaborations; and
- Recognition of upfront and license payments under our Baxalta and Mylan collaborations.

Research and development revenue for 2016 was \$35.0 million, compared with \$41.1 million for 2015 and \$32.3 million for 2014. The decrease in research and development revenue of \$6.1 million, or 15%, from the 2015 period to the 2016 period resulted from \$20 million in milestone payments we earned in 2015 upon GLATOPA 20 mg/mL being the sole generic of COPAXONE 20 mg/mL to receive FDA approval and upon first commercial sale of GLATOPA 20 mg/mL in June 2015, partially offset by the recognition of the remaining balance of the upfront and license payments from Baxalta of \$22 million in the 2016 period as we had no further performance obligations under that collaboration agreement as of the termination effective date of December 31, 2016. The increase in research and development revenue of \$8.8 million, or 27%, from the 2014 period to the 2015 period is due to an increase of \$20 million for 2015 milestone payments we earned on GLATOPA 20 mg/mL's FDA approval and launch partially offset by a decrease of \$12 million in milestone payments we earned in 2014 upon achieving technical development criteria for M923 under our collaboration with Baxalta.

We expect collaborative research and development revenue earned by us related to FTE and external expense reimbursement from Sandoz will fluctuate from quarter to quarter in 2017 depending on our research and development activities. We expect to recognize the upfront payment from Mylan ratably as revenue over our performance period with quarterly revenue in 2017 of approximately \$2.0 million.

### **Research and Development Expense**

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

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

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

- personnel-related expenses, which include salaries, benefits and share-based compensation; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment and laboratory and other supplies.

Beginning on February 9, 2016, under the Mylan Collaboration Agreement, we share collaboration expenses with Mylan. A portion of the net amount due from Mylan for its 50% share of collaboration expenses is recorded as a reduction in research and development expenses based on the nature of the cost reimbursement. Collaboration costs for development of the six biosimilar candidates under the collaboration incurred by us are recorded as research and development expense as incurred.

Research and development expense for 2016 was \$119.9 million, compared with \$126.0 million in 2015 and \$106.5 million in 2014. The decrease of \$6.1 million, or 5%, from the 2015 period to the 2016 period resulted from a decrease of \$26.5 million due to Mylan's 50% share of collaboration costs under the cost-sharing provisions of the Mylan Collaboration Agreement, partially offset by increases of: \$7.6 million in third-party research and process development costs primarily attributable to advance our biosimilar and novel autoimmune programs; \$4.9 million in personnel-related expenses, of which \$2.5 million is due to increased headcount and \$2.4 million is primarily attributed to share-based compensation expense associated with performance-based restricted stock awards granted in 2016 that increased the amount of research and development expenses we recorded; \$4.3 million in nonclinical study costs for M281, M230 and M834; \$2.9 million in costs for the Phase 1 clinical studies of M281 and M834; and \$0.7 million in expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements, equipment and intangible assets.

The increase of \$19.5 million, or 18%, from the 2014 period to the 2015 period primarily resulted from increases of \$17.6 million in third-party research and process development costs primarily attributable to advance M834 and M281 towards the clinic; \$3.3 million in clinical trial expenses as the necuparanib Phase 2 clinical trial continued to accrue patients; and \$1.4 million in nonclinical studies for our novel therapeutics and early stage biosimilar programs. These increases were partially offset by a decrease of \$2.5 million for purchases of antibodies to be used in our novel therapeutics research program and a decrease of \$0.3 million in personnel-related expenses, primarily attributed to the reversal of prior period share-based compensation expense associated with performance-based stock awards. In 2011 and 2012, we granted broad-based performance stock awards that vested 50% upon FDA approval of our GLATOPA 20 mg/mL ANDA and 50% one year later. The awards were scheduled to expire March 28, 2015. In March 2015, we amended the awards to extend the performance period to September 2015, but with share amounts that decreased monthly. Upon the amendment, stock compensation previously recognized was reversed and new stock compensation was recognized ratably based on the date the FDA approved our GLATOPA 20 mg/mL ANDA, which occurred in April 2015, and the one year anniversary of FDA approval, or April 2016. In the year ended December 31, 2015, research and development expense included a stock compensation credit of \$5.1 million and expense of \$4.0 million relating to the performance grants.

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 asset, for each of our principal development programs for the years ended December 31, 2016, 2015 and 2014. 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, 2016	Year Ended December 31,			Project Inception to December 31, 2016
		2016	2015	2014	
External Costs Incurred by Product Candidate:					
GLATOPA	ANDAs filed (1)	\$ 1,911	\$ 856	\$ 920	\$ 50,774
Necuparanib	(2)	8,504	11,801	6,739	45,379
Biosimilars	Various (3)	34,593	23,605	19,583	113,720
Other Novel Therapeutic Programs	Various (4)	21,997	15,999	5,213	
Internal Costs		79,399	73,772	74,027	
Subtotal		\$ 146,404	\$ 126,033	\$ 106,482	
Less: Reimbursable from Mylan (5)		(26,524)	—	—	
Total Research and Development Expenses(5)		\$ 119,880	\$ 126,033	\$ 106,482	

- (1) On April 16, 2015, the FDA approved the ANDA for once-daily GLATOPA 20 mg/mL. Sandoz launched GLATOPA 20 mg/mL on June 18, 2015. The ANDA for GLATOPA 40 mg/mL is under FDA review.
- (2) In August 2016, following the outcome of a planned futility analysis, we discontinued development of necuparanib, an oncology product candidate then being studied in a Phase 2 clinical trial.
- (3) Biosimilars include M923, a biosimilar candidate of HUMIRA® (adalimumab), M834, a biosimilar candidate of ORENCIA® (abatacept), as well as five other biosimilar candidates. In April 2016, enrollment in the pivotal clinical trial for M923 was completed and in November 2016, following an interim analysis, we announced top-line Phase 3 results including that M923 met its primary endpoint in the study. We initiated a Phase 1 clinical trial of M834 in November 2016. Our other biosimilar candidates are in discovery and process development.
- (4) Other novel therapeutic programs include M281, for which a Phase 1 dosing study was initiated in June 2016; M230, for which we and CSL plan to advance this product candidate with a goal of beginning clinical development in 2017 ; hslVIg, which is currently in preclinical development and we are planning to initiate an IND-enabling toxicology study in 2017 ; as well as other discovery and nonclinical stage programs.
- (5) As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately \$26.5 million against research and development costs in 2016 .

GLATOPA external expenditures increased by \$1.1 million , or 123% , from the 2015 period to the 2016 period as we continued to support our GLATOPA 40 mg/mL ANDA filing. Necuparanib external expenditures decreased by \$3.3 million , or 28% , from the 2015 period to the 2016 period following our decision to discontinue development of this product candidate. External expenditures for our biosimilars programs increased by \$11.0 million , or 47% , from the 2015 period to the 2016 period primarily due to increased costs to advance our programs, including M834, under the Mylan Collaboration Agreement. The increase of \$6.0 million , or 37% , in other novel therapeutic programs external expenditures from the 2015 period to the 2016 period was primarily due to costs incurred in the M281 Phase 1 clinical trial as well as nonclinical and process development costs to advance M230 towards the clinic. Finally, internal costs grew by \$5.6 million , or 8% , from the 2015 period to the 2016 period primarily due to headcount-related costs.

Our necuparanib external expenditures increased by \$5.1 million , or 75% , from the 2014 period to the 2015 period for patient accruals and CRO costs for the Phase 1/2 clinical trial. The increase of \$4.0 million , or 21% , in biosimilars external expenditures from the 2014 period to the 2015 period was due to higher third-party process development and contract research costs incurred for M834 and our other early stage biosimilar candidates partially offset by lower costs for M923 as Baxalta was responsible for clinical development of M923. The increase of \$10.8 million , 207% , in other novel therapeutics program external expenditures from the 2014 period to the 2015 period was due to increased nonclinical and process development to advance M281 and M230. The decrease of \$0.3 million , or less than 1% , in research and development internal costs from the 2014 period to the 2015 period was primarily due to the reversal of prior period share-based compensation expense associated with performance-based stock awards discussed under " *Research and Development Expense* " .

Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

## **General and Administrative**

General and administrative expenses consist primarily of salaries and other related costs for personnel in general and administrative functions, professional fees for legal and accounting services, royalty and license fees, insurance costs, and allocated rent, facility and lab supplies, and depreciation expense.

Beginning on February 9, 2016, under our collaboration agreement with Mylan we share collaboration expenses. A portion of the net amount due from Mylan for its 50% share of collaboration expenses under the cost-sharing arrangement is recorded as a reduction in general and administrative expenses based on the nature of the cost reimbursement. Collaboration costs for certain legal expenses for the six biosimilar candidates under the collaboration incurred by us are recorded as general and administrative expense as incurred.

General and administrative expense for 2016 was \$64.5 million, compared with \$48.1 million in 2015 and \$45.2 million in 2014. The increase of \$16.4 million, or 34%, from the 2015 period to the 2016 period was due to increases of: \$9.6 million in personnel-related expenses, of which \$5.1 million is due to increased headcount and \$4.5 million is primarily due to share-based compensation expense associated with performance-based restricted stock awards granted in 2016 that increased the amount of general and administrative expenses we recorded; \$7.2 million in increased professional fees, driven mainly by consulting, legal and recruiting expenses; and \$0.9 million in rent, facility and maintenance expense. These increases were partially offset by a decrease of \$1.3 million for Mylan's 50% share of collaboration costs under the cost-sharing provisions of the Mylan Collaboration Agreement.

The increase of \$2.9 million, or 6%, from the 2014 period to the 2015 period was due to increases of: \$2.3 million in professional fees, driven mainly by increased legal and consulting fees; \$0.8 million in allocated rent and facility-related costs due to additional subleased laboratory and office space; and \$0.4 million in allocated depreciation expense due to higher capital investments. The increases were partially offset by a \$0.6 million decrease in personnel-related expenses primarily due to the reversal of prior period share-based compensation expenses associated with performance-based stock awards discussed under "Research and Development Expense".

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

## **Interest Income**

Interest income was \$2.2 million, \$0.8 million and \$0.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. The increases of \$1.4 million, or 175%, from the 2015 period to the 2016 period and \$0.3 million, or 60%, from the 2014 period to the 2015 period were caused by higher average investment balances due to 2015 fundraising activities.

## **Other Income**

Other income includes income related to a job creation tax award and other items of income. Other income was \$51.5 million, \$0.3 million and \$0.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. In the year ended December 31, 2016, we recorded other income of \$51.2 million in connection with Baxalta's termination of our collaboration agreement. We collected the termination payment in January 2017. Other income also includes \$0.2 million, or one-fifth of a job creation tax award, in each of the years ended December 31, 2016, 2015 and 2014.

## **Liquidity and Capital Resources**

At December 31, 2016, we had \$353.2 million in cash, cash equivalents and marketable securities and \$70.2 million in collaboration receivables, which includes a \$51.2 million receivable due from Baxalta in connection with the termination of the collaboration agreement that was collected in January 2017 and \$15.8 million in profit share from Sandoz' sales of GLATOPA 20 mg/mL. In addition, we also held \$21.8 million in restricted cash, of which \$17.5 million serves as collateral for a security bond posted in the litigation against Amphastar. Our funds at December 31, 2016 were primarily invested in commercial paper, overnight repurchase agreements, asset-backed securities, corporate debt securities and United States money market funds, directly or through managed funds, with remaining maturities of 12 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. We do not believe that our cash equivalents and marketable securities were subject to significant market risk at December 31, 2016.

We have funded our operations primarily through the sale of equity securities and payments received under our collaboration and license agreements, including product revenue from Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL. Since our inception through December 31, 2016, we have received \$638 million through private and public issuances of equity securities, including approximately \$148 million in net proceeds from our May 2015 public offering of common stock and approximately \$83 million under our At-the-Market Equity Offering Sales Agreements, or the ATM Agreements, with Stifel, entered into in May 2014 and April 2015, respectively. As of December 31, 2016, we had received a cumulative total of \$738 million under our collaborations with Sandoz, including \$468.6 million in revenues on sales of Enoxaparin Sodium Injection and regulatory and commercial milestones related to that product, and \$138.1 million in revenues on sales of GLATOPA 20 mg/mL and regulatory and commercial milestones related to that product. In addition, we received \$86.7 million under our collaboration with Baxalta, including a \$33 million upfront payment, \$34.7 million in reimbursement of research and development services and costs and \$19 million in license and milestone payments. In March 2016, we received a \$45 million upfront payment from Mylan under the Mylan Collaboration Agreement. In the fourth quarter of 2016, we received \$60 million in milestone payments from Mylan, of which \$32.9 million will be applied toward the funding of Mylan's 50% share of collaboration expenses that are expected to be incurred in 2017.

We expect to fund our planned operating and expenditure requirements through a combination of current cash, cash equivalents and marketable securities; equity financings, including sales of common stock under our 2015 ATM Agreement; 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 2018.

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash provided by (used in) operating activities	\$ 7,888	\$ (71,515)	\$ (65,168)
Net cash provided by (used in) investing activities	\$ 80,048	\$ (163,834)	\$ 75,173
Net cash provided by financing activities	\$ 1,341	\$ 235,461	\$ 21,578
Net increase in cash and cash equivalents	\$ 89,277	\$ 112	\$ 31,583

*Cash provided by (used in) 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 provided by operating activities was \$7.9 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 in 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 is primarily due to: a \$51.2 million collaboration 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 million in milestone payments from Mylan where \$27.1 million was used to fund Mylan's 50% share of certain 2016 collaboration expenses and \$32.9 million will be applied toward the funding of Mylan's 50% share of collaboration expenses that are expected to be incurred in 2017; and the receipt of a \$45 million upfront payment from 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 million representing the remaining unamortized balance of the \$40 million upfront and license payments from Baxalta.

Cash used in operating activities was \$71.5 million for the year ended December 31, 2015 reflecting a net loss of \$83.3 million, which was partially offset by non-cash charges of \$8.7 million for depreciation and amortization of property, equipment and intangible assets, \$11.4 million for share-based compensation and \$1.4 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities used cash of \$9.7 million, primarily due to: an increase in accounts receivable of \$12.0 million, which includes receivables from Sandoz totaling \$17.8 million for contractual profit on sales of GLATOPA 20 mg/mL and Enoxaparin Sodium Injection and the receipt of Enoxaparin Sodium Injection royalties totaling \$4.7 million; and a decrease in unbilled revenue of \$1.1 million primarily due to lower reimbursable FTEs and external costs for M923.

Cash used in operating activities was \$65.2 million for the year ended December 31, 2014 reflecting a net loss of \$98.6 million, which was partially offset by non-cash charges of \$8.7 million for depreciation and amortization of property, equipment and intangible assets, \$13.6 million for share-based compensation and \$2.2 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of \$9.0 million, primarily driven by decreases in accounts receivable and unbilled revenue totaling \$6.2 million, due to lower reimbursable FTEs and external costs for M923, and an increase in deferred revenue of \$3.3 million, as we initially deferred revenue recognition of a \$7.0 million M834 license payment from Baxalta.

*Cash provided by (used in) investing activities*

Cash provided by investing activities of \$80 million for the year ended December 31, 2016 includes cash inflows of \$445.7 million from maturities of marketable securities offset by cash outflows of \$360 million for purchases of marketable securities and \$5.6 million for capital equipment and leasehold improvements.

Cash used in investing activities of \$163.8 million for the year ended December 31, 2015 includes cash inflows of \$245.9 million from maturities of marketable securities offset by cash outflows of \$405.6 million for purchases of marketable securities and \$4.1 million for capital equipment and leasehold improvements.

Cash provided by investing activities of \$75.2 million for the year ended December 31, 2014 includes cash inflows of \$195.3 million from maturities of marketable securities offset by cash outflows of \$111.8 million for purchases of marketable securities and \$8.3 million for capital equipment and leasehold improvements.

*Cash provided by financing activities*

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 shares 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 employee performance-based restricted stock.

Cash provided by financing activities of \$235.5 million for the year ended December 31, 2015 includes \$148.4 million of net proceeds from the sale of 8.3 million shares of our common stock through an underwritten public offering, \$64.5 million of net proceeds from the sale of 4.3 million shares of our common stock under our ATM Agreements and \$24.6 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan, for total proceeds of \$237.5 million. Total proceeds were partially offset by \$2.0 million of cash paid to tax authorities in connection with the vesting of employee performance-based restricted stock.

Cash provided by financing activities of \$21.6 million for the year ended December 31, 2014 includes \$18.3 million of net proceeds from the ATM facility and \$3.3 million from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

**Contractual Obligations**

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

The following table summarizes our contractual obligations at December 31, 2016 (in thousands):

<b>Contractual Obligations</b>	<b>Total</b>	<b>2017</b>	<b>2018 through 2019</b>	<b>2020 through 2021</b>	<b>After 2021</b>
License maintenance obligations	\$ 1,080	\$ 150	\$ 465	\$ 465	*
Operating lease obligations	140,198	11,144	29,534	29,516	\$ 70,004
Purchase obligations+	125,277	25,874	99,403	—	—
<b>Total contractual obligations</b>	<b>\$ 266,555</b>	<b>\$ 37,168</b>	<b>\$ 129,402</b>	<b>\$ 29,981</b>	<b>\$ 70,004</b>

\* After 2021, the annual obligations, which extend through the life of the patents are approximately \$0.2 million per year.

+ Purchase obligations reflect our estimate of the maximum amount we may be obligated to purchase pursuant to certain non-cancellable minimum purchase commitments. Actual amounts purchased during these periods may be less, potentially significantly less, than the amounts indicated.

**Critical Accounting Policies and Estimates**



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

### ***Revenue Recognition***

We generate revenue from collaboration and license agreements with pharmaceutical companies for the development and commercialization of certain of our product candidates. Collaboration and license agreements may include non-refundable upfront payments, reimbursement of research and development services and costs, payments based upon the achievement of defined collaboration objectives, license fees and profit share and/or royalties on sales of product candidates if they are successfully approved and commercialized. Our performance obligations under the collaborations may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and participation on certain committees with the collaborators. We make judgments that affect the periods over which we recognize revenue.

Our collaboration and license agreements may provide for reimbursement by our collaborators of a portion of our research and development expenses, and we make judgments that affect how these reimbursements are recorded. In collaborations where we are actively engaged in the research and development activities and contract directly with, manage the work of and are responsible for payments to third-party vendors for such development and related services, we recognize reimbursement of our research and development expenses as revenue.

We recognize revenue when persuasive evidence of an arrangement exists; services have been performed or products have been delivered; the fee is fixed and determinable; and collection is reasonably assured.

For collaborations with multiple-elements, at the inception of each agreement, we identify the deliverables included within the agreement and evaluate which deliverables may represent separate units of accounting based on criteria in the applicable revenue guidance, including whether the deliverable has stand-alone value to the collaborator. Deliverables under the arrangement are a separate unit of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) the arrangement includes a general right of return relative to the delivered item and delivery or performance of the undelivered items are considered probable and substantially within the Company's control. As a biotechnology entity with proprietary research and development services, we have been unable to demonstrate stand-alone value for the delivery of product licenses apart from the related research and development services as the services are essential to the functionality of the product licenses.

Arrangement consideration includes upfront payments and license payments. The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The selling price used for each unit of accounting is based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific nor third-party evidence is available. We expect, in general, to use the estimated selling price for allocating consideration to each deliverable. Management may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and in estimating the selling prices of identified units of accounting under its agreements. The estimated selling prices may be based on similar license arrangements, the nature of the research and development services to be performed and market rates for similar services. The impact of any change in expected deliverables or arrangement consideration is accounted for on a prospective basis.

Upfront payments received in connection with licenses of our technology rights are deferred if facts and circumstances dictate that the product license does not have stand-alone value apart from the related research and development services and are recognized as research and development revenue over the estimated period of performance for the product. License payments are treated like upfront payments. Our estimate of the performance period is based on the period we expect to deliver research and development services under the collaboration. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. We evaluate factors such as the scientific,

regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met. We recognize non-substantive milestone payments over the remaining estimated period of performance once the milestone is achieved. Sales-based and commercial milestones are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

We record product revenue on Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL. Product revenue is based upon net sales of licensed products in licensed territories in the period the sales occur as provided by the collaboration agreement. These amounts are determined based on amounts Sandoz provides to us and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations, or GPO, fees, and product returns, which could be adjusted based on actual results in the future.

Sandoz began selling Enoxaparin Sodium Injection in July 2010. Under the original payment terms of our 2003 collaboration agreement with Sandoz, or the 2003 Sandoz Collaboration Agreement, as discussed in Note 9 to our consolidated financial statements " *Collaborations and License Agreements*," Sandoz was obligated to pay us either a contractually-defined profit-share or royalty on net sales depending on the kind and number of other marketed generic versions of LOVENOX. We received 45% of profits from July 2010 through September 2011, a royalty on net sales from October 2011 through December 2011 and a share of profits in January 2012. From February 2012 to March 2015, we received a 10% royalty on net sales ( 12% on net sales above a certain threshold). In June 2015, we and Sandoz amended the 2003 Sandoz Collaboration Agreement, effective April 1, 2015, to provide that Sandoz would pay us 50% of contractually-defined profits on sales of Enoxaparin Sodium Injection.

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. Under the 2006 Sandoz Collaboration Agreement, we are entitled to earn 50% of contractually-defined profits on Sandoz' sales of GLATOPA 20 mg/mL. A portion of certain GLATOPA legal expenses, including any patent infringement damages, is deducted from our profits in proportion to our 50% profit sharing interest.

#### ***Fair Value Measurements***

Financial assets that we measure at fair value on a recurring basis include cash equivalents and marketable securities. 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.

Our 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. We validate 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. We did not adjust or override any fair value measurements provided by its pricing services as of December 31, 2016 and December 31, 2015 .

During the years ended December 31, 2016 and 2015 , there were no transfers between Level 1 and Level 2 financial assets. We did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2016 and December 31, 2015 . The carrying amounts reflected in our consolidated balance sheets for cash, accounts receivable, unbilled revenue, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

#### ***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.

### ***Share-Based Compensation***

We recognize the fair value of share-based compensation in our consolidated statements of operations and comprehensive loss. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under our stock option plans and employee stock purchase plan. For stock options, we recognize share-based compensation expense equal to the fair value of the stock options on a straight-line basis over the requisite service period. For time-based restricted stock awards, we record share-based compensation expense equal to the market value on the date of the grant on a straight-line basis over each award's explicit service period. For performance-based restricted stock awards, at each reporting period we assess the probability that the performance condition(s) will be achieved. We then expense the awards over the implicit service period based on the probability of achieving the performance objectives. 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. We issue new shares upon stock option exercises, upon the grant of restricted stock awards and under our employee stock purchase plan.

We estimate the fair value of each option award on the date of grant using the Black-Scholes-Merton option-pricing model. The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of share-based awards. These assumptions include:

- *Expected term.* The expected term represents the period that share-based awards are expected to be outstanding. We use a blend of our own historical data and peer data to estimate option exercise patterns and post-vesting employment termination behavior, adjusted for known trends, to arrive at the estimated expected life of an option. For purposes of identifying peer entities, we consider characteristics such as industry, stage of life cycle and financial leverage. We review and evaluate these assumptions regularly to reflect recent historical data.
- *Expected volatility.* For our expected volatility assumption, we consider, among other factors, the implied volatilities of our currently traded options to provide an estimate of volatility based upon current trading activity. We use a blended volatility rate based upon our historical performance, as well as the implied volatilities of our currently traded options, as we believe this appropriately reflects the expected volatility of our stock. Changes in

market price directly affect volatility and could cause share-based compensation expense to vary significantly in future reporting periods.

- *Risk-free interest rate.* The risk free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected term.
- *Expected dividends.* We have not paid and do not anticipate paying any dividends in the near future, and therefore we used an expected dividend yield of zero in the valuation model.

In addition to the Black-Scholes assumptions, we apply an estimated forfeiture rate to current period expense to recognize share-based compensation expense only for those stock and option awards expected to vest. We estimate forfeitures based upon historical data, adjusted for known trends, and will adjust our estimate of forfeitures if actual forfeitures differ, or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized in full through a cumulative adjustment in the period of change and will also impact the amount of share-based compensation expense in future periods.

### **Income Taxes**

We determine our deferred tax assets and liabilities based on the differences between the financial reporting and tax bases of assets and liabilities. The deferred tax assets and liabilities are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

We apply judgment in the determination of the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

We file income tax returns in the United States federal jurisdiction and multiple state jurisdictions. We are no longer subject to any tax assessment from an income tax examination for years before 2013 , except to the extent that in the future we utilize net operating losses or tax credit carryforwards that originated before 2013 .

### **New Accounting Standards**

Please see Note 2 to our consolidated financial statements, "*Summary of Significant Accounting Policies*" , 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, 2016 , we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying consolidated balance sheets of Momenta Pharmaceuticals, Inc. as of December 31, 2016 and 2015 , and 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, 2016 . These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Momenta Pharmaceuticals, Inc. at December 31, 2016 and 2015 , and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016 , 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), Momenta Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016 , 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 24, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
February 24, 2017

**MOMENTA PHARMACEUTICALS, INC.**
**CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

	December 31,	
	2016	2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 150,738	\$ 61,461
Marketable securities	202,413	288,583
Collaboration receivable	70,242	21,185
Prepaid expenses and other current assets	4,607	3,479
Total current assets	428,000	374,708
Property and equipment, net	20,847	21,896
Restricted cash	21,761	20,660
Intangible assets, net	5,189	3,528
Other long-term assets	1,940	248
Total assets	\$ 477,737	\$ 421,040
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,632	\$ 4,053
Accrued expenses	26,866	24,499
Collaboration advance	32,895	—
Deferred revenue	7,272	9,770
Other current liabilities	11	460
Total current liabilities	70,676	38,782
Deferred revenue, net of current portion	31,360	12,213
Other long-term liabilities	3,793	69
Total liabilities	105,829	51,064
Commitments and contingencies (Note 14)		
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.01 par value per share; 5,000 shares authorized, 100 shares of Series A Junior Participating Preferred Stock, \$0.01 par value per share designated and no shares issued and outstanding	—	—
Common stock, \$0.0001 par value per share; 100,000 shares authorized, 71,305 shares issued and 71,076 shares outstanding at December 31, 2016 and 69,077 shares issued and 68,958 shares outstanding at December 31, 2015	7	7
Additional paid-in capital	848,304	824,385
Accumulated other comprehensive income	86	4
Accumulated deficit	(473,375)	(452,372)
Treasury stock, at cost, 229 shares and 119 shares at December 31, 2016 and December 31, 2015, respectively	(3,114)	(2,048)
Total stockholders' equity	371,908	369,976
Total liabilities and stockholders' equity	\$ 477,737	\$ 421,040

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



## MOMENTA PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Collaboration revenues:			
Product revenue	\$ 74,648	\$ 48,503	\$ 19,963
Research and development revenue	34,971	41,147	32,287
Total collaboration revenue	109,619	89,650	52,250
Operating expenses:			
Research and development	119,880	126,033	106,482
General and administrative	64,466	48,051	45,164
Total operating expenses	184,346	174,084	151,646
Operating loss	(74,727)	(84,434)	(99,396)
Other income:			
Interest income	2,226	808	548
Other income	51,498	313	248
Total other income	53,724	1,121	796
Net loss	\$ (21,003)	\$ (83,313)	\$ (98,600)
Net loss per share:			
Basic and diluted	\$ (0.31)	\$ (1.32)	\$ (1.91)
Weighted average shares outstanding:			
Basic and diluted	68,656	63,130	51,664
Comprehensive loss:			
Net loss	\$ (21,003)	\$ (83,313)	\$ (98,600)
Net unrealized holding gains (losses) on available-for-sale marketable securities	82	20	(41)
Comprehensive loss	\$ (20,921)	\$ (83,293)	\$ (98,641)

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

**MOMENTA PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(in thousands)

	Common Stock			Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock		Total Stockholders' Equity
	Shares	Par Value	Additional Paid-In Capital			Shares	Amount	
Balances at December 31, 2013	52,357	\$ 5	\$ 540,266	\$ 25	\$ (270,459)	—	\$ —	\$ 269,837
Net proceeds from issuance of common stock pursuant to the ATM facilities	1,612	—	18,305	—	—	—	—	18,305
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	332	—	3,273	—	—	—	—	3,273
Issuance of restricted stock	227	—	—	—	—	—	—	—
Cancellation of restricted stock	(42)	—	—	—	—	—	—	—
Share-based compensation expense for employees	—	—	13,562	—	—	—	—	13,562
Share-based compensation expense for non-employees	—	—	32	—	—	—	—	32
Unrealized loss on marketable securities	—	—	—	(41)	—	—	—	(41)
Net loss	—	—	—	—	(98,600)	—	—	(98,600)
Balances at December 31, 2014	54,486	\$ 5	\$ 575,438	\$ (16)	\$ (369,059)	—	\$ —	\$ 206,368
Proceeds from public offering of common stock, net of issuance costs	8,337	1	148,438	—	—	—	—	148,439
Net proceeds from issuance of common stock pursuant to the ATM facilities	4,303	1	64,502	—	—	—	—	64,503
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	1,846	—	24,567	—	—	—	—	24,567
Repurchase of common stock pursuant to share surrender	—	—	—	—	—	(119)	(2,048)	(2,048)
Issuance of restricted stock	255	—	—	—	—	—	—	—
Cancellation/forfeiture of restricted stock	(150)	—	—	—	—	—	—	—
Share-based compensation expense for employees	—	—	11,189	—	—	—	—	11,189
Share-based compensation expense for non-employees	—	—	251	—	—	—	—	251
Unrealized gain on marketable securities	—	—	—	20	—	—	—	20
Net loss	—	—	—	—	(83,313)	—	—	(83,313)
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	—	—	—	—	—	—	—

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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	<u>71,305</u>	<u>\$ 7</u>	<u>\$ 848,304</u>	<u>\$ 86</u>	<u>\$ (473,375)</u>	<u>(229)</u>	<u>\$ (3,114)</u>	<u>\$ 371,908</u>

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

**MOMENTA PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Year Ended December 31,		
	2016	2015	2014
<b>Cash Flows from Operating Activities:</b>			
Net loss	\$ (21,003)	\$ (83,313)	\$ (98,600)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization of property and equipment	7,593	7,594	7,637
Share-based compensation expense	18,322	11,440	13,594
Amortization of premium on investments	595	1,383	2,162
Amortization of intangibles	1,529	1,061	1,061
Changes in operating assets and liabilities:			
Collaboration receivable	(49,057)	(10,849)	6,172
Prepaid expenses and other current assets	(1,128)	(14)	(64)
Restricted cash	(1,101)	59	—
Other long-term assets	(1,692)	(92)	—
Accounts payable	(1,032)	(3,380)	1,126
Accrued expenses	2,043	14,151	(1,099)
Collaboration advance	32,895	—	—
Deferred revenue	16,649	(9,015)	3,282
Other current liabilities	(449)	(58)	22
Other long-term liabilities	3,724	(482)	(461)
Net cash provided by (used in) operating activities	7,888	(71,515)	(65,168)
<b>Cash Flows from Investing Activities:</b>			
Purchases of property and equipment	(5,609)	(4,068)	(8,360)
Purchases of marketable securities	(360,008)	(405,673)	(111,809)
Proceeds from maturities of marketable securities	445,665	245,907	195,342
Net cash provided by (used in) investing activities	80,048	(163,834)	75,173
<b>Cash Flows from Financing Activities:</b>			
Proceeds from public offering of common stock, net of issuance costs	—	148,439	—
Net proceeds from issuance of common stock under ATM facility	—	64,503	18,305
Proceeds from issuance of common stock under stock plans	2,407	24,567	3,273
Repurchase of common stock pursuant to share surrender	(1,066)	(2,048)	—
Net cash provided by financing activities	1,341	235,461	21,578
Increase in cash and cash equivalents	89,277	112	31,583
Cash and cash equivalents, beginning of period	61,461	61,349	29,766
Cash and cash equivalents, end of period	\$ 150,738	\$ 61,461	\$ 61,349
<b>Non-Cash Investing Activity:</b>			
Common shares issued to Parivid to settle milestone payment	\$ 3,190	\$ —	\$ —
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 935	\$ —	\$ —

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

## MOMENTA PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. The Company

##### Business

Momenta Pharmaceuticals, Inc. (the "Company" or "Momenta") was incorporated in the state of Delaware in May 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for autoimmune diseases. The Company presently derives all of its revenue from its collaborations.

#### 2. Summary of Significant Accounting Policies

##### Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of the Company and the Company's wholly-owned subsidiary Momenta Pharmaceuticals Securities Corporation. All significant intercompany accounts and transactions have been eliminated.

##### Use of Estimates

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

##### Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists; services have been performed or products have been delivered; the fee is fixed or determinable; and collection is reasonably assured.

The Company has entered into collaboration and license agreements with pharmaceutical companies for the development and commercialization of certain of its product candidates. The Company's performance obligations under the terms of these agreements may include (i) transfer of intellectual property rights (licenses), (ii) providing research and development services, and (iii) participation on joint steering committees with the collaborators. Non-refundable payments to the Company under these agreements may include up-front license fees, payments for research and development activities, payments based upon the achievement of defined collaboration objectives and profit share or royalties on product sales.

At December 31, 2016, the Company had collaboration and license agreements with Sandoz AG (formerly Sandoz N.V. and Biochemie West Indies, N.V.), an affiliate of Novartis Pharma AG, and Sandoz Inc. (formerly Geneva Pharmaceuticals, Inc.), collectively referred to as Sandoz; Sandoz AG; and Mylan Ireland Limited, a wholly-owned, indirect subsidiary of Mylan N.V., or Mylan.

The Company evaluates multiple element agreements under the Financial Accounting Standards Board's, or FASB, Accounting Standards Codification, or ASC, Revenue Recognition (Topic 605). When evaluating multiple element arrangements under Topic 605, the Company identifies the deliverables included within the agreement and determines whether the deliverables under the arrangement represent separate units of accounting. Deliverables under the arrangement are a separate unit of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item and delivery or performance of the undelivered items are considered probable and substantially within the Company's control. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The Company considers whether the collaborator can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, and whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered items.

Arrangement consideration generally includes up-front license fees and non-substantive options to purchase additional products or services. The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The Company determines the estimated selling price for deliverables using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE nor TPE is available. Determining the BESP for a deliverable requires significant judgment. The Company uses BESP to estimate the selling price for licenses to the Company's proprietary technology, since the Company often does not have VSOE or TPE of selling price for these deliverables. In those circumstances where the Company utilizes BESP to determine the estimated selling price of a license to the Company's proprietary technology, the Company considers entity specific factors, including those factors contemplated in negotiating the agreements as well as the license fees negotiated in similar license arrangements. Management may be required to exercise considerable judgment in estimating the selling prices of identified units of accounting under its agreements. In validating the Company's BESP, the Company evaluates whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple deliverables.

#### *Up-Front License Fees*

Up-front payments received in connection with licenses of the Company's technology rights are deferred if facts and circumstances dictate that the license does not have stand-alone value. When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, it is combined with other deliverables and the revenue of the combined unit of accounting is recorded based on the method appropriate for the last delivered item. The Company recognizes revenue from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the period over which the research and development services are expected to occur. Accordingly, the Company is required to make estimates regarding the development timelines for product candidates being developed pursuant to any applicable agreement. The determination of the length of the period over which to recognize the revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Quarterly, the Company reassesses its period of substantial involvement over which the Company amortizes its up-front license fees and makes adjustments as appropriate. The Company's estimates regarding the period of performance under its collaborative research and development and licensing agreements have changed in the past and may change in the future. Any change in the Company's estimates could result in changes to the Company's results for the period over which the revenues from an up-front license fee are recognized.

#### *Milestones*

At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive, in accordance with ASU No. 2010-17, Revenue Recognition—Milestone Method. A milestone is defined as an event that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones under accounting guidance. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the Company's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (b) the consideration relates solely to past performance (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement and (d) the milestone fee is refundable or adjusts based on future performance or non-performance. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Payments that are contingent upon the achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met.

Sales-based and commercial milestones are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

#### *Profit Share and Royalties on Sandoz' Sales of Enoxaparin Sodium Injection® and GLATOPA® 20 mg/mL*

Profit share or royalty revenue is reported as product revenue and is recognized based upon net sales or contractual profit of licensed products in licensed territories in the period the sales occur as provided by the collaboration agreement. The amount of net sales or contractual profit is determined based on amounts provided by the collaborator and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organization fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. The Company is highly dependent on its collaborators for



timely and accurate information regarding any net sales or contractual profit realized from sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL in order to accurately report its results of operations.

#### *Research and Development Revenue under Collaborations with Sandoz and Baxalta*

Under its collaborations with Sandoz and Baxalta, the Company is reimbursed at a contractual full-time equivalent, or FTE, rate for any FTE employee expenses as well as any external costs incurred for commercial and related activities. The Company recognizes research and development revenue from FTE services and external costs upon completion of the performance requirements (i.e. as the services are performed and the reimbursable costs are incurred). Revenues are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such commercial and related services.

#### **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, 2016 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, 2016, 2015 and 2014. Realized gains or losses on marketable securities for each of the years ended December 31, 2016, 2015, and 2014 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, 2016 and 2015.

#### **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, 2016 and December 31, 2015.

#### **Concentration of Credit Risk**

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

## **Collaboration Receivable**

Collaboration receivable includes:

- Amounts due to the Company for its contractual profit share on Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL;
- Amounts due to the Company for reimbursement of research and development services and external costs under the collaborations with Sandoz and Baxalta;
- Amounts due from Mylan for its 50% share of certain collaboration expenses under the cost-sharing provisions of the the Mylan Collaboration Agreement that are not funded through the continuation payments; and
- As of December 31, 2016 , the \$51.2 million asset return payment due from Baxalta, as discussed in Note 9, *Collaborations and License Agreements* . In January 2017, the Company received the \$51.2 million payment from Baxalta.

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

## **Collaboration Advance**

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

## **Deferred Revenue**

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

## **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.

## **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. No impairment charges have been recognized through December 31, 2016 .

## **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.

## Share-Based Compensation Expense

The Company recognizes the fair value of share-based compensation in its consolidated statements of operations and comprehensive loss. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under its stock option plans and the employee stock purchase plan ("ESPP"). For stock options, the Company recognizes share-based compensation expense equal to the fair value of the stock options on a straight-line basis over the requisite service period. For time-based restricted stock awards, the Company records share-based compensation expense equal to the market value on the date of the grant on a straight-line basis over each award's explicit service period. For performance-based restricted stock, at each reporting period the Company assesses the probability that the performance condition(s) will be achieved. The Company then expenses the awards over the implicit service period based on the probability of achieving the performance conditions. The Company estimates an award's 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 as of the date of an estimate revision over the revised remaining implicit service period. The Company issues new shares upon stock option exercises, upon the grant of restricted stock awards and under its ESPP.

The Company estimates the fair value of each option award on the date of grant using the Black-Scholes-Merton option-pricing model. The Black-Scholes-Merton option-pricing model requires the Company to develop certain subjective assumptions including the expected volatility of its stock, the expected term of the award and the expected forfeiture rate associated with the Company's stock option plan. The Company considers, among other factors, the implied volatilities of its currently traded options to provide an estimate of volatility based upon current trading activity. The Company uses a blended volatility rate based upon its historical performance, as well as the implied volatilities of its currently traded options, as it believes this appropriately reflects the expected volatility of its stock. Changes in market price directly affect volatility and could cause share-based compensation expense to vary significantly in future reporting periods.

The expected term of awards represents the period of time that the awards are expected to be outstanding. The Company uses a blend of its own historical data and peer data to estimate option exercise and employee termination behavior, adjusted for known trends, to arrive at the estimated expected life of an option. For purposes of identifying peer entities, the Company considers characteristics such as industry, stage of life cycle and financial leverage. 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 Company applies an estimated forfeiture rate to current period expense to recognize share-based compensation expense only for those stock and option awards expected to vest. The Company estimates forfeitures based upon historical data, adjusted for known trends, and will adjust its estimate of forfeitures if actual forfeitures differ, or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of change and will also impact the amount of share-based compensation expense in future periods.

Unvested stock options held by consultants are revalued at each reporting period until vesting occurs using the Company's estimate of fair value.

## Net Loss Per Common Share

The Company computes basic net loss per common share by dividing net loss by the weighted average number of common shares outstanding, which includes common stock issued and outstanding and excludes unvested shares of restricted common stock. The Company computes diluted net loss per common share by dividing net loss by the weighted average number of common shares and potential shares from outstanding stock options and unvested restricted stock 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, 2016 and 2015 .

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 2013 , except to the extent that in the future it utilizes net operating losses or tax credit carry forwards that originated before 2013 . As of December 31, 2016 , 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 medicines in three product areas: complex generics, biosimilars and novel therapeutics for autoimmune disease. The three product areas correspond with their respective regulatory pathways. However, the Company's portfolio of complex generics, biosimilars, and novel therapeutics have 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 the three product areas. Accordingly, the Company views its business as one reportable operating segment—the discovery, development and commercialization of pharmaceutical products.

### **New Accounting Pronouncements**

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

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

- In August 2015 the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date.
- In March 2016 the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations.
- In April 2016 the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance.
- In May 2016 the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers.
- In December 2016 the FASB issued ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which amends certain narrow aspects of the guidance issued in ASU No. 2014-09 including guidance related to the disclosure of remaining performance obligations and prior-period

performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples.

The Company expects to adopt the new standard using the modified retrospective method as permissible under the transitional provisions of Topic 606 for all contracts not yet completed as of the effective date. The modified retrospective method applies the guidance retrospectively only to the most current period presented in the financial statements, recognizing the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings (or deficit) at the date of initial application. The Company is continuing to evaluate the potential impact that these standards will have on its financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40). The ASU requires all entities to evaluate for the existence of conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the issuance date of its financial statements. The accounting standard is effective for the Company as of December 31, 2016 and did not have a material impact on the consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes, Balance Sheet Classification of Deferred Taxes (Topic 740). The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. The adoption of this standard in the first quarter of 2016 did not have a material impact on the Company's financial position or results of operations as its net deferred tax assets have been fully offset by a valuation allowance.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the impact of adopting this new accounting standard on its financial position and results of operations.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Under the new standard all excess tax benefits and tax deficiencies should be recognized as income tax expense or benefit in the income statement. The tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity also should recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. The new standard also provides for companies to make an entity-wide accounting policy election on how to account for award forfeitures. Entities can either estimate the number of awards that are expected to vest (current GAAP) or account for forfeitures when they occur. The accounting standard is effective for interim and annual periods after December 15, 2016. Early adoption is permitted for any entity in any interim or annual period. The Company adopted the new standard on January 1, 2017. The Company adopted a policy to account for forfeitures as they occur. Adoption of this standard is not expected to have a material impact on the Company's financial position and results of operations.

### **3. Fair Value Measurements**

The tables below present information about the Company's assets that are measured at fair value on a recurring basis at December 31, 2016 and 2015, and indicate 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, 2016 and 2015 are summarized as follows (in thousands):

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

<u>Description</u>	<u>Balance as of December 31, 2015</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Other Unobservable Inputs (Level 3)</u>
Assets:				
Cash equivalents:				
Money market funds and overnight repurchase agreements	\$ 54,077	\$ 30,077	\$ 24,000	\$ —
Marketable securities:				
U.S. government-sponsored enterprise securities	24,290	—	24,290	—
Corporate debt securities	73,651	—	73,651	—
Commercial paper obligations	125,805	—	125,805	—
Asset-backed securities	64,837	—	64,837	—
<b>Total</b>	<b>\$ 342,660</b>	<b>\$ 30,077</b>	<b>\$ 312,583</b>	<b>\$ —</b>

As of December 31, 2016, the Company held \$24 million in overnight repurchase agreements. Overnight purchase agreements yields are comparable to money market funds. Principal and interest on the instruments is due the next day. The instruments are classified as Level 2 due to the collateral including both U.S. government-sponsored enterprise securities and treasury instruments.

There have been no impairments of the Company's assets measured and carried at fair value, no changes in valuation techniques and no transfers between Level 1 and Level 2 financial assets during the years ended December 31, 2016 and 2015. The Company did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2016 and 2015. 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.

#### 4. Cash, Cash Equivalents and Marketable Securities



The following tables summarize the Company's cash, cash equivalents and marketable securities as of December 31, 2016 and 2015 (in thousands):

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

<u>As of December 31, 2015</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash, money market funds and overnight repurchase agreements	\$ 61,461	\$ —	\$ —	\$ 61,461
U.S. government-sponsored enterprise securities due in one year or less	24,285	5	—	24,290
Corporate debt securities due in one year or less	73,735	1	(84)	73,652
Commercial paper obligations due in one year or less	125,693	120	(8)	125,805
Asset-backed securities due in one year or less	64,866	—	(30)	64,836
<b>Total</b>	<b>\$ 350,040</b>	<b>\$ 126</b>	<b>\$ (122)</b>	<b>\$ 350,044</b>
Reported as:				
Cash and cash equivalents	\$ 61,461	\$ —	\$ —	\$ 61,461
Marketable securities	288,579	126	(122)	288,583
<b>Total</b>	<b>\$ 350,040</b>	<b>\$ 126</b>	<b>\$ (122)</b>	<b>\$ 350,044</b>

At December 31, 2016 and 2015, the Company held 31 and 66 marketable securities, respectively, which were in a continuous unrealized loss position for less than one year. As the unrealized losses on these securities were caused by fluctuations in interest rates, the Company concluded that no other-than-temporary impairment exists with respect to these securities. At December 31, 2016 and 2015, there were no marketable securities in a continuous unrealized loss position for greater than one year.

The following table summarizes the aggregate fair value of these securities at December 31, 2016 and 2015 (in thousands):

	<u>As of December 31, 2016</u>		<u>As of December 31, 2015</u>	
	<u>Aggregate Fair Value</u>	<u>Unrealized Losses</u>	<u>Aggregate Fair Value</u>	<u>Unrealized Losses</u>
Corporate debt securities due in one year or less	\$ 47,906	\$ (36)	\$ 70,657	\$ (84)
Commercial paper obligations due in one year or less	\$ —	\$ —	\$ 33,734	\$ (8)
Asset-backed securities due in one year or less	\$ 60,787	\$ (14)	\$ 61,337	\$ (30)

## 5. Property and Equipment

As of December 31, 2016 and 2015 , property and equipment, net consists of the following (in thousands):

	2016	2015	Depreciable Lives
Computer equipment	\$ 2,991	\$ 2,426	3 years
Software	10,508	9,900	3 years
Office furniture and equipment	2,645	2,524	5 to 6 years
Laboratory equipment	47,938	43,286	7 years
Leasehold improvements	13,333	12,735	Shorter of asset life or lease term
Less: accumulated depreciation	(56,568)	(48,975)	
	<u>\$ 20,847</u>	<u>\$ 21,896</u>	

During 2015 , the Company disposed of laboratory equipment with a gross carrying amount of \$0.3 million and accumulated depreciation of \$0.3 million . The Company did not dispose of any property and equipment during 2016 . Depreciation and amortization expense amounted to \$7.6 million in each of the years ended December 31, 2016 , 2015 and 2014 .

## 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 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, 2016 and 2015 , intangible assets, net of accumulated amortization, are as follows (in thousands):

	2016		2015	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Total intangible assets for core and developed technology	\$ 13,617	\$ (8,428)	\$ 10,427	\$ (6,899)

Amortization expense was approximately \$1.5 million , \$1.1 million and \$1.1 million in the years ended December 31, 2016 , 2015 and 2014 , respectively.

The Company expects to incur amortization expense of approximately \$1.2 million per year from 2017 to 2020 and \$0.6 million in the final year ( 2021 ).

## 7. Restricted Cash

The Company designated \$17.5 million as collateral for a security bond posted in the litigation against Amphastar, International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. and Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), as discussed within Note 14, *Commitments and Contingencies* . The \$17.5 million is held in an

escrow account by Hanover Insurance. The Company classified this restricted cash as long-term as the timing of a final decision in the Enoxaparin Sodium Injection patent litigation is not known.

The Company designated \$2.4 million as collateral for a letter of credit related to the lease of office and laboratory space located at 675 West Kendall Street in Cambridge, Massachusetts. This balance will remain restricted through April 2018 and therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

The Company designated \$0.7 million as collateral for a letter of credit related to the lease of office and laboratory space located at 320 Bent Street in Cambridge, Massachusetts. This balance will remain restricted through February 2027 and is therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

The Company designated \$1.1 million as collateral for a letter of credit related to the lease of office and laboratory space located at 301 Binney Street in Cambridge, Massachusetts. This balance will remain restricted through June 2025 and is therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

## 8. Accrued Expenses

As of December 31, 2016 and 2015, accrued expenses consisted of the following (in thousands):

	2016	2015
Accrued compensation	\$ 9,414	\$ 7,848
Accrued contract research costs	12,338	14,710
Accrued professional fees	3,979	1,354
Other	1,135	587
	<u>\$ 26,866</u>	<u>\$ 24,499</u>

## 9. Collaboration and License Agreements

At December 31, 2016, the Company had collaboration and license agreements with Sandoz, Sandoz AG and Mylan. M923, the Company's biosimilar HUMIRA® (adalimumab) candidate, was previously developed in collaboration with Baxalta under the Baxalta Collaboration Agreement, as defined below. The Baxalta Collaboration Agreement was terminated effective December 31, 2016.

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

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

The collaboration with Mylan is a cost-sharing arrangement pursuant to which reimbursement for Mylan's 50% share of collaboration expenses is recorded as a reduction to research and development expense and general and administrative expense depending on the nature of the activities.

The following tables provide amounts by year and by line item included in the Company's consolidated statements of operations and comprehensive loss attributable to transactions arising from its significant collaborative arrangements and all other arrangements, as defined in the Financial Accounting Standards Board's Accounting Standards Codification Topic 808, *Collaborative Arrangements*.

	For the Year Ended December 31, 2016 (in thousands)				
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Baxalta Collaboration Agreement (1)	Mylan Collaboration Agreement (2)	Total Collaborations
Collaboration revenues:					
Product revenue	\$ —	\$ 74,648	\$ —	\$ —	\$ 74,648
Research and development revenue:					
Recognition of upfront payments and license payments	—	—	21,983	6,368	28,351
Research and development services and external costs	345	2,545	3,730	—	6,620
Total research and development revenue	\$ 345	\$ 2,545	\$ 25,713	\$ 6,368	\$ 34,971
Total collaboration revenues	\$ 345	\$ 77,193	\$ 25,713	\$ 6,368	\$ 109,619
Operating expenses:					
Research and development expense (3, 4)	\$ 692	\$ 1,911	\$ 1,196	\$ 28,623	\$ 32,422
General and administrative expense (3, 4)	7	470	187	1,763	2,427
Total operating expenses	\$ 699	\$ 2,381	\$ 1,383	\$ 30,386	\$ 34,849

	For the Year Ended December 31, 2015 (in thousands)			
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Baxalta Collaboration Agreement (1)	Total Collaborations
Collaboration revenues:				
Product revenue	\$ 5,063	\$ 43,440	\$ —	\$ 48,503
Research and development revenue:				
Milestone payments	—	20,000	—	20,000
Recognition of upfront payments and license payments	—	—	9,014	9,014
Research and development services and external costs	789	2,861	8,483	12,133
Total research and development revenue	\$ 789	\$ 22,861	\$ 17,497	\$ 41,147
Total collaboration revenues	\$ 5,852	\$ 66,301	\$ 17,497	\$ 89,650
Operating expenses:				
Research and development expense (3)	\$ 324	\$ 856	\$ 1,851	\$ 3,031
General and administrative expense (3)	344	206	963	1,513
Total operating expenses	\$ 668	\$ 1,062	\$ 2,814	\$ 4,544

	For the Year Ended December 31, 2014 (in thousands)			
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Baxalta Collaboration Agreement (1)	Total Collaborations
<b>Collaboration revenues:</b>				
Product revenue	\$ 19,963	\$ —	\$ —	\$ 19,963
<b>Research and development revenue:</b>				
Milestone payments	—	—	12,000	12,000
Recognition of upfront payments and license payments	—	480	3,239	3,719
Research and development services and external costs	1,043	2,452	13,073	16,568
<b>Total research and development revenue</b>	<b>\$ 1,043</b>	<b>\$ 2,932</b>	<b>\$ 28,312</b>	<b>\$ 32,287</b>
<b>Total collaboration revenues</b>	<b>\$ 21,006</b>	<b>\$ 2,932</b>	<b>\$ 28,312</b>	<b>\$ 52,250</b>
<b>Operating expenses:</b>				
Research and development expense (3)	\$ 341	\$ 920	\$ 16,637	\$ 17,898
General and administrative expense (3)	125	299	527	951
<b>Total operating expenses</b>	<b>\$ 466</b>	<b>\$ 1,219</b>	<b>\$ 17,164</b>	<b>\$ 18,849</b>

- (1) The Baxalta Collaboration Agreement, as defined below, was terminated effective December 31, 2016 .
- (2) The Mylan Collaboration Agreement, as defined below, became effective on February 9, 2016.
- (3) The amounts represent external expenditures, including amortization of an intangible asset, and exclude salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies, as these costs are not directly charged to programs.
- (4) As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, the Company offset approximately \$26.5 million against research and development costs and \$1.3 million against general and administrative costs during the year ended December 31, 2016 .

### **2003 Sandoz Collaboration Agreement**

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

Under the terms of the 2003 Sandoz Collaboration Agreement, the Company and Sandoz agreed to exclusively work with each other to develop and commercialize Enoxaparin Sodium Injection for any and all medical indications within the United States. In addition, the Company granted Sandoz an exclusive license under its intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States.

Sandoz began selling Enoxaparin Sodium Injection in July 2010. Under the original payment terms of the 2003 Sandoz Collaboration Agreement, Sandoz was obligated to pay the Company either a contractually-defined profit-share or royalty on net sales depending on the kind and number of other marketed generic versions of LOVENOX. The Company received 45% of profits from July 2010 through September 2011, a royalty on net sales from October 2011 through December 2011 and a share of profits in January 2012. From February 2012 to March 2015, the Company received a 10% royalty on net sales ( 12% on net sales above a certain threshold). In June 2015, the Company and Sandoz amended the 2003 Sandoz Collaboration Agreement, effective April 1, 2015, to provide that Sandoz would pay the Company 50% of contractually-defined profits on sales. Sandoz did not record any profit on sales of Enoxaparin Sodium Injection for the year ended December 31, 2016 , and therefore the Company did not record product revenue for Enoxaparin Sodium Injection in the period. For the year ended December 31, 2015 , the Company earned \$5.1 million in product revenue consisting of \$6.9 million in a combination of profit share and royalties, net of an annual claw-back adjustment of \$1.8 million for the product year ended June 30, 2015, on Sandoz' sales of Enoxaparin Sodium Injection. For the year ended December 31, 2014 , the Company earned \$19.9 million in product revenue, which consisted of \$20 million in royalties on Sandoz' sales of Enoxaparin Sodium Injection, offset by \$2.2 million of its contractual share of development and other expenses for the product year ended June 30, 2014, and increased by \$2.1 million to reflect an adjustment to royalties earned in the product year ended June 30, 2012.

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. The Company's

contractual share of such development and legal expenses is subject to an annual claw-back adjustment at the end of each of the first five product years, with the product year beginning on July 1 and ending on June 30. The annual adjustment can only reduce the Company's profits, royalties and milestones by up to 50% in a given calendar quarter and any excess amount due will be carried forward into future quarters and reduce any profits in those future periods until it is paid in full. Annual adjustments, including amounts carried forward into future periods, are recorded as a reduction in product revenue.

The Company recognized research and development revenue from FTE services and external costs of \$0.3 million , \$0.8 million , and \$1.0 million in the years ended December 31, 2016 , 2015 , and 2014 , respectively.

#### ***2006 Sandoz Collaboration Agreement***

In 2006 and 2007, the Company entered into a series of agreements, including a collaboration and license agreement, as amended, or the 2006 Sandoz Collaboration Agreement, with Sandoz AG; and a stock purchase agreement and an investor rights agreement, with Novartis Pharma AG. Under the 2006 Sandoz Collaboration Agreement, the Company and Sandoz agreed to exclusively collaborate on the development and commercialization of GLATOPA, among other products. Costs, including development costs and the costs of clinical studies, will be borne by the parties in varying proportions depending on the type of expense. For GLATOPA, the Company is generally responsible for all of the development costs in the United States. For GLATOPA outside of the United States, the Company shares development costs in proportion to its profit sharing interest. The Company is reimbursed at a contractual FTE rate for any FTE employee expenses as well as any external costs incurred in the development of products to the extent development costs are borne by Sandoz. All commercialization costs are borne by Sandoz.

The term of the 2006 Sandoz Collaboration Agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party pursuant to the provisions of the 2006 Sandoz Collaboration Agreement. The 2006 Sandoz Collaboration Agreement may be terminated if either party breaches the 2006 Sandoz Collaboration Agreement or files for bankruptcy. In addition, either the Company or Sandoz may terminate the 2006 Sandoz Collaboration Agreement with respect to GLATOPA 40 mg/mL, if clinical trials are required for regulatory approval of GLATOPA 40 mg/mL.

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. Under the 2006 Sandoz Collaboration Agreement, the Company earns 50% of contractually-defined profits on Sandoz' worldwide net sales of GLATOPA 20 mg/mL. The Company is entitled to earn 50% of contractually-defined profits on Sandoz' worldwide net sales of GLATOPA 40 mg/mL, if and when GLATOPA 40 mg/mL is commercialized. Profits on net sales of GLATOPA are calculated by deducting from net sales the costs of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. With respect to GLATOPA, Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement, except for FTE costs with respect to certain legal activities for GLATOPA; however a portion of certain legal expenses, including any patent infringement damages, can be offset against the profit-sharing amounts in proportion to the Company's 50% profit sharing interest.

For the year ended December 31, 2016 , the Company recorded \$74.6 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting \$78.2 million in profit share net of a deduction of \$3.6 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz. For the year ended December 31, 2015 , the Company recorded \$43.4 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting \$52.5 million in profit share net of a deduction of \$9.1 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz since 2008. The Company is eligible to receive in the aggregate up to \$120 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA in the United States. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. Sandoz 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.

The Company recognized research and development revenue from FTE services and external costs of \$2.5 million , \$2.9 million , and \$2.5 million in the years ended December 31, 2016 , 2015 , and 2014 , respectively.

#### ***Baxalta Collaboration Agreement***

The Company and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (or collectively referred to as Baxter) entered into a global collaboration and license agreement, or the Baxter Collaboration Agreement, effective February 2012, to develop and commercialize biosimilars, including M923. In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned the Baxter Collaboration Agreement to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated (or collectively referred to as Baxalta). Subsequent to the assignment, the Company refers to "Baxter" as "Baxalta" and the "Baxter Collaboration Agreement" as the "Baxalta Collaboration Agreement." On September 27, 2016, Baxalta gave the Company twelve months' prior written notice of the exercise of its right to terminate for its convenience the

Baxalta Collaboration Agreement. On December 31, 2016, the Company and Baxalta entered into an asset return and termination agreement, or the Baxalta Termination Agreement, which made the termination of the Baxalta Collaboration Agreement effective as of December 31, 2016.

Under the Baxalta Collaboration Agreement, the Company and Baxalta agreed to collaborate, on a world-wide basis, on the development and commercialization of M923 and M834, the Company's biosimilar ORENCIA® (abatacept) candidate, and Baxalta had the right to select four additional reference products to target for biosimilar development under the collaboration. In July 2012, Baxalta selected an additional product candidate and in December 2013, following an internal portfolio review, terminated its option to license the product candidate. In February 2015, Baxalta's right to select additional programs expired without further exercise. Also, in February 2015, Baxalta terminated in part the Baxalta Collaboration Agreement as it related to M834 and all worldwide development and commercialization rights for M834 reverted to the Company.

Under the Baxalta Collaboration Agreement, each party granted the other an exclusive license under its intellectual property rights to develop and commercialize M923 for all therapeutic indications. The Company agreed to provide development and related services on a commercially reasonable basis through the filing of an IND or equivalent application in the European Union for M923. Development and related services included high-resolution analytics, characterization, and product and process development. Baxalta was responsible for clinical development, manufacturing and commercialization activities for M923. The Company had the right to participate in a joint steering committee, consisting of an equal number of members from the Company and Baxalta, to oversee and manage the development and commercialization of M923 under the collaboration. Costs, including development costs, payments to third parties for intellectual property licenses, and expenses for legal proceedings, including the patent exchange process pursuant to the Biologics Price Competition and Innovation Act of 2009, was to be borne by the parties in varying proportions, depending on the type of expense and the stage of development. The Company was generally responsible for research and process development costs prior to filing an IND or equivalent application in the European Union, and the cost of in-human clinical trials, manufacturing in accordance with current good manufacturing practices and commercialization was borne by Baxalta.

Under the terms of the Baxalta Collaboration Agreement, the Company received an upfront payment of \$33 million, a \$7 million license payment for achieving pre-defined "minimum development criteria" for M834, and \$12 million in technical and development milestone payments in connection with the UK Medicines and Healthcare Products Regulatory Agency's acceptance of Baxalta's clinical trial application to initiate a pharmacokinetic clinical trial for M923. The Company was reimbursed at a contractual FTE rate for any FTE employee expenses and external development costs for reimbursable activities related to M923. Had M923 been successfully developed and launched under the Baxalta Collaboration Agreement, Baxalta would have been required to pay the Company royalties on net sales of licensed products worldwide, with a base royalty rate in the high single digits with the potential for significant tiered increases based on the number of competitors, the interchangeability of the product, and the sales tier for the product. The maximum royalty with all potential increases would have been slightly more than double the base royalty.

On June 3, 2016, Baxalta Incorporated and Shire plc, or Shire, announced the completion of the combination of Baxalta Incorporated and Shire. As a result of the combination, Baxalta Incorporated, of which Baxalta US Inc. and Baxalta GmbH are wholly-owned subsidiaries, is a wholly-owned subsidiary of Shire. On September 27, 2016, Baxalta gave the Company twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement. Under the terms of the Baxalta Collaboration Agreement, the effective date of the termination was twelve months following the date Baxalta gave the termination notice, as more particularly set forth in the Baxalta Collaboration Agreement. As of the termination effective date, (i) Baxalta was obligated to transfer to the Company all ongoing regulatory, development, manufacturing and commercialization activities and related records for M923 and, at the Company's request, assign to the Company any third party agreements reasonably necessary for and primarily related to the development, manufacture, and commercialization of M923 to the extent permitted by the agreements' terms, (ii) the licenses granted pursuant to the Baxalta Collaboration Agreement by the Company to Baxalta under the Company's intellectual property rights relating to M923 would terminate, the licenses granted pursuant to the Baxalta Collaboration Agreement by Baxalta to the Company under Baxalta's intellectual property rights relating to M923 would survive, and Baxalta was obligated to grant to the Company additional licenses under Baxalta's intellectual property rights relating to M923 existing as of the termination effective date, and (iii) the Company was obligated to pay to Baxalta a royalty of 5% of net sales, as such term is defined in the Baxalta Collaboration Agreement, until Baxalta's development expenses and commercialization costs, as such terms are defined in the Baxalta Collaboration Agreement, occurring through the termination effective date were reimbursed. Following receipt of the termination notice, the Company is no longer eligible to receive any regulatory milestone payments under the Baxalta Collaboration Agreement. Prior to the termination effective date, Baxalta was obligated to continue to perform development and manufacturing activities for M923.

On December 31, 2016, the Company and Baxalta entered into the Baxalta Termination Agreement, amending certain termination provisions of the Baxalta Collaboration Agreement. Under the terms of the Baxalta Termination Agreement, the



termination of the Baxalta Collaboration 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 are expected to be completed by April 2017, and in January 2017, Baxalta paid the Company a one-time cash payment of \$51.2 million representing the costs Baxalta would have incurred in performing the activities it would have performed under Baxalta Collaboration Agreement through the original termination date.

In accordance with FASB's ASU No. 2009-13: Multiple-Deliverable Revenue Arrangements (Topic 615), the Company identified all of the deliverables at the inception of the Baxalta Collaboration Agreement. The deliverables were determined to include (i) six development and product licenses for each of M923, M834 and the four additional collaboration products, (ii) research and development services related to each of M923, M834 and the four additional collaboration products and (iii) the Company's participation in a joint steering committee. The Company determined that each of the license deliverables do not have stand-alone value apart from the related research and development services deliverables because (1) there are no other vendors selling similar, competing products on a stand-alone basis, (2) Baxalta does not have the contractual right to resell the license, and (3) Baxalta is unable to use the license for its intended purpose without the Company's performance of research and development services. As such, the Company determined that with respect to this arrangement separate units of accounting exist for each of the six licenses together with the related research and development services, as well as the one unit of accounting for the joint steering committee. The estimated selling price for these units of accounting was determined based on similar license arrangements and the nature of the research and development services to be performed for Baxalta and market rates for similar services. At the inception of the Baxalta Collaboration Agreement, arrangement consideration of \$61.0 million , which included the \$33.0 million upfront payment and aggregate option payments for the four additional collaboration products of \$28.0 million , was allocated to the units of accounting based on the relative selling price method. Of the \$61.0 million , \$10.3 million was allocated to the M923 product license together with the related research and development services, \$10.3 million to each of the four additional collaboration product licenses with the related research and development services, \$9.4 million was allocated to the M834 product license together with the related research and development services due to that product's stage of development at the time the license was delivered, and \$114,000 was allocated to the joint steering committee unit of accounting.

At the inception of the Baxalta Collaboration Agreement, the Company delivered development and product licenses for M923 and M834 and commenced revenue recognition of the arrangement consideration allocated to those products. In addition, the Company began revenue recognition for the arrangement consideration allocated to the joint steering committee unit of accounting. Baxalta's termination of its option to license M511 in December 2013 as well as its termination of M834 and the lapse of its right to select additional products in February 2015 reduced the number of deliverables from seven to two and decreased the total consideration from \$61 million to \$40 million . The Company determined that the change in total consideration received and total deliverables under the arrangement represented a change in estimate and, as a result, the Company reallocated the revised total consideration of \$40 million , less the amount recognized as revenue to date, to the remaining deliverables under the agreement using the original best estimate of selling price. The remaining deliverables were the combined unit of account for the M923 license and the related research and development services and the Company's participation on the joint steering committee. The Company recognized the resulting change in revenue as a result of the decrease in deliverables and expected consideration on a prospective basis. The Company recorded this revenue on a straight-line basis over the applicable performance period, which began with delivery of the development and product license and ends upon FDA approval of the product.

As a result of termination of the Baxalta Collaboration Agreement, the Company's performance period for M923 and the joint steering committee 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 . The total impact of the change in performance period was \$11.0 million , or \$0.16 per share. In addition, the Company recorded the \$51.2 million asset return payment in other income in the fourth quarter of 2016 as a result of Baxalta's accelerated termination and funding of anticipated development costs pursuant to the Baxalta Collaboration Agreement.

### ***Mylan Collaboration Agreement***

On January 8, 2016, the Company and Mylan entered into a collaboration agreement, or the Mylan Collaboration Agreement, which became effective on February 9, 2016, pursuant to which the Company and Mylan agreed to collaborate exclusively, on a worldwide basis, to develop, manufacture and commercialize six of the Company's biosimilar candidates, including M834.

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

its share of collaboration expenses incurred by the Company, in part, through up to six contingent milestone payments, totaling up to \$200 million across the six product candidates.

For each product candidate other than M834, at a specified stage of early development, the Company and Mylan will each decide, based on the product candidate's development progress and commercial considerations, whether to continue the development, manufacture and commercialization of such product candidate under the collaboration or to terminate the collaboration with respect to such product candidate.

Under the Mylan Collaboration Agreement, the Company granted Mylan an exclusive license under the Company's intellectual property rights to develop, manufacture and commercialize the product candidates for all therapeutic indications, and Mylan granted the Company a co-exclusive license under Mylan's intellectual property rights for the Company to perform its development and manufacturing activities under the product work plans agreed by the parties, and to perform certain commercialization activities to be agreed by the joint steering committee for such product candidates if the Company exercises its co-commercialization option described below. The Company and Mylan established a joint steering committee consisting of an equal number of members from the Company and Mylan to oversee and manage the development, manufacture and commercialization of product candidates under the collaboration. Unless otherwise determined by the joint steering committee, it is anticipated that, in collaboration with the other party, (a) the Company will be primarily responsible for nonclinical development activities and initial clinical development activities for product candidates; additional (pivotal or Phase 3 equivalent) clinical development activities for M834; and regulatory activities for product candidates in the United States through regulatory approval; and (b) Mylan will be primarily responsible for additional (pivotal or Phase 3 equivalent) clinical development activities for product candidates other than M834; regulatory activities for the product candidates outside the United States; and regulatory activities for products in the United States after regulatory approval, when all marketing authorizations for the products in the United States will be transferred to Mylan. Mylan will commercialize any approved products, with the Company having an option to co-commercialize, in a supporting commercial role, any approved products in the United States. The joint steering committee is responsible for allocating responsibilities for other activities under the collaboration.

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

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party will have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries. In the case of a termination for convenience, the other party will have the right to continue. If a termination occurs, the licenses granted to the non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that has the right to continue the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

In accordance with Topic 605, the Company identified the deliverables at the inception of the Mylan Collaboration Agreement. The deliverables were determined to include (i) six development and product licenses, for each of M834 and the five additional collaboration products, (ii) research and development services related to each of M834 and the five additional collaboration products and (iii) the Company's participation in the joint steering committee. The Company has determined that each of the license deliverables does not have stand-alone value apart from the related research and development services deliverables because (1) there are no other vendors selling similar, competing products on a stand-alone basis, (2) Mylan does not have the contractual right to resell the license, and (3) Mylan is unable to use the license for its intended purpose without the Company's performance of research and development services. As such, the Company determined that with respect to this arrangement, separate units of accounting exist for each of the six licenses together with the related research and development services, or the combined units of accounting, as well as a separate unit of accounting for participation in the joint steering committee. VSOE and TPE were not available for the combined units of accounting. As such, the Company determined BESP for the combined units of accounting based on an analysis of its existing license arrangements and other available data and the nature and extent of the research and development services to be performed. BESP for the joint steering committee unit of accounting was based on market rates for similar services. At the inception of the Mylan Collaboration Agreement, total arrangement consideration of \$45 million was allocated to each of the units of accounting based on the relative selling price method. Of the \$45 million, \$8.2 million was allocated to the M834 combined unit of accounting, between \$5.7 million and

\$9.0 million to the five additional combined units of accounting, considering the products' stage of development at the time the licenses were delivered, and \$51,000 was allocated to the joint steering committee unit of accounting. Changes in the key assumptions used to determine BESP for the units of accounting would not have a significant effect on the allocation of arrangement consideration.

At the inception of the Mylan Collaboration Agreement, the Company delivered development and product licenses for all six collaboration products and commenced revenue recognition of the arrangement consideration allocated the respective units of accounting. In addition, the Company began revenue recognition for the arrangement consideration allocated to the joint steering committee unit of accounting. The Company is recording revenue on a straight-line basis over the applicable performance period during which the research and development services are expected to be delivered, which begins upon delivery of the development and product license and ends upon FDA approval of the product. The Company currently estimates that the performance period for the M834 unit of accounting is approximately five years, an average of approximately seven years for the additional five combined units of accounting and approximately eight years for the joint steering committee unit of accounting. As of December 31, 2016, \$38.7 million was deferred under this agreement, of which \$7.3 million was included in current liabilities and \$31.4 million was included in non-current liabilities in the consolidated balance sheet.

As the Mylan Collaboration Agreement became effective on February 9, 2016, beginning on February 9, 2016, the Company and Mylan share collaboration expenses. Collaboration costs incurred by the Company are recorded as research and development expense and/or general and administrative expense, depending on the nature of the activities, as incurred. Mylan's share of collaboration expenses is recorded as a reduction in research and development and/or general and administrative expenses in the consolidated statements of operations and comprehensive loss, in accordance with the Company's policy, which is consistent with the nature of the cost reimbursement.

Mylan will initially fund a portion of its 50% share of collaboration expenses through contingent milestone payments of up to \$200 million across the six product candidates and any unused portion of the contingent payment(s) will be available to offset Mylan's 50% share of future collaboration costs. If in a given year a contingent payment is not expected to be made by Mylan and there is no balance available from a prior contingent payment balance as of the beginning of the collaboration year, the parties will reconcile total collaboration expenses on a semi-annual basis and Mylan will make a payment to the Company. For the year ended December 31, 2016, the Company reduced research and development expenses by \$26.5 million and general and administrative expenses by \$1.3 million, representing Mylan's 50% share of collaboration expenses. In the year ended December 31, 2016, the Company received two milestone payments totaling \$60 million, of which \$32.9 million will be applied toward the funding of Mylan's 50% share of certain collaboration expenses yet to be incurred and is included in collaboration advance in the Company's consolidated balance sheet.

## **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, 2016 and 2015, the Company had no shares of preferred stock issued or outstanding.

### ***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, the date the Company received stockholder approval for the plan. 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.

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 and restricted stock awards 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 are granted to employees and board members and generally vest ratably over four years. Performance-based restricted stock awards are granted to employees and vest in connection with the attainment of certain company milestones as described in more detail below under "Restricted Stock Awards". Incentive and non-statutory stock options generally expire ten years after the date of grant.

The total number of shares reserved for issuance under the 2013 Plan equals the sum of: (a) 11,900,000, (b) one share for each share subject to a stock option that was granted through December 31, 2012 under the 2004 Stock Incentive Plan and the Amended and Restated 2002 Stock Incentive Plan (together, the "Prior Plans") that subsequently expires, is forfeited or is settled in cash (up to a maximum of 4,337,882 shares) and (c) 1.67 shares for each share subject to an award other than a stock option that was granted through December 31, 2012 under the Prior Plans and that subsequently expires, is forfeited, is settled in cash or repurchased (up to a maximum of 950,954 shares). As of December 31, 2016, there were 5,372,297 shares available for issuance under the 2013 Plan.

**Share-Based Compensation**

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

The table below presents share-based compensation expense for research and development as well as general and administration included in operating expenses in the years ended December 31, 2016, 2015 and 2014 (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Research and development	\$ 7,558	\$ 5,145	\$ 6,204
General and administrative	10,764	6,295	7,390
Total compensation cost	<u>\$ 18,322</u>	<u>\$ 11,440</u>	<u>\$ 13,594</u>

The following table summarizes share-based compensation expense recorded in the years ended December 31, 2016, 2015 and 2014 (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Outstanding employee and non-employee stock option grants	\$ 9,831	\$ 10,548	\$ 9,617
Outstanding restricted stock awards	8,064	504	3,549
Employee stock purchase plan	427	388	428
Total compensation cost	<u>\$ 18,322</u>	<u>\$ 11,440</u>	<u>\$ 13,594</u>

During the year ended December 31, 2016, the Company granted 1,521,327 stock options, of which 812,302 were granted in connection with annual merit awards, 181,000 were granted to the Company's board of directors, and 528,025 were primarily granted to new hires. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions 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		
	2016	2015	2014	2016	2015	2014
Expected volatility	58%	59%	66%	57%	59%	63%
Expected dividends	—	—	—	—	—	—
Expected life (years)	6.1	6.1	6.1	0.5	0.5	0.5
Risk-free interest rate	1.6%	1.9%	2.2%	0.4%	0.1%	0.1%

The following table presents stock option activity of the 2013 Plan and Prior Plans for the year ended December 31, 2016 :

	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, 2015	6,611	\$ 14.54		
Granted	1,521	11.11		
Exercised	(106)	12.73		
Forfeited	(362)	13.51		
Expired	(655)	16.63		
Outstanding at December 31, 2016	7,009	\$ 13.68	6.04	\$ 14,288
Exercisable at December 31, 2016	4,475	\$ 14.13	4.68	\$ 7,459
Vested or expected to vest at December 31, 2016	6,738	\$ 13.74	5.93	\$ 13,459

The weighted average grant date fair value of option awards granted during 2016 , 2015 and 2014 was \$6.04 , \$8.11 and \$10.51 per option, respectively. The total intrinsic value of options exercised during 2016 , 2015 and 2014 was \$0.2 million , \$11.4 million and \$1.3 million , respectively. At December 31, 2016 , the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to \$13.0 million , including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.5 years . The total fair value of options vested during 2016 , 2015 and 2014 was \$9.9 million , \$9.9 million and \$10.1 million , respectively.

Cash received from option exercises for 2016 , 2015 and 2014 was \$1.4 million , \$23.6 million and \$2.2 million , respectively.

### Restricted Stock Awards

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

During the year ended December 31, 2016 , the Company awarded 407,321 shares of time-based restricted common stock to its employees and officers in connection with its annual merit grant. The time-based restricted common stock 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. The time-based awards are generally forfeited if the employment relationship terminates with the Company prior to vesting.

During the year ended December 31, 2016 , the Company awarded 27,500 shares of time-based restricted common stock to its board members. The time-based restricted common stock vest as to 100% on the one year anniversary of the grant date.

Between 2011 and early 2013, the Company awarded 949,620 shares of performance-based restricted common stock to employees and officers. The performance-based restricted common 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 historically determined that the performance condition was probable of being achieved by March 28, 2015 and, as a result, had recognized approximately \$10.5 million of stock compensation costs related to the awards. On March 11, 2015, the Board of Directors approved an amendment to the awards that extended the performance

deadline date to September 1, 2015 and provided for the forfeiture of 15% of the number of shares originally subject to each award on the 29th of each month, beginning March 29, 2015 until the shares vested or were forfeited in full. On March 29, 2015, 117,898 shares of performance-based restricted common stock were forfeited pursuant to the modified awards. The Company evaluated the modification and determined it was a Type III modification or "Improbable to Probable" pursuant to ASC 718 as the awards, on the date of modification, were no longer deemed to be probable of being earned by March 28, 2015. As a result, the Company reversed the cumulative compensation cost related to the original awards of \$10.5 million in the first quarter of 2015. Also, in accordance with ASC 718, the Company re-measured the modified awards with a measurement date of March 11, 2015, and determined the aggregate compensation was \$9.8 million. The FDA approved the GLATOPA 20 mg/mL ANDA on April 16, 2015. The Company recognized the compensation cost attributed to the modified awards as follows: the first 50% of the awards was expensed over the period beginning on March 11, 2015 and ending on April 16, 2015, the date of FDA approval, and the remaining 50% of the awards was expensed over the period beginning on March 11, 2015 and ending on April 16, 2016, the one year anniversary of FDA approval.

Between April 13, 2016 and December 31, 2016, the Company awarded 1,646,580 shares of performance-based restricted common stock to employees and officers. The vesting of the shares is subject to the Company achieving up to two of three possible performance milestones on or before April 13, 2019. Upon achieving each of the first and second milestones, 25% of the shares will vest on the later of the milestone achievement date and the first anniversary of the grant date, and an additional 25% of the shares will vest on the one year anniversary of such achievement date, subject to a requirement that recipients remain employees through each applicable vesting date. Each quarter, the Company evaluates the probability of achieving the milestones on or before April 13, 2019, and its estimate of the implicit service period over which the fair value of the awards will be recognized and expensed. As a result of discontinuing its necuparanib program in the third quarter of 2016, the Company determined that only two of the three performance milestones are possible to achieve prior to April 13, 2019. However, the Company has determined that attainment of the remaining performance conditions is probable and is expensing the fair value of the shares over the implicit service period using the accelerated attribution method. For the year ended December 31, 2016, the Company recognized approximately \$3.7 million of stock compensation costs related to these awards.

As of December 31, 2016, the total remaining unrecognized compensation cost related to all nonvested restricted stock awards amounted to \$14.6 million, which is expected to be recognized over the weighted average remaining requisite service period of approximately 2 years.

A summary of the status of nonvested shares of restricted stock as of December 31, 2016 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, 2016	761	\$ 14.61
Granted	2,081	10.16
Vested	(519)	14.55
Forfeited	(331)	10.65
Nonvested at December 31, 2016	1,992	\$ 10.63

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2016 are summarized below (in thousands):

<u>Vesting Schedule</u>	<u>Nonvested Shares</u>
Time-based	575
Performance-based	1,417
Nonvested at December 31, 2016	1,992

The total fair value of shares of restricted stock vested during 2016, 2015 and 2014 was \$7.6 million, \$7.9 million and \$2.0 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 1,024,652 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 104,892 shares of common stock to employees under the ESPP during the year ended December 31, 2016. As of December 31, 2016, 742,366 shares of common stock have been issued to the Company's employees under the ESPP, and 282,286 shares remain available for future issuance. 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, 2016, subscriptions were outstanding for an estimated 64,138 shares at a fair value of approximately \$3.61 per share. The weighted average grant date fair value of the offerings during 2016, 2015 and 2014 was \$4.32, \$4.05 and \$4.51 per share, respectively. Cash received from the ESPP for 2016, 2015 and 2014 was approximately \$1.1 million, \$1.0 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. Furthermore, 1,417,230 performance-based restricted common stock awards that were granted between April 13, 2016 and December 31, 2016 had not vested as of December 31, 2016, and were excluded from diluted shares outstanding as the vesting conditions for the awards, discussed further in Note 11 "*Share-Based Payments - Restricted Stock Awards*," had not been met as of December 31, 2016.

The following table presents anti-dilutive shares for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	2016	2015	2014
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	6,569	4,148	5,941
Restricted stock awards	1,202	519	847

## 13. Income Taxes

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 establishes a valuation allowance when uncertainty exists as to whether all or a portion of the net deferred tax assets will be realized. Components of the net deferred tax (liability) asset at December 31, 2016 and 2015 are as follows, in thousands:



	2016	2015
Deferred tax assets:		
Federal and state net operating losses	\$ 94,793	\$ 115,606
Research credits	30,007	23,088
Deferred compensation	9,701	10,031
Deferred revenue	28,096	8,635
Accrued expenses	5,053	3,023
Intangibles	3,220	3,300
Depreciation	475	686
Unrealized loss on marketable securities	—	1
Total deferred tax assets	171,345	164,370
Deferred tax liabilities:		
Unrealized gain on marketable securities	(30)	—
Total deferred tax liabilities	(30)	—
Valuation allowance	(171,315)	(164,370)
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, 2016, 2015 and 2014 is as follows (in thousands):

	2016	2015	2014
Benefit at federal statutory tax rate	\$ (7,137)	\$ (28,323)	\$ (33,521)
State taxes, net of federal benefit	(1,108)	(4,398)	(5,206)
Share-based compensation	5,148	3,634	2,411
Tax credits	(4,120)	(2,652)	(5,529)
Other	272	42	23
Change in valuation allowance	6,945	31,697	41,822
Income tax provision	\$ —	\$ —	\$ —

The Company generated U.S. taxable income during the years ended December 31, 2011 and 2010, and as a result, utilized \$190.9 million and \$26.3 million, respectively, of its historical available federal net operating loss carryforwards that were generated from 2001 to 2009 to offset this income.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. 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. Accordingly, the Company has recorded a full valuation allowance against the deferred tax assets as management believes the assets may not be realized. The Company reevaluates the positive and negative evidence on an annual basis. The valuation allowance increased by \$6.9 million for the year ended December 31, 2016 due primarily to the current period net loss.

At December 31, 2016, the Company had federal and state net operating loss carryforwards of \$260.7 million and \$233.8 million, respectively, available to reduce future taxable income that will expire at various dates through 2036. Of this amount, approximately \$15.8 million of federal and state net operating loss carryforwards relate to stock option deductions for which the related tax benefit will be recognized in equity when realized. At December 31, 2016, the Company had federal and state research and development and other credit carryforwards, including the orphan drug credit, of \$29.1 million and \$11.0 million, respectively, available to reduce future tax liabilities that expire at various dates through 2036. 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, 2016 and 2015 is as follows (in thousands):

	2016	2015	2014
Balance, beginning of year	\$ 5,116	\$ 4,064	\$ 4,465
Additions for tax positions related to the current year	1,602	1,395	940
Reductions of tax positions of prior years	(40)	(343)	(1,341)
Balance, end of year	\$ 6,678	\$ 5,116	\$ 4,064

As of December 31, 2016 and 2015, the Company had \$6.7 million and \$5.1 million of gross unrecognized tax benefits, respectively, of which \$6.4 million and \$4.9 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's policy is to recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company has not recognized any interest and penalties.

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.

The Company files income tax returns in the United States federal jurisdiction and in the Massachusetts jurisdiction. The Company is no longer subject to any tax assessment from an income tax examination for years before 2013, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2013.

In March 2012, the Company entered into a Tax Incentive Agreement with the Massachusetts Life Sciences Center, or MLSC, under the MLSC's Life Sciences Tax Incentive Program, or the Program, to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences in the Commonwealth of Massachusetts. The Program was established in 2008 in order to incentivize life sciences companies to create new sustained jobs in Massachusetts. Under the Tax Incentive Agreement, companies receive an award from the MLSC upon attaining job creation commitment. Jobs had to be maintained for at least five years, 2012 - 2016, during which time a portion of the grant proceeds can be recovered by the Massachusetts Department of Revenue if the Company did not maintain its job creation commitments. As the Company maintained its job creation commitment for five years, it recorded one-fifth of the \$1.1 million job creation tax award, or \$0.2 million, on a straight-line basis over the five year period as other income.

#### 14. 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 \$18.5 million, \$16.4 million and \$16.3 million for the years ended December 31, 2016, 2015 and 2014, respectively.

In September 2004, the Company entered into an agreement with Vertex Pharmaceuticals, or Vertex, to lease 53,323 square feet of office and laboratory space located on the fourth and fifth floors at 675 West Kendall Street, Cambridge, Massachusetts, for an initial term of 80 months, or the West Kendall Sublease. In November 2005, the Company amended the West Kendall Sublease to lease an additional 25,131 square feet through April 2011. In April 2010, the Company exercised its right to extend the West Kendall Sublease for one additional term of 48 months. During the extension term, which commenced on May 1, 2011, annual rental payments increased by approximately \$1.2 million over the previous annual rental rate. In July 2014, the Company and Vertex entered into an agreement to extend the term of the West Kendall Sublease from May 1, 2015 through April 30, 2018, or such other earlier date as provided in accordance with the West Kendall Sublease. During the extension term, annual rental payments are approximately \$4.8 million.

On February 5, 2013, the Company and BMR-Rogers Street LLC, or BMR, entered into a lease agreement, or the Bent Street Lease, to lease 104,678 square feet of office and laboratory space located in the basement and first and second floors at 320 Bent Street, Cambridge, Massachusetts, beginning on September 1, 2013 and ending on August 31, 2016. Annual rental payments due under the lease were approximately \$6.1 million during the first lease year, \$6.2 million during the second lease year and \$6.3 million during the third lease year. BMR agreed to pay the Company a tenant improvement allowance of \$0.7 million for reimbursement of laboratory and office improvements made by the Company (and subsequently reimbursed by BMR). The Company has recorded short and long-term liabilities for the construction allowance in its consolidated balance sheet, which is being amortized on a straight-line basis through a reduction to rental expense over the term of the lease. The

Company had two consecutive options to extend the term of the lease for one year each at the then-current fair market value. In addition, the Company has two additional consecutive options to extend the term of the lease for five years each for the office and laboratory space located in the basement portion of the leased space at the then-current fair market value. In October 2015, the Company exercised its option to extend the term of the lease for one year to August 31, 2017.

On December 30, 2015, the Company and BMR entered into an amendment ("the Amendment") to the Bent Street Lease. The Amendment voids the October 2015 option exercise and extends the expiration date of the lease term from August 31, 2016 to February 28, 2027. Under the Amendment, the Company is not required to pay BMR any base rent from September 1, 2016 through February 28, 2017, however the Company is required to pay BMR certain operating expenses. Beginning on March 1, 2017 and ending on August 31, 2017, the Company is obligated to pay BMR an initial monthly base rent of approximately \$0.6 million, or \$68.00 per square foot. The Company's monthly base rent will increase by three percent of the then-current base rent on September 1 of each year during the extended term of the lease, beginning on September 1, 2017. During the period from September 1, 2016 through June 30, 2018, BMR has agreed to pay the Company a tenant improvement allowance not to exceed \$4.7 million for reimbursement of certain laboratory and office improvements.

On September 14, 2016, the Company entered into a sublease with Biogen MA Inc., or Biogen, pursuant to which the Company will sublease approximately 79,683 square feet of office and laboratory space on the fifth floor of 301 Binney Street, Cambridge, Massachusetts. Biogen leases the premises from BMR pursuant to a lease agreement dated as of March 31, 2015, as amended. The term of the sublease will commence on January 1, 2018, and will expire on June 29, 2025, unless terminated earlier in accordance with the terms of the sublease. Over the term of the sublease, the Company is obligated to pay monthly base rent of \$504,659, or \$76 per square foot, increasing by approximately 3% of the then-current monthly base rent on each of January 1, 2019, and January 1, 2020, and approximately 1.85% thereafter on January 1 of each of the remaining years of the term. In addition, the Company is obligated to pay certain costs and expenses otherwise payable by Biogen under their lease. Simultaneous with the execution of the sublease, the Company delivered a security deposit to Biogen in the form of an irrevocable standby letter of credit in the amount of approximately two months of the monthly base rent at the average rate per square foot.

Total operating lease commitments as of December 31, 2016 are as follows (in thousands):

	<b>Operating Leases</b>
2017	\$ 11,144
2018	15,369
2019	14,165
2020	14,581
2021	14,935
2022 and beyond	70,004
<b>Total future minimum lease payments</b>	<b>\$ 140,198</b>

## Legal Contingencies

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

### *GLATOPA 40 mg/mL-Related Litigation*

On September 10, 2014, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and sought declaratory and injunctive relief prohibiting the launch of the Company's product until the last to expire of these patents. In April 2015, Teva and Yeda filed an additional suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the

initial suit that was filed in September 2014. In November 2015, Teva and Yeda filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. In December 2015, this suit was also consolidated with the initial suit that was filed in September 2014. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of these patents. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017, decision to the Court of Appeals for the Federal Circuit.

On December 19, 2016, Teva and Yeda filed suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware again in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL for alleged infringement of an Orange Book-listed patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,402,874. On January 31, 2017, Teva filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, which issued in October 2015 and expires in October 2035. The Company and Sandoz Inc. filed a motion to dismiss and a motion to transfer the suit to the United States District Court for the District of Delaware. On January 31, 2017, Teva voluntarily dismissed the Company from the New Jersey suit, maintaining the suit against Sandoz Inc. 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. On February 17, 2017, Teva filed a motion for preliminary injunction against Sandoz Inc. in the New Jersey suit for U.S. Patent No. 9,155,775.

#### *Enoxaparin Sodium Injection-related Litigation*

On September 21, 2011, the Company and Sandoz Inc. sued Amphastar and Actavis in the United States District Court for the District of Massachusetts for infringement of two of the Company's patents. Also in September 2011, the Company filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar and Actavis from selling their Enoxaparin product in the United States. In October 2011, the District Court granted the Company's motion for a preliminary injunction and entered an order enjoining Amphastar and Actavis from advertising, offering for sale or selling their Enoxaparin product in the United States until the conclusion of a trial on the merits and required the Company and Sandoz Inc. to post a security bond of \$100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded the case to the District Court. In September 2012, the Company filed a petition with the CAFC for a rehearing by the full court *en banc*, which was denied. In February 2013, the Company filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court which was denied in June 2013.

In July 2013, the District Court granted a motion by Amphastar and Actavis for summary judgment. The Company filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling, which the CAFC denied in May 2014. On November 10, 2015, the CAFC affirmed the District Court summary judgment decision with respect to Actavis, reversed the District Court summary judgment decision with respect to Amphastar, and remanded the case against Amphastar to the District Court. On January 11, 2016, Amphastar filed a petition for rehearing by the CAFC, which was denied on February 17, 2016. On May 17, 2016, Amphastar filed a petition for writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied on October 3, 2016. The District Court trial is scheduled to begin on July 10, 2017. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company is not successful in further prosecution or settlement of this action against Amphastar, and Amphastar is able to prove they suffered damages as a result of the preliminary injunction, the Company could be liable for damages for up to \$35 million of the security bond. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz Inc. will prevail in this patent enforcement suit.

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

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against the Company and Sandoz Inc. in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic Enoxaparin Sodium Injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz Inc. sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. Hearings on the motions were held before a US magistrate in April 2016 and February 2016, respectively. On September 29, 2016, the magistrate judge filed a Report and Recommendation to the District Court to deny the motions to dismiss and to transfer. These motions are subject to briefing and review by the District Court. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and it intends to vigorously defend itself in this litigation.

#### **15. 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. In March 2005, the Company's Board of Directors approved a match of 50% of the first 6% contributed by employees, effective for the 2004 plan year and thereafter. The Company recorded \$1.0 million, \$0.9 million and \$0.9 million of such match expense in the years ended December 31, 2016, 2015 and 2014, respectively.

#### **16. Equity Financings**

In May 2015, the Company sold an aggregate of 8,337,500 shares of its common stock through an underwritten public offering at a price to the public of \$19.00 per share. As a result of the offering, which included the full exercise of the underwriters' option to purchase additional shares, the Company received aggregate net proceeds of approximately \$148.4 million, after deducting underwriting discounts and commissions and other offering expenses.

In May 2014, the Company entered into an At-the-Market Equity Offering Sales Agreement, or the 2014 ATM Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which the Company was authorized to issue and sell shares of its common stock having aggregate sales proceeds of up to \$75 million from time to time through Stifel, acting as sales agent and/or principal. The Company paid Stifel a commission of 2.0% of the gross proceeds from the sale of shares of its common stock under this facility. The offering was conducted by the Company pursuant to an effective shelf registration statement previously filed with the Securities and Exchange Commission (Reg. No. 333-188227) and a related prospectus supplement. The Company concluded sales under the 2014 ATM Agreement in April 2015. In the year ended December 31, 2014, the Company sold approximately 1.6 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately \$18.3 million. In the year ended December 31, 2015, the Company sold approximately 3.8 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately \$55.2 million.

In April 2015, the Company entered into a new ATM Agreement, or the 2015 ATM Agreement, with Stifel, under which the Company is authorized to issue and sell shares of its common stock having aggregate sales proceeds of up to \$75 million from time to time through Stifel, acting as sales agent and/or principal. The Company is required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of its common stock under the 2015 ATM Agreement. Sales of common stock under this facility are made pursuant to an effective shelf registration statement previously filed with the Securities and Exchange Commission (Reg. No. 333-188227) and a related prospectus supplement. In the year December 31, 2015, the Company sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement, raising aggregate net proceeds of approximately \$9.3 million. No shares were sold under the 2015 ATM Agreement for the year ended December 31, 2016.

**17. Selected Quarterly Financial Data (Unaudited)**

(in thousands, except per share data)	Quarter Ended			
	March 31	June 30	September 30	December 31
<b>2016</b>				
Product revenue	\$ 14,800	\$ 20,692	\$ 23,339	\$ 15,817
Research and development revenue	\$ 5,050	\$ 5,738	\$ 5,805	\$ 18,378
Total collaboration revenue	\$ 19,850	\$ 26,430	\$ 29,144	\$ 34,195
Net (loss) income	\$ (24,012)	\$ (20,986)	\$ (17,544)	\$ 41,539
Comprehensive (loss) income	\$ (23,879)	\$ (20,837)	\$ (17,580)	\$ 41,375
Net (loss) income per share:				
Basic	\$ (0.35)	\$ (0.31)	\$ (0.26)	\$ 0.60
Diluted	\$ (0.35)	\$ (0.31)	\$ (0.26)	\$ 0.60
Shares used in calculating net (loss) income per share:				
Basic	68,285	68,532	68,799	69,003
Diluted	68,285	68,532	68,799	69,362
<b>2015</b>				
Product revenue	\$ 2,722	\$ 19,305	\$ 8,666	\$ 17,810
Research and development revenue	\$ 5,840	\$ 25,595	\$ 5,129	\$ 4,583
Total collaboration revenue	\$ 8,562	\$ 44,900	\$ 13,795	\$ 22,393
Net loss	\$ (21,877)	\$ (2,222)	\$ (30,050)	\$ (29,164)
Comprehensive loss	\$ (21,859)	\$ (2,204)	\$ (30,054)	\$ (29,176)
Basic and diluted net loss per common share	\$ (0.40)	\$ (0.04)	\$ (0.44)	\$ (0.43)
Shares used in computing basic and diluted net loss per common share	54,492	61,680	68,004	68,138

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.

**18. Subsequent Events****Pfizer FDA Warning Letter**

On February 17, 2017, the Company announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States; however, the FDA may withhold approval of pending drug applications listing the facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. The Company therefore believes that an approval of the GLATOPA 40 mg/mL ANDA in the first quarter of 2017 is unlikely.

**CSL License and Option Agreement**

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

Pursuant to the terms of the CSL License Agreement, CSL has agreed to pay the Company a non-refundable upfront payment of \$50 million. For the development and commercialization of M230, the Company is eligible to receive up to \$550



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

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

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

Unless earlier terminated, the term of the CSL License Agreement commences on the Effective Date and continues until the later of (i) the expiration of all payment obligations with respect to products under the CSL License Agreement, (ii) the Company is no longer co-funding development or commercialization of any products and (iii) the Company and CSL are not otherwise collaborating on the development and commercialization of products or product candidates. CSL may terminate the CSL License Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. The Company may terminate the CSL License Agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the CSL License Agreement. Either party may terminate the CSL License Agreement (i) on a product-by-product basis if certain patent challenges are made, (ii) on a product-by-product or country-by-country basis for material breaches, or (iii) due to the other party's bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, the Company or CSL has the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

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

## **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, 2016. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2016, 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, 2016, based on the criteria set forth in the Committee of Sponsoring Organizations of the Treadway Commission (COSO)'s updated 2013 framework entitled "Internal Control—Integrated Framework." Based on its assessment, our management concluded that, as of December 31, 2016, 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.

### **Report of Independent Registered Public Accounting Firm**

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

We have audited Momenta Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016, 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). Momenta Pharmaceuticals, Inc.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, Momenta Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Momenta Pharmaceuticals, Inc. as of December 31, 2016 and 2015, and 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, 2016 of Momenta Pharmaceuticals, Inc. and our report dated February 24, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 24, 2017

### **Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting during the quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.

## 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 2017 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](http://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 2017 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 2017 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 2017 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 2017 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 2017 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

**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:

	<u>Page number in this report</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">67</a>
<a href="#">Consolidated Balance Sheets at December 31, 2016 and 2015</a>	<a href="#">68</a>
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2016, 2015 and 2014</a>	<a href="#">69</a>
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016, 2015 and 2014</a>	<a href="#">70</a>
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014</a>	<a href="#">72</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">73</a>

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 in the Exhibit Index immediately preceding the Exhibits are filed as a part of this Annual Report on Form 10-K.

**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 24, 2017

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ CRAIG A. WHEELER</u> Craig A. Wheeler	President, Chief Executive Officer and Director (Principal Executive Officer)	February 24, 2017
<u>/s/ SCOTT M. STORER</u> Scott M. Storer	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 24, 2017
<u>/s/ JAMES SULAT</u> James Sulat	Chairman of the Board of Directors	February 24, 2017
<u>/s/ GEORGES GEMAYEL, Ph.D.</u> Georges Gemayel, Ph.D.	Director	February 24, 2017
<u>/s/ BRUCE DOWNEY</u> Bruce Downey	Director	February 24, 2017
<u>/s/ THOMAS KOESTLER, Ph.D.</u> Thomas Koestler, Ph.D.	Director	February 24, 2017
<u>/s/ COREY N. FISHMAN</u> Corey N. Fishman	Director	February 24, 2017
<u>/s/ ELIZABETH STONER, M.D.</u> Elizabeth Stoner, M.D.	Director	February 24, 2017
<u>/s/ STEVEN C. GILMAN, Ph.D.</u> Steven C. Gilman, Ph.D.	Director	February 24, 2017
<u>/s/ JOSE-CARLOS GUTIERREZ-RAMOS, Ph.D.</u> Jose-Carlos Gutierrez-Ramos, Ph.D.	Director	February 24, 2017

**EXHIBIT INDEX**

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
<b>Articles of Incorporation and By-Laws</b>					
3.1	Third Amended and Restated Certificate of Incorporation	S-3	3.1	4/30/2013	333-188227
3.2	Certificate of Designations of Series A Junior Participating Preferred Stock of the Registrant	8-K	3.1	11/8/2005	000-50797
3.3	Third Amended and Restated By-Laws	8-K	3.1	12/15/2014	000-50797
<b>Instrument Defining the Rights of Security Holders</b>					
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	4.1	6/15/2004	333-113522
<b>Material Contracts—Collaboration and License Agreements</b>					
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
10.4	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†	Development, License and Option Agreement by and between the Registrant and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA dated December 22, 2011	10-K	10.21	2/28/2012	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†	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.				
<b>Material Contracts—Management Contracts and Compensation Plans</b>					
10.8#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.9#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.10#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.11#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797
10.12#	Form of Restricted Stock Agreement Under 2004 Stock Incentive Plan	8-K	10.2	2/28/2008	000-50797
10.13#	2004 Employee Stock Purchase Plan (as amended and restated)	8-K	10.2	6/17/2014	000-50797

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
*10.14#	Non-Employee Director Compensation Summary				
10.15#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.15.1#	Amendment dated 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
10.16#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.16.1#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.9	11/8/2006	000-50797
10.17#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.10	11/8/2006	000-50797
10.18#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/8/2007	000-50797
10.19#	Form of Employment Agreement for executive officers	10-Q	10.3	5/9/2008	000-50797
10.20#	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
10.21#	Form of Amendment to the Employment Agreement for executive officers dated December 15, 2010	10-K	10.39	3/10/2011	000-50797
10.22#	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
10.23#	Form of Restricted Stock Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan	8-K	10.1	4/1/2011	000-50797
10.24#	Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan (as amended and restated)	10-Q	10.2	8/5/2016	000-50797
10.25#	Form of Stock Option Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan	8-K	10.1	6/13/2013	000-50797
10.26#	Form of Restricted Stock Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan	8-K	10.2	6/13/2013	000-50797
*10.27#	Form of Restricted Stock Unit Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan				
10.28#	Momenta Pharmaceuticals, Inc. Equity Award Retirement Policy	8-K	10.1	12/16/2016	000-50797
*10.29#	Executive Employment Agreement, effective as of October 27, 2016, by and between the Registrant and Scott M. Storer				
*10.30#	Industry Consulting Agreement, dated as of December 30, 2016, by and between the Registrant and Richard P. Shea				
	<b>Material Contracts—Leases</b>				
10.31†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.31.1	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
10.31.2	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



Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.31.3	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
10.31.4	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
10.31.5	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
10.32	Lease, dated February 5, 2013, by and between BMR-Rogers Street LLC and the Registrant	10-Q	10.1	5/10/2013	000-50797
10.32.1	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
10.32.2	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
10.32.3	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
10.33	Sublease, between Biogen MA Inc. and the Registrant, dated September 14, 2016	10-Q	10.1	11/4/2016	000-50797
<b>Material Contracts—At-the-Market Facility</b>					
10.34	At-The-Market Equity Offering Sales Agreement, dated as of April 21, 2015, by and between the Registrant and Stifel, Nicolaus & Company, Incorporated	8-K	10.1	4/21/2015	000-50797
<b>Additional Exhibits</b>					
*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.				

\* Filed herewith.

\*\* Furnished herewith

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- † 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, 2016, filed with the SEC on February 24, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2016, 2015 and 2014, (ii) the Consolidated Balance Sheets as of December 31, 2016 and 2015, (iii) the Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016, 2015 and 2014 and (v) Notes to Consolidated Financial Statements.

Confidential Treatment Requested by Momenta Pharmaceuticals, Inc.

EXECUTION COPY

**ASSET RETURN AND TERMINATION AGREEMENT**

This Asset Return and Termination Agreement (this “Agreement”), effective as of December 31, 2016 (the “Effective Date”), is made by and between Momenta Pharmaceuticals, Inc., a Delaware corporation (“Momenta”), Baxalta Incorporated, a Delaware corporation (“BI”), Baxalta US Inc., a Delaware corporation (“BUSI”), and Baxalta GmbH, a Swiss corporation (“BGMBH” and, together with BI and BUSI, collectively, “Baxalta”). Momenta and Baxalta are sometimes referred to herein individually as a “Party” and collectively as the “Parties”.

**RECITALS**

**WHEREAS**, Momenta, Baxter International Inc. (“BII”), Baxter Healthcare Corporation (“BHC”), and Baxter Healthcare SA (“BHSA”) entered that certain Development, License and Option Agreement dated as of December 22, 2011 (as amended, the “Original Agreement”), and BII, BHC, and BHSA subsequently assigned the Original Agreement to BI, BUSI, and BGMBH, respectively, on July 1, 2015;

**WHEREAS**, Momenta and BHC entered into that certain Quality Agreement, effective October 25, 2013 (the “Quality Agreement”), and BHC subsequently assigned the Quality Agreement to BUSI on July 1, 2015;

**WHEREAS**, pursuant to the Original Agreement, the Parties agreed to Develop and Commercialize (a) Momenta’s development compound referred to as “M923”, a monoclonal antibody product for which adalimumab (Humira<sup>®</sup>) is the reference brand product (“M923”), and (b) Momenta’s development compound referred to as “M834”, a fusion protein for which abatacept (Orencia<sup>®</sup>) is the reference brand product (“M834”), and whereas the Development and Commercialization of M834 was previously terminated in accordance with the Original Agreement;

**WHEREAS**, on September 26, 2016, Baxalta delivered to Momenta a written notice of termination of the Original Agreement in its entirety pursuant to Section 10.2(c) of the Original Agreement (the “Termination Notice”) and, pursuant to the terms of the Original Agreement, in the absence of this Agreement, such termination would be effective on September 27, 2017 (the “Original Termination Date”); and

**WHEREAS**, the Parties desire to effect an earlier termination of the Original Agreement, an earlier return to Momenta of all rights to M923 and an assignment of certain contracts to Momenta, and an early termination of the Quality Agreement, in each case pursuant to the terms and subject to the conditions set forth in this Agreement.

**AGREEMENT**

**NOW, THEREFORE**, in consideration of the foregoing recitals, which are incorporated into this Agreement, the mutual agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

**ARTICLE 1  
DEFINITIONS**

Capitalized terms not defined herein shall have the meanings ascribed to them in the Original Agreement, a copy of which is attached hereto as Exhibit A. As used herein, the following terms have the meanings set forth below:

“Aggregate Transition Services Development Expenses and Commercialization Costs” shall mean *the sum of* (a) the costs actually incurred by or on behalf of Baxalta, including, without limitation, all FTE Costs and out-of-pocket costs paid by Baxalta to a Third Party (collectively) after the Effective Date in connection with the Development of M923, in accordance with this Agreement, as determined from the books and records of Baxalta and/or its Affiliates maintained in accordance with the Accounting Standards and Baxalta’s policies and practices as such may be modified from time to time, *plus* (b) the out-of-pocket costs paid by Baxalta to a Third Party related to Commercialization and FTE Costs actually incurred, after the Effective Date, in

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Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

connection with the Commercialization of M923 by or on behalf of Baxalta, in accordance with this Agreement, as determined from the books and records of Baxalta and/or its Affiliates maintained in accordance with the Accounting Standards; provided, that, for the avoidance of doubt, "Aggregate Transition Services Development Expenses and Commercialization Costs" shall not include (x) any Development and Commercialization costs included in the Asset Return Payment or (y) any Development Expenses and Commercialization Costs incurred during the period beginning on the Original Effective Date and through the Effective Date.

"Agreement" has the meaning set forth in the preamble.

"Allocable Legal Expense Share of the Legal Expenses" shall mean \$[\*\*\*].

"Asset Return Payment" has the meaning set forth in Section 3.1.

"Assigned Agreement" has the meaning set forth on Exhibit C.

"Baxalta" has the meaning set forth in the preamble.

"Baxalta's Knowledge" shall mean the actual knowledge, as of the Effective Date, of Baxalta employees [\*\*\*], Sr. Director, Alliance Management, and [\*\*\*], Business Development, Finance Lead.

"Baxalta Indemnitees" has the meaning set forth in Section 7.2.

"Baxalta Innovations" shall mean Baxalta Innovations GmbH, a wholly-owned subsidiary of BI.

"Baxalta Losses" has the meaning set forth in Section 7.2.

"Baxalta Personnel" shall mean the specific Baxalta Personnel set forth on Exhibit D.

"BI" has the meaning set forth in the preamble.

"BII" has the meaning set forth in the recitals.

"BGMBH" has the meaning set forth in the preamble.

"BHC" has the meaning set forth in the recitals.

"BHSA" has the meaning set forth in the recitals.

"BUSI" has the meaning set forth in the preamble.

"Clinical Transition Services" shall mean the services performed by Baxalta pursuant to Section 4.1.

"Clinical Transition Services Term" shall mean the period beginning on the Effective Date and ending on the Last Safety Visit Date, such Last Safety Visit Date expected to be no later than April 17, 2017.

"Clinical Trials" shall mean clinical trial numbers 911301, 911401, 911501 and 911502, as such clinical trials are numbered under the Quintiles Agreement, which are being conducted under the Quintiles Agreement.

"Confidential Information" shall mean (a) all proprietary information and materials, patentable or otherwise, of a Party which is disclosed by or on behalf of such Party to the other Party pursuant to and in contemplation of this Agreement, including, without limitation, biological or chemical substances, formulations, techniques, methodology, equipment, data, reports, know-how, sources of supply, patent positioning and business plans, including any negative developments, and (b) any other information designated by the disclosing Party to the other Party in writing as confidential or proprietary, whether or not related to making, using or selling a Product.

Notwithstanding the foregoing, the term “Confidential Information” shall not include information: (w) which is or becomes generally available to the public other than as a result of disclosure thereof by the receiving Party; (x) which is lawfully received by the receiving Party on a non-confidential basis from a Third Party that is not, to the receiving Party’s knowledge, itself under any obligation or confidentiality or nondisclosure to the disclosing Party or any other Person with respect to such information; (y) which is already known to the receiving Party at the time of disclosure by the disclosing Party; or (z) which can be shown by the receiving Party to have been independently developed by the receiving Party without reference to the disclosing Party’s Confidential Information.

“Effective Date” has the meaning set forth in the preamble.

“Inquiry Period” shall mean the period beginning on the Effective Date and ending on the Original Termination Date.

“Inquiry Topic Period” shall mean the period beginning on December 22, 2011 and ending on the Effective Date or, in the case of the Regulatory Services and the Clinical Services, the last date of the Regulatory Transition Services Term or the Clinical Transition Services Term, as applicable.

“Last Safety Visit Date” shall mean the date on which all patients in the Clinical Trials have attended all of their safety follow-up visits with respect to such Clinical Trials.

“Legal Activities Letter Agreement” has the meaning set forth in Section 2.4.

“M834” has the meaning set forth in the recitals.

“M923” has the meaning set forth in the recitals.

“Momenta” has the meaning set forth in the preamble.

“Momenta Indemnitees” has the meaning set forth in Section 7.1.

“Momenta Losses” has the meaning set forth in Section 7.1.

“Original Agreement” has the meaning set forth in the recitals.

“Original Effective Date” shall mean February 13, 2012.

“Original Termination Date” has the meaning set forth in the recitals.

“Party” or “Parties” has the meaning set forth in the preamble.

“Quintiles” shall mean Quintiles, Inc.

“Quintiles Agreement” shall mean that certain Strategic Partnership Agreement, dated July 29, 2014, between Quintiles and Baxalta Innovations, as amended through the Effective Date, together with related Work Orders (as amended through the Effective Date) entered into by Quintiles and Baxalta Innovations regarding the Clinical Trials.

“Regulatory Transition Services” shall mean the services performed by Baxalta pursuant to Section 4.2.

“Regulatory Transition Services Term” shall mean the period beginning on the Effective Date and ending upon the completion of the activities set forth on Exhibit F hereto, such end date expected to be on or about March 15, 2017.

“Securities Filing” has the meaning set forth in Section 6.2.

“September 2016 Disclosure of Confidential Information Letter Agreement” has the meaning set forth in Section 2.4.

“Termination Notice” has the meaning set forth in the recitals.

“Total Reimbursement Payment” has the meaning set forth in Section 2.3.

“Transition Period” has the meaning set forth on Exhibit E hereto.

“Unplanned Costs” has the meaning set forth in Section 3.8.

“VAT” has the meaning set forth in Section 3.3.

## ARTICLE 2 TERMINATION

2.1 Termination Date for Original Agreement. Notwithstanding anything to the contrary in the Original Agreement (including, without limitation, in Section 10.1 (Term) and Section 10.2(c) (Termination Prior to First Regulatory Approval) of the Original Agreement), and in accordance with Section 12.7 (Complete Agreement) of the Original Agreement, the “Termination Date” for all purposes under the Original Agreement shall be December 31, 2016 and no provisions of the Original Agreement will thereafter be of any force or effect except to the extent otherwise expressly provided in Section 10.9 (Survival) of the Original Agreement or herein. The Parties acknowledge and agree that the termination of the Original Agreement is pursuant to Section 10.2(c) of the Original Agreement and that Momenta is hereby waiving the 12-month termination notice period set forth in Section 10.2(c) of the Original Agreement.

2.2 Consequences of Termination. For the avoidance of doubt, all applicable provisions of the Original Agreement that, in accordance with its terms, survive termination of the Original Agreement (including, without limitation, Section 10.6(a) and Section 10.6(c)(ii) of the Original Agreement), shall survive in accordance with the terms of the Original Agreement, except to the extent expressly otherwise provided herein. Without limiting the foregoing in this Section 2.2, and subject to Section 4.3 below, Baxalta shall use Commercially Reasonable Efforts to deliver or otherwise transfer to Momenta or its designee the materials, documents and records set forth on Exhibit H hereto, in each case no later than January 31, 2017 (except as otherwise expressly provided on Exhibit H hereto), and in each case, except to the extent expressly provided otherwise in the Original Agreement, strictly on an “as-is” basis as of the date of transfer and without any representations or warranties (whether express or implied) with respect thereto; provided, that for the avoidance of doubt, the Parties shall have the obligations with respect to the costs and expenses of the foregoing deliveries and transfers as set forth in Section 10.6(a) of the Original Agreement.

2.3 Baxalta Development Expenses and Commercialization Costs. The Parties acknowledge and agree that, for purposes of Section 10.6(c)(ii) of the Original Agreement and notwithstanding anything to the contrary in Section 10.6(c)(ii) of the Original Agreement, “Baxter’s Development Expenses and Commercialization Costs” with respect to the Development and Commercialization of M923 that are reimbursable through the royalty mechanism set forth in Section 10.6(c) of the Original Agreement *shall equal the sum of* (a) the Development Expenses and Commercialization Costs incurred from the Original Effective Date through the Effective Date, such amount agreed by the Parties to be [\*\*\*] dollars (\$[\*\*\*]), *plus* (b) the lesser of (i) the Aggregate Transition Services Development Expenses and Commercialization Costs and (ii) [\*\*\*] dollars (\$[\*\*\*]) (provided, that within thirty (30) days after the conclusion of the Clinical Transition Services Term or the Regulatory Transition Services Term, whichever last concludes, Baxalta shall provide Momenta with a final written report setting forth, in reasonable detail, the Aggregate Transition Services Development Expenses and Commercialization Costs), *plus* (c) the Asset Return Payment, *minus* (d) the Allocable Legal Expense Share of the Legal Expenses (such result of (a) + (b) + (c) – (d), the “Total Reimbursement Payment”). For the sake of clarity, such Total Reimbursement Payment to exclude any costs of Third Party financings and those Legal Expenses incurred by Baxalta in accordance with Section 5.3 of the Original Agreement.

2.4 Termination of Other Agreements. Except for the (a) Disclosure of Confidential Information to Third Parties letter agreement dated September 27, 2016 (the “September 2016 Disclosure of Confidential Information Letter Agreement”) and (b) legal activities letter agreement dated December 15, 2016 (the “Legal Activities Letter Agreement”), the Quality Agreement and each other ancillary agreement, arrangement or understanding under or contemplated by the Original Agreement or the Quality Agreement are hereby terminated in their entirety and shall have no further force or effect, and all rights and obligations of the Parties and their Affiliates thereunder shall cease and terminate.

### ARTICLE 3 PAYMENTS; ASSIGNMENT

3.1 Asset Return Payment. In order to fund Baxalta’s (a) Allocable Legal Expense Share of the Legal Expenses and (b) the Development and Commercialization activities, in each case of (a) and (b), the costs for which would have been incurred by Baxalta under the Original Agreement for the period beginning on the Effective Date and ending on the Original Termination Date, Baxalta shall pay to Momenta a one-time cash payment in the amount of fifty one million two hundred thousand dollars (\$51,200,000.00) (the “Asset Return Payment”) within ten (10) business days after the Effective Date. The Asset Return Payment, together with the services provided by Baxalta pursuant to Article 4 below and any amounts set off against the Total Reimbursement Payment pursuant to Section 3.8 below, shall fully satisfy Baxalta’s obligations to perform Development and Commercialization activities under the Original Agreement through the Original Termination Date, and neither Baxalta nor any of its Affiliates shall have any further obligations to fund any Development, Commercialization or other activities with respect to any of the Products under the Original Agreement. During the period beginning on the Effective Date and ending on the Original Termination Date, Momenta shall use Commercially Reasonable Efforts to further Develop and Commercialize M923.

3.2 Payment Terms. The Asset Return Payment shall be made by electronic wire transfer of immediately available funds to the account, and pursuant to the instructions, set forth on Exhibit B to this Agreement.

3.3 Tax Matters. The Parties shall use all reasonable and legal efforts to minimize income tax, withholding tax, and value added tax (“VAT”) exposure on all payments made pursuant to this Agreement. All amounts payable under this Agreement are exclusive of VAT or any other sales tax or duties. The Parties are not obligated to charge VAT on any such payments as the place of supply is outside of Switzerland (in the case of payments made or received by Baxalta GmbH) or because the paying or receiving Party is neither registered nor obligated to register for VAT or any equivalent in any jurisdiction. Each Party agrees to cooperate in good faith to provide the other Party with such documents and certifications as are reasonably necessary to enable such other Party to minimize any withholding tax or VAT obligations and/or liabilities. The Parties will reasonably cooperate in providing one another with documentation of the payment of any withholding tax or VAT paid pursuant to this Section 3.3 and in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable law in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment. If either Party is required to make any deduction or withholding from payments due to the other Party, the paying Party will (i) promptly notify the receiving Party of such requirement, (ii) pay to the relevant authorities on the receiving Party’s behalf the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the receiving Party, and (iii) promptly forward to the receiving Party an official receipt (or certified copy) or other documentation reasonably acceptable to the receiving Party evidencing such payment to such authorities.

3.4 United States Dollars. All dollar (\$) amounts specified in this Agreement are U.S. Dollar amounts. All payments shall be made in U.S. Dollars.

3.5 Late Payments. If a Party does not receive payment of any sum due to it under this Agreement on or before the due date, interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment, such interest to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, each month during the period from the time any payment was due until paid in full, plus two percent (2%) per annum.



3.6 No Set-Off. Except to the extent otherwise expressly provided under Section 3.8, no Person shall have the right to set off any amount to which a Party is entitled under this Agreement against any payment such Person is required to make under this Agreement or under any other agreement.

3.7 Assignment and Assumption of Certain Agreements. Concurrently with the execution of this Agreement, each of Momenta and Baxalta shall duly execute (or cause to be duly executed, as applicable) and deliver to the other the Assignment and Assumption Agreement in the form attached hereto as Exhibit C, pursuant to which Baxalta will assign to Momenta all of Baxalta's (and its Affiliates', as applicable) existing and future right, title and interest of every nature in each Assigned Agreement, and Momenta will accept and assume each Assigned Agreement, in each case as of the Effective Date, and will assume, undertake and agree to pay, perform, fulfill and discharge, from and after the Effective Date, all of Baxalta's liabilities and obligations under each Assigned Agreement, in each case in accordance with the terms and conditions of the applicable Assigned Agreement and this Agreement. Following the Effective Date, (a) Momenta shall enforce its rights under, and, without limiting the foregoing in this Section, each Party shall otherwise cooperate with the other Party with respect to, each Assigned Agreement and (b) without limiting the foregoing in this Section (including, without limitation, clause (a)), upon the other Party's request, a Party shall use commercially reasonable efforts to permit such other Party to communicate directly with the third-party service providers, and to cause such third-party service providers to communicate directly with such other Party, under each Assigned Agreement, in each case of clause (a) and clause (b), as is necessary or reasonably useful for each Party to perform its obligations under Article 4. Each Party hereby agrees that, if the other Party fails to satisfy any of its obligations hereunder and such failure resulted (in whole or in part) from such Party's failure to comply with the immediately preceding sentence, the other Party shall have no liability to such Party for such failure and shall not be deemed in breach of this Agreement (including, without limitation, Article 4) as a result of such failure.

3.8 Development Expenses and Commercial Costs/Unplanned Activities. If, after the Effective Date, Momenta, acting in good faith, reasonably incurs Development Expenses or Commercialization Costs (a) as the result of an activity (i) that is required by a Regulatory Authority to be completed in order to continue the Development and Commercialization of Products and (ii) that, as of the Effective Date, was not accounted for in Baxalta's budget for the M923 program through the Original Termination Date, and that was not accounted for in the Parties' calculation of the Asset Return Payment amount, and (b) that, pursuant to the Original Agreement, Baxalta would have been required to incur if the Term expired on the Original Termination Date (" Unplanned Costs "), Momenta shall be entitled to set off such Unplanned Costs against the Total Reimbursement Payment due and owed to Baxalta as hereunder contemplated; provided, that in no event shall Momenta be entitled to set off Unplanned Costs (x) in excess of [\*\*\*] dollars (\$[\*\*\*]), in the aggregate, or (y) with respect to which Momenta has not delivered to Baxalta a written report setting forth, in reasonable detail, such Unplanned Costs, including, without limitation, a reasonably-detailed description of why such Unplanned Costs satisfy clauses (a) and (b) of this Section 3.8, within fifteen (15) business days after such Unplanned Costs are incurred and, in any event, no later than the Original Termination Date. Upon Baxalta's request, Momenta will, as promptly as practicable, provide Baxalta with supporting documentation related to Unplanned Costs. For the avoidance of doubt, Baxalta shall have no liability or other obligation with respect to Unplanned Costs, except to the extent expressly provided in this Section 3.8. Additionally, for the avoidance of doubt, any disputes among the Parties regarding any Unplanned Costs (including, without limitation, whether clauses (a) and (b) of this Section 3.8 have been satisfied) are subject to the dispute resolution procedure set forth in Section 8.10 below.

#### ARTICLE 4 TRANSITION SERVICES

4.1 Clinical Services. During the Clinical Transition Services Term, Baxalta shall (and, as applicable, shall cause Baxalta Innovations to), with respect to M923 and at Baxalta's sole cost and expense, use Commercially Reasonable Efforts to (a) cause Quintiles to perform, and to monitor Quintiles' performance of, the clinical trial activities for the Clinical Trials in accordance with the Quintiles Agreement (and, for the avoidance of doubt, no other clinical activities), and (b) perform (or cause to be performed) the drug safety monitoring activities to be performed by Baxalta as set forth on Exhibit E hereto (and, for the avoidance of doubt, no other drug safety activities).

4.2 Regulatory Services. During the Regulatory Transition Services Term, Baxalta shall, in each case with respect to M923 and at Baxalta's sole cost and expense, use Commercially Reasonable Efforts to perform (or

cause to be performed) the regulatory activities set forth on Exhibit F hereto (and, for the avoidance of doubt, no other regulatory activities).

4.3 Retention. Notwithstanding anything to the contrary in the Original Agreement (including, without limitation, Section 10.6(a) thereof), the Parties agree that Baxalta shall, solely to the extent reasonably necessary or useful for Baxalta to perform the services described in Section 4.1 and Section 4.2 above (as determined by Baxalta), be entitled to retain possession, ownership and control of activities, information, correspondence, agreements, documents, data, reports, records, filings, approvals, materials, rights, titles and interests related to the Development or Commercialization of M923, in each case solely to the extent, and for so long as, Baxalta reasonably expects to rely on or otherwise utilize such activities, information, correspondence, documents, data, reports, records, filings, approvals, materials, rights, titles, and interests in connection with the services described in this Article 4. Following the conclusion of the Clinical Transition Services Term or the Regulatory Transition Services Term, whichever last concludes, the applicable provisions of Section 2.2 above and Section 10.6(a) of the Original Agreement shall apply with respect to the transition of the possession, ownership and control of any activities, information, correspondence, agreements, documents, data, reports, records, filings, approvals, materials, rights, titles, and interests retained by Baxalta pursuant to this Section 4.3, in each case as if the last day of the Clinical Transition Services Term or the Regulatory Transition Services Term, as applicable, was the “Effective Date” for purposes of Section 2.2 above or the “effective date of such termination” for purposes of Section 10.6(a) of the Original Agreement, as applicable. For the sake of clarity, nothing in this Section 4.3 or Section 2.2 shall be interpreted to block Momenta’s access during the Clinical Transition Services Term and/or the Regulatory Transition Services Term to such information, correspondence, agreements, documents, data, reports, records, filings, approvals, materials, rights, titles and interests to the extent such is reasonably necessary and primarily related to the Development, manufacture or Commercialization of the Product.

#### 4.4 Licenses.

(a) Baxalta hereby grants to Momenta (i) a royalty-bearing (consistent with Section 10.6(c)(ii) of the Original Agreement), non-exclusive, sublicensable (subject to the prior written consent of Baxalta which consent shall not be unreasonably withheld, conditioned or delayed) license under the Baxter Intellectual Property existing as of the conclusion of the Clinical Transition Services Term or the Regulatory Transition Services Term, whichever last concludes; and (ii) an exclusive, sublicensable license under the Collaboration Intellectual Property, in each case of (i) and (ii), to make, have made, use, have used, import, have imported, sell and have sold the Product.

(b) Notwithstanding anything to the contrary in the Original Agreement, the licenses granted to Baxalta under Section 6.1 of the Original Agreement will survive for all Momenta Intellectual Property (whether or not existing as of the Effective Date) and the licenses granted to Baxalta under Section 6.3 of the Original Agreement will survive for all Collaboration Intellectual Property (whether or not existing as of the Effective Date), in each case solely to the extent reasonably necessary or useful for Baxalta to perform the services described in Section 4.1 and Section 4.2 above (as determined by Baxalta).

4.5 Post-Termination Inquiries. During the Inquiry Period, Momenta shall be permitted to contact the Baxalta Personnel using the applicable contact information set forth on Exhibit D, in each case solely to ask questions related to the applicable Baxalta Personnel’s “Functional Area” (as set forth on Exhibit D) with respect to Baxalta’s operation of the M923 program during the applicable Inquiry Topic Period; provided, that each time Momenta so contacts a Baxalta Personnel, Momenta must first send a request to ask questions pursuant to this Section 4.5 via electronic mail to the applicable Baxalta Personnel and copy [\*\*\*], Sr. Director, Alliance Management ([\*\*\*]) on such electronic mail. Baxalta shall use commercially reasonable efforts to make such Baxalta Personnel available to answer such questions; *provided*, that in no event shall Baxalta be required to (a) make any Baxalta Personnel so available, or replace such Baxalta Personnel with another employee or contractor of Baxalta or any of its Affiliates, in each case at any time after such Baxalta Personnel is no longer employed or contracted by Baxalta or its Affiliates, (b) cause the Baxalta Personnel to spend, in the aggregate for all Baxalta Personnel, more than [\*\*\*] ([\*\*\*)] hours per calendar month on the services described in this Section 4.5, (c) cause any Baxalta Personnel to provide any services under this Section 4.5 (including, without limitation, providing any advice or recommendations) other than providing fact-based answers to questions regarding Baxalta’s operation of the M923 program during the applicable Inquiry Topic Period,

or (d) cause any Baxalta Personnel to investigate the answer to any question from Momenta, other than such Baxalta Personnel seeking input from other individuals listed on Exhibit D, as reasonably determined by the applicable Baxalta Personnel, to answer the question posed by Momenta. For the sake of clarity, any interactions between the Parties regarding disclosures of Confidential Information to Third Parties as such are contemplated at Article 6, the Clinical Services or Regulatory Services as such are contemplated at Sections 4.1 and 4.2, respectively, and any post termination inquiries regarding Baxalta's failure to provide the Deliverables, as such are contemplated at Section 2.2, shall not be counted toward the [\*\*\*] ([\*\*\*) hour limit contemplated in this Section 4.5.

**ARTICLE 5**  
**REPRESENTATIONS, WARRANTIES AND COVENANTS**

5.1 Representations and Warranties by Momenta. Momenta represents and warrants that, as of the Effective Date: (a) it has the full right, power and authority to enter in to this Agreement and the Assignment and Assumption Agreement and to grant any rights granted by it hereunder or thereunder; (b) to the knowledge of Momenta, there are no existing or threatened actions, suits or claims pending with respect to the subject matter hereof or the right of Momenta to enter into and perform its obligations under this Agreement or the Assignment and Assumption Agreement; (c) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the Assignment and Assumption Agreement and the performance of its obligations hereunder and thereunder; (d) each of this Agreement and the Assignment and Assumption Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof or thereof, as applicable; and (e) the execution and delivery of this Agreement and the Assignment and Assumption Agreement and the performance of its obligations hereunder and thereunder do not conflict with or violate any requirement of applicable Laws or regulations and do not conflict with, or constitute a default under, any contractual obligation of it.

5.2 Representations and Warranties by Baxalta. Baxalta represents and warrants that, as of the Effective Date: (a) it has the full right, power and authority to enter in to this Agreement and the Assignment and Assumption Agreement, as applicable, and to grant any rights granted by it hereunder or thereunder; (b) to the knowledge of Baxalta, there are no existing or threatened actions, suits or claims pending with respect to the subject matter hereof or the right of Baxalta to enter into and perform its obligations under this Agreement or the Assignment and Assumption Agreement; (c) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the Assignment and Assumption Agreement and the performance of its obligations hereunder; (d) each of this Agreement and the Assignment and Assumption Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof or thereof, as applicable; (e) the execution and delivery of this Agreement and the Assignment and Assumption Agreement and the performance of its obligations hereunder and thereunder do not conflict with or violate any requirement of applicable Laws or regulations and do not conflict with, or constitute a default under, any contractual obligation of it; (f) Baxalta and its affiliates actually incurred Development Expenses and Commercialization Costs, in the aggregate, equal to or greater than the amount set forth at Section 2.3(a); (g) the Total Reimbursement Payment does not include any Third Party financing costs, Baxalta's Allocable Legal Expense Share of the Legal Expenses, or Legal Expenses incurred by Baxalta in accordance with Section 5.3 of the Original Agreement; and (h) to Baxalta's Knowledge, the Asset Return Payment includes all amounts that are, as of the Effective Date, due and payable by Baxalta (or its assignee) to Third Parties under the Assigned Agreements, or will become due and payable by Baxalta (or its assignee) to Third Parties under the Assigned Agreements prior to the Original Termination Date, and in each case that will be payable by Momenta after the Effective Date.

5.3 Compliance with Laws. Each Party shall carry out its obligations under this Agreement in material compliance with all applicable Laws, including, without limitation, (a) the Food, Drug and Cosmetic Act and any applicable implementing regulations, and relevant foreign equivalents thereof; (b) GMPs; (c) all other applicable FDA guidelines and relevant guidelines of other applicable Regulatory Authorities; (d) all other applicable laws and regulations, including, without limitation, all applicable federal, national, multinational, state, provincial and local environmental, health and safety laws and regulations in effect at the time and place of manufacture of a Product; and (e) all applicable export and import control laws and regulations.

5.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF TECHNOLOGY OR PATENT CLAIMS, WHETHER ISSUED OR PENDING.

## ARTICLE 6 CONFIDENTIAL INFORMATION

6.1 Confidentiality. Except as contemplated by this Agreement or to the extent permitted under the September 2016 Disclosure of Confidential Information Letter Agreement, each Party shall hold in confidence and shall not publish or otherwise disclose and shall not use for any purpose (a) any Confidential Information of the other Party disclosed to it pursuant to the terms of this Agreement, (b) the terms of this Agreement, and (c) the transactions contemplated hereby, in each case until ten (10) years after the Effective Date.

6.2 Public Disclosure. The Parties have attached hereto as Exhibit G a mutually acceptable securities filing regarding the Parties' execution of this Agreement (the "Securities Filing"). *Except as* otherwise required by Law (as reasonably determined by counsel) and *except for* the Securities Filing, neither Party shall issue a press release or make any other public disclosure of the terms of this Agreement without the prior written approval of such press release or public disclosure by the other Party. Each Party shall submit any such press release or public disclosure to the other Party, and the receiving Party shall have five (5) business days from receipt to review and approve any such press release or public disclosure, which approval shall not be unreasonably withheld. If the receiving Party does not respond to the other Party within such five (5) business day period, the press release or public disclosure shall be deemed approved. In addition, if a public disclosure is required by Law, including, without limitation, in a filing with the Securities and Exchange Commission, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure for the non-disclosing Party's prior review and comment. The first approval of the contents of a press release or public disclosure shall constitute permission to use such contents subsequently without submission of the press release or public disclosure to the other Party for approval.

6.3 Legally-Required Disclosures. If the receiving Party or any of its representatives is required by law, rule or regulation or by order of a court of law, administrative agency, or other governmental body to disclose any of the Confidential Information, the receiving Party will (a) promptly provide the disclosing Party with reasonable advance written notice to enable the disclosing Party the opportunity to seek, where appropriate, a protective order or to otherwise prevent or limit such legally-required disclosure, (b) use Commercially Reasonable Efforts to cooperate with the disclosing Party to obtain such protection, and (c) disclose only the legally-required portion of the Confidential Information. Any such legally-required disclosure will not relieve the receiving Party from its obligations under this Agreement to otherwise limit the disclosure and use of such information as Confidential Information.

6.4 Confidential Terms. Except as expressly provided herein, each Party agrees not to disclose any terms of this Agreement to any Third Party without the consent of the other Party; provided, however, that disclosures may be made on a strict need-to-know basis to actual or prospective investors, acquirers, financing sources or licensees, or to a Party's accountants, attorneys and other professional advisors.

6.5 Regulatory Disclosures. With respect to a Product, each of the Parties agrees to share, upon request, its relevant data from laboratory, preclinical and clinical studies conducted in support of the regulatory filings for the Development, approval and marketing of such Product with the other Party and its Affiliates and sublicensees on a royalty-free basis, provided, however, that any data so transferred shall be used by the receiving Party and its Affiliates and sublicensees solely for the purposes authorized under this Agreement. Except as set forth in the preceding sentence, if an Affiliate or sublicensee of a Party shall fail to agree to a reciprocal data sharing agreement, such Affiliate or sublicensee, as the case may be, shall not be entitled to receive the data of the other Party or its Affiliates or sublicensees. Each Party agrees to grant to the other the right to cross-reference any regulatory filing made by a Party with regard to a Product or any Regulatory Approval received by a Party with regard to a Product as the other Party believes may be useful or necessary for it to obtain approval to distribute and sell such Product, consistent with the terms of this Agreement.

6.6 Prior Confidentiality Agreements. Baxalta and Momenta are parties to a Mutual Confidential Disclosure Agreement dated April 8, 2011, as amended; a Community of Interest Letter dated September 9, 2011, as amended on September 23, 2011; a Common Interest and Joint Defense Agreement, entered into on or about May 10, 2012; the Common Interest and Joint Defense Agreement with a last execution date of April 9, 2013; the September 2016 Disclosure of Confidential Information Letter Agreement; and the Original Agreement (collectively, the “Prior Confidentiality Agreements”). The following shall be considered Confidential Information hereunder, subject to the exceptions in the definition of “Confidential Information” in Article 1 of this Agreement: (a) all Confidential Information (as that term is defined in the applicable Prior Confidentiality Agreement) disclosed pursuant to the applicable Prior Confidentiality Agreement, and (b) the Position Statements (as that term is defined in the Community of Interest Letter referenced above, as amended), which, notwithstanding anything in this Agreement to the contrary, shall also remain subject to the provisions of Section 3 of such Community of Interest Letter.

## ARTICLE 7 INDEMNIFICATION AND LIMITATION OF LIABILITY

7.1 Baxalta Indemnification. Baxalta agrees to defend Momenta and its Affiliates, and their respective agents, directors, officers and employees (the “Momenta Indemnitees”), at Baxalta’s cost and expense, and will indemnify and hold harmless the Momenta Indemnitees from and against any and all Third Party product liability related losses, costs, damages, fees or expenses (collectively, “Momenta Losses”) arising out of any act or omission of Baxalta, its Affiliates, sublicensees, contractors or agents in connection with the development, use, manufacture, distribution or sale of M923, including, without limitation, any actual or alleged injury, damage, death or other consequence occurring to any person claimed to result, directly or indirectly, from the possession, use or consumption of, or treatment with, M923, whether claimed by reason of breach of warranty, negligence, product defect or otherwise, and regardless of the form in which any such claim is made, provided that the foregoing indemnity shall not apply to the extent that any such Momenta Losses are attributable to (a) the material breach by Momenta of the Original Agreement, the Work Plan for M923 or this Agreement, or (b) the gross negligence or willful misconduct of the Momenta Indemnitees. In the event of any such claim against any Momenta Indemnitee, Momenta shall promptly notify Baxalta in writing of the claim and Baxalta shall manage and control, at its sole expense, the defense of the claim and its settlement. Notwithstanding the foregoing no settlements shall be finalized without obtaining Momenta’s prior written consent, which shall not be unreasonably withheld, except that in the case of a settlement that does not require an admission or action on the part of Momenta, and does not harm Momenta or its ability to comply with its obligations hereunder or under the Original Agreement, Momenta’s consent shall not be required so long as Momenta is unconditionally released from all liability in such settlement. Momenta shall cooperate with Baxalta and may, at its option and expense, be represented in any such action or proceeding. Baxalta shall not be liable for any settlements, litigation costs or expenses incurred by Momenta Indemnitees without Baxalta’s written authorization.

7.2 Momenta Indemnification. Momenta agrees to defend Baxalta and its Affiliates, and their respective agents, directors, officers and employees (the “Baxalta Indemnitees”), at Momenta’s cost and expense, and will indemnify and hold harmless the Baxalta Indemnitees from and against any and all Third Party product liability related losses, costs, damages, fees or expenses (collectively, “Baxalta Losses”) arising out of any act or omission of Momenta, its Affiliates, sublicensees, contractors or agents in connection with the development, use, manufacture, distribution or sale of M923, including, without limitation, any actual or alleged injury, damage, death or other consequence occurring to any person claimed to result, directly or indirectly, from the possession, use or consumption of, or treatment with, M923, whether claimed by reason of breach of warranty, negligence, product defect or otherwise, and regardless of the form in which any such claim is made, provided that the foregoing indemnity shall not apply to the extent that any such Baxalta Losses are attributable to (a) the material breach by Baxalta of the Original Agreement, the Work Plan for M923 or this Agreement, or (b) the gross negligence or willful misconduct of the Baxalta Indemnitees. In the event of any such claim against any Baxalta Indemnitee, Baxalta shall promptly notify Momenta in writing of the claim and Momenta shall manage and control, at its sole expense, the defense of the claim and its settlement. Notwithstanding the foregoing no settlements shall be finalized without obtaining Baxalta’s prior written consent, which shall not be unreasonably withheld, except that in the case of a settlement that does not require an admission or action on the part of Baxalta, and does not harm Baxalta or its ability to comply with its obligations hereunder or under the Original Agreement, Baxalta’s consent shall not be required so long as Baxalta is unconditionally released from all liability in such settlement. Baxalta shall cooperate with Momenta and may, at its option and expense, be represented in any such

action or proceeding. Momenta shall not be liable for any settlements, litigation costs or expenses incurred by Baxalta Indemnitees without Momenta's written authorization.

7.3 No Consequential Damages. UNLESS RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR FROM A PARTY'S BREACH OF ARTICLE 6 (CONFIDENTIAL INFORMATION), NO PARTY WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 7.3 (NO CONSEQUENTIAL DAMAGES) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER THIS AGREEMENT.

## ARTICLE 8 MISCELLANEOUS

8.1 Governing Law. This Agreement shall be governed by, interpreted and construed in accordance with the substantive Laws of the State of Delaware, without regard to conflicts of law principles.

8.2 Waiver. It is agreed that no waiver by any Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.

8.3 Assignments. Neither this Agreement nor any right or obligation hereunder may be assigned or delegated, in whole or in part, by either Party without the prior written consent of the other or pursuant to subcontracting or sublicensing arrangements expressly contemplated herein; *provided, however*, that either Party may, without the written consent of the other, assign this Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 8.3 shall be void.

8.4 Independent Contractors. The relationship of the Parties hereto is that of independent contractors. The Parties hereto are not deemed to be agents, partners or joint ventures of the others for any purpose as a result of this Agreement or the transactions contemplated hereby.

8.5 Notices. Any notice required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and sent by certified or registered mail, return receipt requested, postage prepaid, or sent by a nationally recognized overnight courier service, or sent by hand delivery, to the representative for such Party at the address set forth below for such Party. If a Party changes its representative or address, written notice shall be given promptly to the other Party of the new representative or address. Notice shall be deemed given on the third business day after being sent in the case of delivery by mail, on the first business day after being sent in the case of delivery by overnight courier, and on the date of delivery in the case of delivery by hand. The addresses of the Parties and representatives are as follows:

If to Momenta:

Momenta Pharmaceuticals, Inc.  
675 West Kendall Street  
Cambridge, MA 02142  
USA  
Attention: President and CEO

with a copy to:

Momenta Pharmaceuticals, Inc.  
675 West Kendall Street  
Cambridge, MA 02142  
USA  
Attention: General Counsel

If to Baxalta:

Baxalta Incorporated  
c/o Shire plc  
300 Shire Way  
Lexington, MA 02421  
Attention: General Counsel

and

Baxalta Incorporated  
c/o Shire plc  
300 Shire Way  
Lexington, MA 02421  
Attention: Head of Corporate Legal

8.6 Force Majeure. Neither Party shall be held liable or responsible to the other nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (excluding payment obligations) to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of such Party including, without limitation, fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, and other similar causes. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in Article 4 above that falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. Each Party shall immediately notify the other if, by reason of any of the disabilities referred to herein, it is unable to meet any deadline or time for performance specified in Article 4 above. The Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from this force majeure. If a condition constituting force majeure, as defined herein, exists for more than one-hundred eighty (180) consecutive days, either Party may terminate this Agreement.

8.7 Complete Agreement; Assignment. Except with regards to the Prior Confidentiality Agreements, the Legal Activities Letter Agreement, and except with regards to the provisions of the Original Agreement that, by the terms of the Original Agreement, survive the termination of the Original Agreement, it is understood and agreed between Momenta and Baxalta that this Agreement constitutes the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and that all prior agreements respecting the subject matter hereof, whether written or oral, expressed or implied, shall be of no force or effect. No amendment or change hereof or addition hereto shall be effective or binding on either of the Parties hereto unless reduced to writing and executed by the respective duly authorized representatives of Momenta and Baxalta.

8.8 Severability. In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without such provision. In such event, the Parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement.



8.9 Counterparts. This Agreement may be executed in counterparts (including by electronic transmission), each of which shall be deemed to be an original and all together shall be deemed to be one and the same agreement. Signatures provided by facsimile transmission or by electronic delivery in .pdf or similar electronic format shall be deemed to be original signatures.

8.10 Alternative Dispute Resolution. The Parties recognize that bona fide disputes may arise which relate to the Parties' rights and obligations under this Agreement. In attempting to resolve any such disputes, the matter shall first be elevated through each Party's respective senior management representatives (in the case of Baxalta, to the [\*\*\*], which, as of the Effective Date, is (on an interim basis) [\*\*\*], [\*\*\*], and in the case of Momenta, to the [\*\*\*], which, as of the Effective Date, is [\*\*\*], [\*\*\*]) for resolution. If the matter remains unresolved fifteen (15) days after referral to such senior management representatives, the matter shall be resolved by binding dispute resolution proceedings in accordance with the procedure set forth on Exhibit 12.11 to the Original Agreement.

8.11 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

8.12 Headings; Waiver of Rule of Construction. Headings are inserted for convenience and shall not affect the meaning or interpretation of this Agreement. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement, and, accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

8.13 Conflict with Other Agreements. In the event of any conflict between this Agreement (or any portion thereof) and any other agreement now existing or hereafter entered into between the Parties (including, without limitation, the Original Agreement), the terms of this Agreement shall prevail.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

BAXALTA INCORPORATED

By: /s/ Jeffrey Prowda  
Name: Jeffrey Prowda  
Title: Assistant Secretary

BAXALTA US INC.

By: /s/ Jeffrey Prowda  
Name: Jeffrey Prowda  
Title: Assistant Secretary

BAXALTA GMBH

By: /s/ Paola Granati  
Name: Paola Granati  
Title: Lead HR Business Partner HQ

By: /s/ Yvo Aebli  
Name: Yvo Aebli  
Title: Controller Switzerland & ECG

[SIGNATURES CONTINUE ON FOLLOWING PAGE]

*[Signature Page to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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MOMENTA PHARMACEUTICALS, INC.

By: /s/ Craig A. Wheeler  
Name: Craig A. Wheeler  
Title: President and CEO

[END OF SIGNATURES]

*[Signature Page to Asset Return and Termination Agreement]*

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**EXHIBIT A**

**ORIGINAL AGREEMENT**

*[see attached]*

*[Exhibit A to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**EXHIBIT B**

**Wire Instructions**

Bank Name:	***
Bank Address:	***
Account Name:	***
Account Number:	***
Sort code:	***
Swift Address:	***

*[Exhibit B to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**EXHIBIT C**

**Form of Assignment and Assumption Agreement**

*[see following pages]*

*[Exhibit C to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**ASSIGNMENT AND ASSUMPTION AGREEMENT**

This Assignment and Assumption Agreement (this “Assignment and Assumption Agreement”) is made as of December 31, 2016, by and between Baxalta GmbH, a Swiss entity (“BGMBH”), Baxalta US Inc., a Delaware corporation (“BUSI”), Baxalta Innovations GmbH, an Austrian entity (“Baxalta Innovations”) and, together with BGMBH and BUSI, collectively, the “Assignors”), and Momenta Pharmaceuticals, Inc., a Delaware corporation (the “Assignee”). Capitalized terms not defined herein shall have the meanings ascribed to them in that certain Asset Return and Termination Agreement, effective as of December 31, 2016, between the Assignors and the Assignee (the “AR&T Agreement”).

WHEREAS, pursuant to the AR&T Agreement, the Assignors and the Assignee agreed to effect an early termination of that certain Development, License and Option Agreement dated as of December 22, 2011, as amended, between the Assignee, Baxter International Inc. (“BII”), Baxter Healthcare Corporation (“BHC”) and Baxter Healthcare SA (“BHSA”), which was assigned by BII, BHC and BHSA to Baxalta Incorporated, BUSI and BGMBH, respectively, on July 1, 2015, and an early return to Assignee of all rights to Momenta’s development compound referred to as “M923”, a monoclonal antibody product for which adalimumab (Humira) is the reference brand product;

WHEREAS, pursuant to Section 3.7 of the AR&T Agreement, the Assignors have agreed to assign to Assignee, and Assignee has agreed to assume from Assignors, each of the agreements set forth on Exhibit A hereto (collectively, the “Assigned Agreements”), as evidenced by this Assignment and Assumption Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby act and agree as follows:

1. Assignment and Assumption. Effective as of the date hereof, for value received, each Assignor hereby assigns to the Assignee all of its existing and future right, title and interest of every nature in each Assigned Agreement, and the Assignee hereby accepts and assumes each Assigned Agreement and hereby assumes, undertakes and agrees to pay, perform, fulfill and discharge, from and after the date hereof, all of the Assignors’ liabilities and obligations under each Assigned Agreement, in each case in accordance with the terms and conditions of the applicable Assigned Agreement.

2. Power of Attorney. Each Assignor appoints the Assignee, its successors and assigns, as the true and lawful attorney-in-fact of such Assignor, with full power of substitution, having full right and authority, in the name of such Assignor to collect or enforce for the account of the Assignee, liabilities and obligations of third parties under each Assigned Agreement; to institute and prosecute all proceedings that the Assignee may deem proper in order to enforce any claim to obligations owed under each Assigned Agreement, to defend and compromise any and all actions, suits or proceedings in respect of each Assigned Agreement, and to do all such acts in relation to each Assigned Agreement that the Assignee may deem advisable. Each Assignor agrees that the above-stated powers are coupled with an interest and shall be irrevocable by such Assignor.

3. Notice of Assignment. Written notice of the assignment of the DCMSA (as defined on Exhibit A hereto) and the LSA (as defined on Exhibit A hereto) under this Assignment and Assumption Agreement shall be given by the Assignors to HGSI (as defined on Exhibit A hereto) in accordance with the terms of the Second Amendment to DCMSA (as defined on Exhibit A hereto) and the LSA (as defined on Exhibit A hereto), respectively.

4. Further Assurances. Assignors and the Assignee, at the request of the other and without further consideration, hereby agree to execute and deliver after the date of this Assignment and Assumption Agreement such other instruments or documents and to take such additional actions as may be reasonably requested by the other party in order to effect or complete the assignment and assumption contemplated hereby.

5. Waiver. The terms and provisions of this Assignment and Assumption Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions.

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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6. Governing Law. This Agreement shall be governed by, interpreted and construed in accordance with the substantive Laws of the State of Delaware, without regard to conflicts of law principles.

7. Alternative Dispute Resolution. The parties hereto recognize that bona fide disputes may arise which relate to the parties' rights and obligations under this Assignment and Assumption Agreement. In attempting to resolve any such disputes, the matter shall first be elevated through each party's respective senior management representatives (in the case of the Assignor, to its Head of Biosimilars, in the case of the Assignee, to its President) for resolution. If the matter remains unresolved fifteen (15) days after referral to such senior management representatives, the matter shall be resolved by binding dispute resolution proceedings in accordance with the procedure set forth on Exhibit 12.11 to the Original Agreement.

8. Miscellaneous. This Assignment and Assumption Agreement (i) shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, (ii) may be executed in counterparts (including by electronic transmission), each of which shall be deemed to be an original and all together shall be deemed to be one and the same agreement, and (iii) may be modified or amended only by written agreement executed by each of the parties hereto. Signatures provided by facsimile transmission or by electronic delivery in .pdf or similar electronic format shall be deemed to be original signatures.

*[SIGNATURE PAGES FOLLOW]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

---

**IN WITNESS WHEREOF**, the parties have caused this Assignment and Assumption Agreement to be executed by their duly authorized representatives as of the date first above written.

**ASSIGNEE:**

MOMENTA PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**[SIGNATURES CONTINUE ON FOLLOWING PAGE]**

*[Signature Page to Assignment and Assumption Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

---

**IN WITNESS WHEREOF**, the parties have caused this Assignment and Assumption Agreement to be executed by their duly authorized representatives as of the date first above written.

**ASSIGNORS:**

BAXALTA INNOVATIONS GMBH

By: \_\_\_\_\_  
Name:  
Title:

By: \_\_\_\_\_  
Name:  
Title:

BAXALTA US INC.

By: \_\_\_\_\_  
Name:  
Title:

BAXALTA GMBH

By: \_\_\_\_\_  
Name:  
Title:

By: \_\_\_\_\_  
Name:  
Title:

*[Signature Page to Assignment and Assumption Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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Exhibit A

Assigned Agreements

\*\*\*

*[end of Exhibit A]*

*[Exhibit A to Assignment and Assumption Agreement]*

Confidential Portions of this Exhibit marked as \*\*\* have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**EXHIBIT D**

**Baxalta Personnel**

<b>Baxalta Personnel</b>	<b>Function Area</b>	<b>Contact Information</b>
***	Regulatory Lead	***
***	Commercial	***
***	External Manufacturing	***
***	Analytical	***
***	Ops	***
***	Drug Safety	***
***	GDL & Medical Affairs Lead	***
***	NPO	***
***	Legal	***
***	CMC PM	***
***	Extractable and Leachable	***
***	CMC Regulatory	***
***	CMC Regulatory Lead	***
***	Delivery Sys PM	***
***	Alliance Management	***
***	Delivery Sys	***
***	Clin Ops	***
***	PM	***
***	QPO	***
***	Commercial	***
***	QPO	***
***	Regulatory	***
***	External Quality	***
***	Drug Safety	***
***	Device Quality Engineer	***
***	Quality	***
***	Quality – Method Transfer PPD	***
***	Clinical	***
***	Clinical	***
***	Data Management	***
***	Statistics	***
***	Clinical	***

\*\*\*\*\*

*[Exhibit D to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as \*\*\* have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

## EXHIBIT E

### Drug Safety Monitoring

#### Objective

The objective of this Exhibit E is to define each Party's pharmacovigilance-related responsibilities with respect to the Investigational New Drug (IND) and Clinical Trials Applications (CTAs) transfers from Baxalta to Momenta for M923. This Exhibit formalizes the Parties' respective responsibilities with regard to safety data exchange, reporting, and pharmacovigilance pursuant to applicable laws, regulations, and guidelines.

#### Transition Period

The Transition Period is from the point in time the M923 IND and CTAs are transferred, such specific transfer date to be as agreed to by the Parties but no later than April 17<sup>th</sup> 2017, and the last patient safety visit for ongoing M923 Clinical Trials (911401 and 911502) where the roles and responsibilities outlined below will apply. Per the clinical protocols, the last patient visit date is anticipated to be no later than 17 April 2017 (the "Transition Period"). At the end of the Transition Period, unless otherwise specified herein, all safety data exchange, reporting and pharmacovigilance activities shall be the responsibility of Momenta. For clarity, from the Effective Date of the Agreement up until the Transition Period, all roles and responsibilities for the Parties remain as covered in the Original Agreement.

#### Safety Database

Baxalta shall maintain the Global Safety Database for the collection and maintenance of all serious adverse events (SAEs) and pregnancy reports related to M923 under the scope of the Original Agreement and as described in the Safety Management Plans for Clinical Trials 911401 and 911502. Quintiles IMS will continue to perform services under M923 study (911401 and 911502) work orders and the Quintiles/Baxalta master agreement. For the transition of database responsibility, database migration will take place no later than May 2017 following the completion of the last patient visit in the last ongoing clinical trial (911401). The M923 safety database containing all safety reports and data collected for the Clinical Trials will be migrated by Baxalta to Momenta or third-party vendor as specified by Momenta and as agreed by the Parties.

#### Safety Management Plan and Governing SOPs

By the start of the Transition Period, Baxalta and Quintiles IMS will work with Momenta to update the Safety Management Plans for the ongoing Clinical Trials (911401 and 911502) to reflect any changes for transferring responsibilities, processes, and governing SOPs from Baxalta to Momenta. Baxalta will provide the safety reports prepared pursuant to its SOPs. Such SOPs to be in compliance with applicable laws, and specifically GCP. Baxalta will work with Momenta or Momenta's designee to transfer the M923 program within Eudravigilance.

#### Case Processing

During the Transition Period, Baxalta will continue case processing activities for M923 including but not limited to data entry, narrative writing, coding, safety query generation, translation of source documents and follow up. Baxalta will work directly with Quintiles IMS for resolution of queries and follow-up of case processing, as described in the SMP for each trial. Baxalta shall also continue to perform medical review of all SAEs with verification of expectedness and causality and shall formulate the analysis of similar events for inclusion in applicable Individual Case Safety Reports (ICSRs). If needed, Baxalta will complete unbinding of expedited safety reports. Baxalta will perform reconciliation until the ending of the Transition Period where Momenta will assume responsibility.

#### Safety Reporting

During the Transition Period, Baxalta shall forward to Momenta at [\*\*\*] for regulatory reporting purposes cases that require expedited reporting within timelines specified in the Safety Management Plan in Medwatch format for US expedited regulatory reporting and CIOMS for all ex-US expedited regulatory reporting. Exchange of all cases will be followed by an acknowledgment of receipt by Momenta and Quintiles IMS no later than one (1) business day of receipt to [\*\*\*]. Reconciliation in the form of a case number listing may be performed during the Transition Period in an interval agreed to between both parties to ensure receipt of all cases by Momenta. Preparation of cover letters to regulatory authorities, ethics commissions, and investigators for notification of expedited safety reports and cross reporting of events to other active trials will occur as specified in the current Baxalta Safety Management Plan.

*[Exhibit E to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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Aggregate Safety Reporting

As applicable during the Transition Period, Baxalta will generate and forward to Momenta at [\*\*\*] any required periodic safety reports for submission to the Regulatory Authorities.

\*\*\*\*\*

*[Exhibit E to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**EXHIBIT F**

**Regulatory Services**

Module	Major Sections	Regulatory Services to be Performed by Baxalta in Accordance with Section 4.2
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[\*\*\*] [\*\*\*] [\*\*\*]

\* \* \* \* \*

*[Exhibit F to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**EXHIBIT G**

**Form of Securities Filing**

*[see attached]*

*[Exhibit G to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): December 31, 2016

**Momenta Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-50797**  
(Commission File Number)

**04-3561634**  
(IRS Employer Identification No.)

**675 West Kendall Street, Cambridge, MA**  
(Address of principal executive offices)

**2142**  
(Zip Code)

Registrant's telephone number, including area code: **(617) 491-9700**

**Not applicable**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

*[Exhibit G to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**Item 1.01 Entry into a Material Definitive Agreement.**

As previously reported, on September 26, 2016, Momenta Pharmaceuticals, Inc. (the “Company”) received written notice (the “Termination Notice”) from Baxalta US Inc., Baxalta GmbH and Baxalta Incorporated (collectively, “Baxalta”) stating that Baxalta has exercised its right to terminate for its convenience (the “Termination”) the Development, License and Option Agreement, by and between the Company and Baxalta, dated as of December 22, 2011, as amended (the “Original Agreement”), pursuant to which the Company and Baxalta agreed to collaborate, on a world-wide basis, on the development and commercialization of M923, the Company’s biosimilar HUMIRA® (adalimumab) candidate. Under the terms of the Original Agreement, the effective date of the Termination was twelve months from the date of receipt of the Termination Notice (the “Original Effective Date”).

On December 31, 2016, the Company and Baxalta entered into an Asset Return and Termination Agreement (the “Termination Agreement”) amending certain terms of the Original Agreement relating to the termination of the Original Agreement. Under the terms of the Termination Agreement, the effective date of the Termination is December 31, 2016 (the “New Effective Date”). Baxalta is not obligated to continue to perform development, manufacturing or commercialization activities for M923 after the New Effective Date except for certain clinical and regulatory activities that are expected to be completed by April 2017 (the “Transition Services”). In order to fund the other activities that Baxalta was required to perform under the Original Agreement through the Original Effective Date, Baxalta is obligated to pay the Company a one-time cash payment of \$51.2 million within 10 business days of the New Effective Date (the “Upfront Payment”). The Company is obligated to pay to Baxalta a royalty of 5% of net sales (as such term is defined in the Original Agreement) until Baxalta’s development expenses and commercialization costs (as such terms are defined in the Original Agreement) incurred through the New Effective Date, plus those incurred in providing the Transition Services and plus the Upfront Payment, are reimbursed. The licenses granted pursuant to the Original Agreement by the Company to Baxalta under the Company’s intellectual property rights relating to M923 terminate as of the New Effective Date except solely to extent reasonably necessary or useful for Baxalta to perform the Transition Services. The licenses granted by Baxalta to the Company under its intellectual property rights relating to M923 survive, and Baxalta has granted to the Company licenses under additional Baxalta intellectual property rights, if any, relating to M923 existing upon completion of the Transition Services. The Termination Agreement also assigns to the Company certain third party agreements relating to the development, manufacture, and commercialization of M923.

**1.02 Termination a Material Definitive Agreement.**

The information provided in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 1.02.

*[Exhibit G to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**SIGNATURE**

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

**MOMENTA PHARMACEUTICALS, INC.**

Date: December 31, 2016

By:           /s/ Scott M. Storer          

Scott M. Storer  
Chief Financial Officer  
(Principal Financial Officer)

*[Exhibit G to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**EXHIBIT H**

**Deliverables**

1. Consent to outside counsel regarding disclosing all attorney work product produced in support of the M923 program and pre-litigation preparations therefor to Momenta.
2. Master cell banks solely related to the M923 program (notwithstanding anything to the contrary in Section 2.2 of the Agreement, the shipment thereof to Momenta or its designee to begin no later than January 31, 2017, but which may arrive after January 31, 2017)
3. Two freezers that are solely used for the M923 program and located at [\*\*\*]
4. One freezer that is solely used for the M923 program and located at [\*\*\*]
5. One assembly jig that is solely used for the M923 program and located at [\*\*\*]
6. Two assembly jigs that are solely used for the M923 program and located at [\*\*\*]
7. All electronic records, documents, and other information in Shire-Vienna's possession, in each case that is relevant to the M923 program and required to be delivered to Momenta pursuant to Section 10.6(a) of the Original Agreement (notwithstanding anything to the contrary in Section 2.2 of the Agreement, such records, documents, and other information to be delivered to Momenta or its designee no later than February 28, 2017)
8. Copies of the contents of the joint collaboration SharePoint site set up and maintained by Baxalta and Momenta for the M923 program (original to be retained by Baxalta as part of the litigation hold), the delivery or transfer thereof shall be satisfied solely by Baxalta keeping the site active through February 28, 2017 to allow Momenta to download the contents
9. Copies of the contents of the know-how database set up pursuant to Section 5.10 of the Original Agreement
10. Samples stored at [\*\*\*] for the M923 program, the delivery and transfer obligations with respect to which will be satisfied by Baxalta's delivery of notice to [\*\*\*] to transfer such samples to Momenta
11. Inventory and equipment, in each case related solely to the M923 program, stored at Quintiles, [\*\*\*], [\*\*\*], or [\*\*\*], or subcontractors of any of the foregoing, in each case the delivery and transfer obligations with respect to which shall be satisfied by Baxalta's delivery of notice to each of Quintiles, [\*\*\*], [\*\*\*], and [\*\*\*] to transfer such inventory and equipment to Momenta
12. URLs related solely to the M923 program
13. SmPC/PI/PPI/primary/secondary/IFU label and artwork electronic files related to the M923 program and which are to be included in the regulatory filings for the M923 program
14. Trademark applications for each of "[\*\*\*]" and "[\*\*\*]"
15. BLA modules related to the M923 program, in each case pursuant to and subject to the processes and timelines set forth in Section 4.2 of the Agreement and Exhibit F (Regulatory Services) thereto
16. Copies of the contents of the [\*\*\*]/Shire SharePoint site established for purposes of the M923 program (notwithstanding anything to the contrary in Section 2.2 of the Agreement, such copies to be delivered to Momenta)

*[Exhibit H to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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or its designee no later than February 28, 2017). Such copy of the contents of the SharePoint site to include a source document list and associated matching source documents.

17. Draft of the clinical trial manuscript for the 911301 clinical trial of M923
18. Copy of safety database for M923 clinical trials, pursuant to and subject to the processes and timelines set forth in Section 4.1 of the Agreement and Exhibit E (Drug Safety Monitoring) thereto
19. [\*\*\*] completed risk assessment and Shire risk assessment final report, in each case with respect to the [\*\*\*] for M923
20. Shire risk assessment report with respect to the [\*\*\*] ([\*\*\*]) for M923
21. Documents and records held by Baxalta and its affiliates as of the Effective Date and that are reasonably necessary to compile Design History Files (DHF) for [\*\*\*], [\*\*\*], and [\*\*\*] for M923
22. Provide consent to Quintiles to grant Momenta access to all eTMF files controlled by Quintiles, such eTMF files to be transferred to Momenta at a date to be agreed upon by Momenta and Quintiles. Shire to provide any additional eTMF related documents under Shire control

\* \* \* \* \*

*[Exhibit H to Asset Return and Termination Agreement]*

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the

**Non-Employee Director Compensation Summary**

The following is a summary of the compensation program for non-employee directors of Momenta Pharmaceuticals, Inc. (the “Company”):

*Stock Option Grant Upon Initial Appointment or Election*

Each new non-employee director receives an option to purchase up to 33,000 shares of the Company’s common stock upon his or her initial election or appointment to the Board of Directors (the “Board”), with 1/3 of such option to vest on the first anniversary of the date of grant and an additional 8 1/3% to vest at the end of every three-month period thereafter, subject to the director’s continued service to the Company. Each option is granted pursuant to, and subject to the terms of, the Company’s incentive award plan and a stock option award agreement in substantially the form of the Company’s standard stock option agreement approved by the Board.

*Annual Option and Restricted Stock Grant*

Each non-employee director who served as a director in the previous year receives restricted shares of common stock of the Company and an option to purchase shares of the Company’s common stock. Each award is granted on the date of the scheduled meeting of the Board coinciding with each annual meeting of the Company’s stockholders. The number of shares subject to the option and the number of restricted shares is determined annually by the Board so that the total value of the option and restricted shares targets the 50<sup>th</sup> percentile of total value of equity grants made by the Company’s peer group to their respective directors on an individual director basis. The number of restricted shares is equal to 50% of the number of shares subject to the option.

The option vests in full on the first anniversary of the date of grant, subject to the director’s continued service to the Company. Each option is granted pursuant to, and subject to the terms of, the Company’s incentive award plan and a stock option award agreement in substantially the form of the Company’s standard stock option agreement approved by the Board.

One hundred percent of the restricted shares vest and become free from forfeiture and transfer restrictions on the first anniversary of date of grant, subject to the director’s continued service to the Company. The shares of restricted common stock are granted pursuant to, and subject to the terms of, the Company’s incentive award plan and a restricted stock award agreement in substantially the form of the Company’s standard restricted stock award agreement approved by the Board.

*Payment of Retainer Fee; Reimbursement of Travel and Other Expenses*

Each non-employee director is entitled to receive an annual retainer for his or her service on the Board as well as additional fees for committee service as follows:

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Annual Retainer	\$50,000
Non-Employee Board Chairperson	\$30,000
Audit Committee Chairperson	\$20,000
Audit Committee Members (other than the Chairperson)	\$12,500
Compensation Committee Chairperson	\$15,000
Compensation Committee Members (other than the Chairperson)	\$10,000
Nominating and Corporate Governance Committee Chairperson	\$12,000
Nominating and Corporate Governance Committee Members (other than the Chairperson)	\$7,000
Science Committee Chairperson	\$17,500
Science Committee Members (other than the Chairperson)	\$12,500

Retainers are paid quarterly in arrears during the fiscal year. Non-employee directors also receive reimbursement for reasonable travel and other expenses in connection with attending meetings of the Board of Directors.

\* \* \* \* \*



MOMENTA PHARMACEUTICALS, INC.  
2013 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

Momenta Pharmaceuticals, Inc., a Delaware corporation (the “Company”), pursuant to its 2013 Incentive Award Plan, as amended from time to time (the “Plan”), hereby grants to the holder listed below (“Participant”) the number of Restricted Stock Units (the “RSUs”) set forth below. The RSUs are subject to the terms and conditions set forth in this Restricted Stock Unit Grant Notice (the “Grant Notice”) and the Restricted Stock Unit Agreement attached hereto as Exhibit A (the “Agreement”) and the Plan, which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in the Grant Notice and the Agreement.

**Participant:**

**Grant Date:**

**Number of RSUs:**

**Type of Shares Issuable:** Common Stock

**Vesting Schedule:** [To be specified in individual agreements]

By his or her signature, and the Company’s signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Agreement, the Plan and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Grant Notice or the Agreement.

MOMENTA PHARMACEUTICALS, INC.

PARTICIPANT

**HOLDER:**

By: \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_

By: \_\_\_\_\_  
Print Name: \_\_\_\_\_

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**EXHIBIT A  
TO RESTRICTED STOCK UNIT GRANT NOTICE**

**RESTRICTED STOCK UNIT AGREEMENT**

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the number of RSUs set forth in the Grant Notice.

**ARTICLE I.  
GENERAL**

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice.

1.2 Incorporation of Terms of Plan. The RSUs and the shares of Common Stock (“Stock”) issued to Participant hereunder (“Shares”) are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

**ARTICLE II.  
AWARD OF RESTRICTED STOCK UNITS AND DIVIDEND EQUIVALENTS**

2.1 Award of RSUs and Dividend Equivalents.

(a) In consideration of Participant’s past and/or continued employment with or service to the Company or a Subsidiary and for other good and valuable consideration, effective as of the grant date set forth in the Grant Notice (the “Grant Date”), the Company has granted to Participant the number of RSUs set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement, subject to adjustments as provided in the Plan. Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash as set forth in Section 2.3(b), in either case, at the times and subject to the conditions set forth herein. However, unless and until the RSUs have vested, Participant will have no right to the payment of any Shares subject thereto. Prior to the actual delivery of any Shares, the RSUs will represent an unsecured obligation of the Company, payable only from the general assets of the Company.

(b) The Company hereby grants to Participant, with respect to each RSU granted pursuant to the Grant Notice, a Dividend Equivalent for all ordinary cash dividends which are paid to all or substantially all holders of the outstanding shares of Stock between the Grant Date and the date when the applicable RSU is distributed or paid to Participant or is forfeited or expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single share of Stock. The Company will establish a separate Dividend Equivalent bookkeeping account (a “***Dividend Equivalent Account***”) for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

2.2 Vesting of RSUs and Dividend Equivalents.

(a) Subject to Participant’s continued employment with or service to the Company or a Subsidiary on each applicable vesting date and subject to the terms of this Agreement, the RSUs shall vest in such amounts and at such times as are set forth in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest upon the vesting of the corresponding RSU.

(b) In the event Participant incurs a Termination of Service, except as may be otherwise provided by the Administrator or as set forth in a written agreement between Participant and the Company, Participant shall

immediately forfeit any and all RSUs and Dividend Equivalents granted under this Agreement which have not vested or do not vest on or prior to the date on which such Termination of Service occurs, and Participant's rights in any such RSUs and Dividend Equivalents which are not so vested shall lapse and expire.

2.3 Distribution or Payment of RSUs.

(a) Participant's RSUs shall be distributed in Shares (either in book-entry form or otherwise) or, at the option of the Company, paid in an amount of cash as set forth in Section 2.3(b), in either case, as soon as administratively practicable following the vesting of the applicable RSU pursuant to Section 2.2, and, in any event, within sixty (60) days following such vesting. Notwithstanding the foregoing, the Company may delay a distribution or payment in settlement of RSUs if it reasonably determines that such payment or distribution will violate Federal securities laws or any other Applicable Law, *provided* that such distribution or payment shall be made at the earliest date at which the Company reasonably determines that the making of such distribution or payment will not cause such violation, as required by Treasury Regulation Section 1.409A-2(b)(7)(ii), and *provided further* that no payment or distribution shall be delayed under this Section 2.3(a) if such delay will result in a violation of Section 409A of the Code.

(b) In the event that the Company elects to make payment of Participant's RSUs in cash, the amount of cash payable with respect to each RSU shall be equal to the Fair Market Value of a Share on the day immediately preceding the applicable distribution or payment date set forth in Section 2.3(a). All distributions made in Shares shall be made by the Company in the form of whole Shares.

2.4 Conditions to Issuance of Certificates. The Company shall not be required to issue or deliver any certificate or certificates for any Shares prior to the fulfillment of all of the following conditions: (A) the admission of the Shares to listing on all stock exchanges on which such Shares are then listed, (B) the completion of any registration or other qualification of the Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable, and (C) the obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable.

2.5 Tax Withholding. Notwithstanding any other provision of this Agreement:

(a) The Company and its Subsidiaries have the authority to deduct or withhold, or require Participant to remit to the Company or the applicable Subsidiary, an amount sufficient to satisfy applicable federal, state, local and foreign taxes (including the employee portion of any FICA obligation) required by law to be withheld with respect to any taxable event arising pursuant to this Agreement. The Company and its Subsidiaries may withhold or Participant may make such payment in one or more of the forms specified below:

(i) by cash or check made payable to the Company or the Subsidiary with respect to which the withholding obligation arises;

(ii) by the deduction of such amount from other compensation payable to Participant;

(iii) with respect to any withholding taxes arising in connection with the distribution of the RSUs, with the consent of the Administrator, by requesting that the Company and its Subsidiaries withhold a net number of vested shares of Stock otherwise issuable pursuant to the RSUs having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the minimum applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(iv) with respect to any withholding taxes arising in connection with the distribution of the RSUs, with the consent of the Administrator, by tendering to the Company vested shares of Stock having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company

and its Subsidiaries based on the minimum applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(v) with respect to any withholding taxes arising in connection with the distribution of the RSUs, through the delivery of a notice that Participant has placed a market sell order with a broker acceptable to the Company with respect to shares of Stock then issuable to Participant pursuant to the RSUs, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company or the Subsidiary with respect to which the withholding obligation arises in satisfaction of such withholding taxes; *provided* that payment of such proceeds is then made to the Company or the applicable Subsidiary at such time as may be required by the Administrator, but in any event not later than the settlement of such sale; or

(vi) in any combination of the foregoing.

(b) With respect to any withholding taxes arising in connection with the RSUs, in the event Participant fails to provide timely payment of all sums required pursuant to Section 2.5(a), the Company shall have the right and option, but not the obligation, to treat such failure as an election by Participant to satisfy all or any portion of Participant's required payment obligation pursuant to Section 2.5(a)(ii) or Section 2.5(a)(iii) above, or any combination of the foregoing as the Company may determine to be appropriate. The Company shall not be obligated to deliver any certificate representing shares of Stock issuable with respect to the RSUs to Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes applicable with respect to the taxable income of Participant resulting from the vesting or settlement of the RSUs or any other taxable event related to the RSUs.

(c) In the event any tax withholding obligation arising in connection with the RSUs will be satisfied under Section 2.5(a)(iii), then the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of shares from those shares of Stock then issuable to Participant pursuant to the RSUs as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the tax withholding obligation and to remit the proceeds of such sale to the Company or the Subsidiary with respect to which the withholding obligation arises. Participant's acceptance of this Award constitutes Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 2.5(c), including the transactions described in the previous sentence, as applicable. The Company may refuse to issue any shares of Stock in settlement of the RSUs to Participant until the foregoing tax withholding obligations are satisfied, *provided* that no payment shall be delayed under this Section 2.5(c) if such delay will result in a violation of Section 409A of the Code.

(d) Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

2.6 Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares (which may be in book-entry form) will have been issued and recorded on the records of the Company or its transfer agents or registrars, and delivered to Participant (including through electronic delivery to a brokerage account). Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such Shares, including, without limitation, the right to receipt of dividends and distributions on such Shares.

### ARTICLE III. OTHER PROVISIONS

3.1 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

3.2 RSUs Not Transferable. The RSUs may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution, unless and until the Shares underlying the RSUs have been issued, and all restrictions applicable to such Shares have lapsed. No RSUs or any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

3.3 Adjustments. The Administrator may accelerate the vesting of all or a portion of the RSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 14.2 of the Plan.

3.4 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.4, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

3.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

3.6 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

3.7 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws, including, without limitation, the provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the RSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to Applicable Law.

3.8 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of Participant.

3.9 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company.

Subject to the restrictions on transfer set forth in Section 3.2 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

3.10 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the RSUs (including RSUs which result from the deemed reinvestment of Dividend Equivalents), the Dividend Equivalents, the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

3.11 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

3.12 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

3.13 Section 409A. This Award is not intended to constitute “nonqualified deferred compensation” within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, “Section 409A”). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

3.14 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

3.15 Limitation on Participant’s Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents.

3.16 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

3.17 Broker-Assisted Sales. In the event of any broker-assisted sale of shares of Stock in connection with the payment of withholding taxes as provided in Section 2.5(a)(iii) or Section 2.5(a)(v): (A) any shares of Stock to be sold through a broker-assisted sale will be sold on the day the tax withholding obligation arises or as soon thereafter as practicable; (B) such shares of Stock may be sold as part of a block trade with other participants in the Plan in which all participants receive an average price; (C) Participant will be responsible for all broker’s fees and other costs of sale, and Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (D) to the extent the proceeds of such sale exceed the applicable tax withholding obligation,

the Company agrees to pay such excess in cash to Participant as soon as reasonably practicable; (E) Participant acknowledges that the Company or its designee is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the applicable tax withholding obligation; and (F) in the event the proceeds of such sale are insufficient to satisfy the applicable tax withholding obligation, Participant agrees to pay immediately upon demand to the Company or its Subsidiary with respect to which the withholding obligation arises an amount in cash sufficient to satisfy any remaining portion of the Company's or the applicable Subsidiary's withholding obligation.

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A-6

**EXECUTIVE EMPLOYMENT AGREEMENT**

THIS EMPLOYMENT AGREEMENT (the "Agreement"), effective as of October 27, 2016, is entered into by Momenta Pharmaceuticals, Inc., a Delaware corporation with its principal place of business at 675 West Kendall Street, Cambridge, Massachusetts (the "Company"), and Scott M. Storer, an individual residing at XXX (the "Employee").

In consideration of the mutual covenants and promises contained herein, and other good and valuable consideration, the receipt and sufficiency of which are acknowledged by the parties hereto, the parties agree as follows:

1. Term of Employment. The Employee's employment shall be upon the terms set forth in this Agreement. There shall be no definite term of employment, and the Employee's employment shall be at-will, such that both the Company and the Employee shall be free to end the employment relationship for any reason, at any time, with or without notice.

2. Title and Capacity. The Employee shall serve as Senior Vice President, Chief Financial Officer and shall report to the President and Chief Executive Officer of the Company, beginning as of November 28, 2016 (the "Commencement Date"). The Employee shall be based at the Company's headquarters in Cambridge, Massachusetts. The Employee hereby accepts such employment and agrees to undertake the duties and responsibilities inherent in such position and such other duties and responsibilities as the Company shall from time to time reasonably assign to the Employee. The Employee agrees to devote his/her entire business time, attention and energies to the business and interests of the Company. The Employee agrees to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

3. Compensation and Benefits.

3.1 Base Salary. The Company shall pay the Employee, in accordance with the Company's regular payroll practices, a base salary at the annualized rate of \$420,000. Such salary shall be subject to adjustment thereafter, as determined by the Board or a committee or designee thereof.

3.2 Annual Discretionary Bonus. If the Company's Board approves an annual bonus for calendar year 2017 or any calendar year thereafter, the Employee will be eligible for a discretionary bonus award. The annual target for the Employee's bonus will be at 40% of the Employee's annualized base salary. The Company will determine, in its sole discretion, whether (and in what amount) a bonus award is payable to the Employee. In determining whether a bonus award in any given year shall be granted, the Company will review whether it has achieved its annually approved corporate goals as well as whether the Employee has achieved his/her personal objectives as established by the Company. In order to be eligible for any bonus hereunder, the Employee must be an active employee of the Company on the date such bonus is distributed.

3.3 Employee Benefits. Subject to the provisions of this Section 3.3, the Employee shall be entitled to participate in all benefit plans and programs that the Company establishes and makes available to its employees to the extent that the Employee is eligible under (and subject to the provisions of) the plan documents governing those programs. The Employee shall be entitled to twenty (20) days of paid vacation time per year (pro-rated for any partial year worked), to be administered in accordance with Company policy.

3.4 Reimbursement of Expenses. The Company shall reimburse the Employee for all reasonable travel, entertainment and other expenses incurred or paid by the Employee in connection with, or related to, the performance of his/her duties, responsibilities or services under this Agreement, upon presentation by the Employee of documentation, expense statements, vouchers and/or such other supporting information as the Company may reasonably request; provided, however, that the amount available for such travel, entertainment and other expenses may be fixed in advance by the Company.

3.5 Withholding. All salary, bonus and other compensation or benefits payable to the Employee shall be subject to applicable withholdings and taxes.

4. Payments Upon Resignation By The Employee Without Good Reason or Termination By The Company For Cause.

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4.1 Payment upon Voluntary Resignation or Termination for Cause. If the Employee voluntarily resigns his/her employment other than for Good Reason (as defined in Section 4.2), or if the Company terminates the Employee for Cause (as defined in Section 4.3), the Company shall pay the Employee all accrued and unpaid base salary through the Employee's date of termination and any vacation that is accrued but unused as of such date. The Employee shall not be eligible for any severance or separation payments (including, but not limited to, those described in Sections 5 and 6 of this Agreement) or any continuation of benefits (other than those provided for under the Federal Consolidated Omnibus Budget Reconciliation Act ("COBRA")), or any other compensation pursuant to this Agreement or otherwise. The Employee also shall have such rights, if any, with respect to outstanding stock options and restricted stock grants as may be provided under the agreement applicable to each.

4.2 Definition of "Good Reason". For purposes of this Agreement, "Good Reason" means the occurrence, without the Employee's written consent, of any of the events or circumstances set forth in clauses (a) through (d) below, provided, however, that an event described in clauses (a) through (d) below shall not constitute Good Reason unless it is communicated in writing, within 90 days of the event giving rise to the claim, by the Employee to the Company or its successor and unless it is not corrected by the Company or its successor and the Employee has not been reasonably compensated for any loss or damages resulting therefrom within thirty (30) days of the Company's or successor's receipt of such written notice:

- (a) the assignment to the Executive of duties inconsistent in any material respect with the Executive's position (including status, offices, titles and reporting requirements), authority or responsibilities, or any other action or omission by the Company which results in a material diminution in such position, authority or responsibilities;
- (b) a material breach of this Agreement by the Company;
- (c) a material reduction in the Employee's base salary; or
- (d) a change by the Company in the location at which the Employee performs his/her principal duties for the Company to a new location that is both (i) outside a radius of 50 miles from the Employee's principal residence and (ii) more than 30 miles from the location at which the Employee performed his/her principal duties for the Company.

4.3 Definition of "Cause". For purposes of this Agreement, "Cause" is defined as: (i) a good faith finding by no fewer than two-thirds of the members of the Board (excluding the Employee, if applicable) of (a) the Employee's failure to (1) perform reasonably assigned lawful duties or (2) comply with a lawful instruction of the Board, Chief Executive Officer or such other executive officer with direct supervisory authority over the Employee so long as, in the case of (2), the instruction is consistent with the scope and responsibilities of the Employee's position, or (b) the Employee's dishonesty, willful misconduct or gross negligence, or (c) the Employee's substantial and material failure or refusal to perform according to, or to comply with, the policies, procedures or practices established by the Company or the Board and, in the case of (a) or (c), the Employee has had ten (10) days written notice to cure his/her failure to so perform or comply; or (ii) the Employee's indictment, or the entering of a guilty plea or plea of "no contest" with respect to, a felony or any crime involving moral turpitude.

5. Termination Without Cause, Termination by Reason of Death or Disability, Resignation for Good Reason.

5.1 If the Employee's employment with the Company is terminated by reason of the Employee's death or Disability (as defined in Section 5.2), by the Company without Cause (as defined in Section 4.3), or by the Employee's voluntary resignation for Good Reason (as defined in Section 4.2), other than in connection with a Change in Control (as defined in Section 6.1(a)), then the Employee shall be paid all accrued and unpaid base salary and any accrued but unused vacation through the date of termination. In addition, if the Employee's employment with the Company is terminated by reason of the Employee's Disability, by the Company without Cause, or by the Employee's voluntary resignation for Good Reason, subject to the Employee's execution and non-revocation of a binding severance and mutual release agreement in a form provided by and satisfactory to the Company (hereinafter, a "Severance Agreement"), which Severance Agreement must be executed and any applicable revocation period with respect thereto must have expired within sixty (60) days of the date of termination, the Employee shall be eligible to receive the following separation benefits:

- (a) an amount equal to the sum of (i) twelve (12) months of the Employee's base salary as of the date of termination (which amount shall be payable in installments in accordance with the Company's regular payroll practices, beginning on the next payroll date following the 60th day after the date of termination) and (ii) the greater of (x) the annual discretionary target bonus established by the Board (or any other person or persons having authority with respect thereto) for the Employee for the fiscal year in which the date of termination occurs or (y) the annual bonus paid to the

Employee for the most recently completed fiscal year (which amount shall be payable in one lump sum on the next payroll date following the 60<sup>th</sup> day after the date of termination);

(b) if the Employee is eligible for and elects to continue his/her medical and/or dental health insurance coverage pursuant to COBRA, the Company shall continue to contribute, until the earlier of (x) twelve (12) months following the date of termination or (y) the date on which the Employee becomes eligible to receive group medical and/or dental insurance coverage through a new employer (the "Contribution Period"), toward the cost of the Employee's COBRA premiums the same amount that it pays on behalf of active and similarly situated employees receiving the same type of coverage. The remaining balance of any premium costs, and all premium costs after the Contribution Period, shall be paid by the Employee on a monthly basis. After the Contribution Period, the Employee may continue receiving coverage under COBRA at his/her own cost if and to the extent that he/she remains eligible for COBRA continuation. The Employee agrees that he/she shall notify the Company in writing immediately following the date on which he/she becomes eligible for group medical and/or dental insurance coverage through another employer;

(c) the Company shall continue to provide benefits to the Employee in accordance with any applicable life insurance, accident and/or disability plans under which the Employee was eligible as of the date of termination consistent with such benefits as may be provided to active and similarly situated employees covered by such plans, until the earlier of (x) twelve (12) months following the date of termination or (y) the date on which the Employee becomes eligible to receive substantially comparable coverage through a new employer (the "Extended Benefits Period"); provided, however, that if such plans do not permit continued coverage of the Employee following the date of termination, the Company shall instead reimburse the Employee for the reasonable cost of purchasing substantially comparable coverage during the Extended Benefits Period. The Employee agrees that he/she shall notify the Company in writing immediately following the date on which he/she becomes eligible for life insurance, accident and/or disability coverage through a new employer. The benefits provided and/or payments made under this subsection shall be in installments in accordance with the Company's regular payroll practices, beginning with the payroll date following the 60<sup>th</sup> day after the date of termination; and

(d) The Employee shall be entitled to continued vesting of any unvested stock options and any future stock option grants awarded to the Employee after the date of this Agreement (collectively, the "Outstanding Stock Options") for a period of twelve (12) months from the date of termination (the "Extended Vesting Date") and the right to exercise any Outstanding Stock Options shall terminate on the earlier of three months after the Extended Vesting Date and the original expiration date of the Outstanding Stock Option (assuming no termination of employment occurred). The Employee shall also be entitled to immediate vesting, on the date of termination, of any restricted stock awards with underlying shares that vest solely through the passage of time (*i.e.*, service-based vesting) and not upon the achievement of specified conditions or milestones (*i.e.*, performance-based vesting), including any future restricted stock awards granted to the Employee after the date of this Agreement that contain service-based vesting provisions (collectively, "Outstanding Restricted Stock Awards"), in each case that would have vested during the period of twelve (12) months from the date of termination. The Employee shall have no further rights with respect to any Outstanding Restricted Stock Awards that remain unvested after taking into account the previous sentence.

5.2 For purposes of this Agreement, "Disability" shall mean the Employee's absence from the full-time performance of the Employee's duties with the Company for 180 consecutive calendar days as a result of incapacity due to mental or physical illness which is determined to be total and permanent by a physician selected by the Company or its insurers and acceptable to the Employee or the Employee's legal representative.

### 5.3 Taxes.

(a) Notwithstanding any other provision of this Agreement, except as set forth in Section 5.3(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the Company shall not be obligated to provide to the Employee a portion of any "Contingent Compensation Payments" (as defined below) that the Employee would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Section 280G(b)(1) of the Internal Revenue Code of 1986, as amended (the "Code")) for the Employee. For purposes of this Section 5.3, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."

(b) Notwithstanding the provisions of Section 5.3(a), no such reduction in Contingent Compensation Payments shall be made if (i) the Eliminated Amount (computed without regard to this sentence) exceeds (ii) 110% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31, Q/A-32 and Q/A-33 or any successor provisions) of the amount of any additional taxes that would be incurred by the Employee if the Eliminated Payments (determined without regard to this sentence) were paid to him/her (including, state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Employee's "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 5.3(b) shall be referred to as a "Section 5.3(b) Override." For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 5.3 the following terms shall have the following respective meanings:

(i) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(ii) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Employee following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 5.3(d). Within 30 days after each date on which the Employee first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify the Employee (with reasonable detail regarding the basis for its determinations): (i) which Potential Payments constitute Contingent Compensation Payments, (ii) the Eliminated Amount and (iii) whether the Section 5.3(b) Override is applicable. The Eliminated Amount shall be determined by reducing or eliminating Potential Payments in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the Excise Tax, to the extent necessary to maximize the Eliminated Payments. Within 30 days after delivery of such notice to the Employee, the Employee shall deliver a response to the Company (the "Employee Response") stating either (A) that he/she agrees with the Company's determinations pursuant to the preceding two sentences or (b) that he/she disagrees with such determinations, in which case he/she shall set forth (i) which Potential Payments should be characterized as Contingent Compensation Payments, (ii) the Eliminated Amount (which must be determined based on the ordering rules set forth in the preceding sentence) and (iii) whether the Section 5.3(b) Override is applicable. In the event that the Employee fails to deliver an Employee Response on or before the required date, the Company's initial determination shall be final. If the Employee states in the Employee Response that he/she agrees with the Company's determination, the Company shall make the Potential Payments to the Employee within three business days following delivery to the Company of the Employee Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Employee states in the Employee Response that he/she disagrees with the Company's determination, then, for a period of 60 days following delivery of the Employee Response, the Employee and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Employee Response, make to the Employee those Potential Payments as to which there is no dispute between the Company and the Employee regarding whether they should be made (except for any such Potential Payments which are not due to be paid until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute. Subject to the limitations contained in Sections 5.3(a) and (b) hereof, the amount of any payments to be made to the Employee following the resolution of such

dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by the *Wall Street Journal*, compounded monthly from the date such payments originally were due.

(e) The provisions of this Section 5.3 are intended to apply to any and all payments or benefits available to the Employee under this Agreement or any other agreement or plan of the Company under which the Employee receives Contingent Compensation Payments.

## 6. Termination Following Change of Control.

6.1 Key Definitions. As used herein, the following terms shall have the following respective meanings:

(a) “Change in Control” means an event or occurrence set forth in any one or more of subsections (i) through (iv) below (including an event or occurrence that constitutes a Change in Control under one of such subsections but is specifically exempted from another such subsection), provided that such event or occurrence also constitutes a change in ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company, each within the meaning of Section 409A (as defined below):

(i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) (a “Person”) of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the “Outstanding Company Common Stock”) or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the “Outstanding Company Voting Securities”); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (a) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (b) any acquisition by the Company, (c) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (d) any acquisition by any corporation pursuant to a transaction which complies with clauses (x) and (y) of subsection (iii) of this Section 6.1; or

(ii) such time as the Continuing Directors (as defined below) do not constitute a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term “Continuing Director” means at any date a member of the Board (x) who was a member of the Board on the date of the execution of this Agreement or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(iii) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company, in one or a series of transactions (a “Business Combination”), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company’s assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the “Acquiring Corporation”) in substantially the same proportions as their ownership, immediately prior to such Business Combination, of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively; and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the

then outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(iv) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company.

(b) “Change in Control Date” means the first date during the period of time the Employee is employed pursuant to this Agreement on which a Change in Control occurs. Anything in this Agreement to the contrary notwithstanding, if (a) a Change in Control occurs, (b) the Employee’s employment with the Company is terminated prior to the date on which the Change in Control occurs, and (c) it is reasonably demonstrated by the Employee that such termination of employment (i) was at the request of a third party who has taken steps reasonably calculated to effect a Change in Control or (ii) otherwise arose in connection with or in anticipation of a Change in Control, then for all purposes of this Agreement the “Change in Control Date” shall mean the date immediately prior to the date of such termination of employment.

(c) Change of Control Termination occurs where the Employee is terminated without Cause (as defined in Section 4.3) or resigns for Good Reason (as defined in Section 4.2), in either case within twelve (12) months following the Change in Control Date. In addition, any termination of the Employee’s employment that occurs within twelve (12) months following the Change in Control Date shall be communicated by a written notice to the other party (the “Notice of Termination”), given in accordance with Section 11 hereof. Any such Notice of Termination shall: (i) indicate the specific termination provision of this Agreement relied upon by the party giving such notice, (ii) in the case of a termination by the Company for Cause or by the Employee for Good Reason, set forth in reasonable detail the facts and circumstances claimed to provide a basis for such Cause or Good Reason, and (iii) specify the Date of Termination (as defined below). The effective date of an employment termination (the “Date of Termination”) shall be the close of business on the date specified in the Notice of Termination (which date, other than in the case of a termination due to the Employee’s death, or a termination by the Company for Cause (which notice shall be governed by Section 4.3)), may not be less than 15 days or more than 120 days after the date of delivery of such Notice of Termination). In the event the Company fails to satisfy the requirements of this Section 6.1(c) regarding a Notice of Termination, the purported termination of the Employee’s employment pursuant to such Notice of Termination shall not be effective for purposes of this Agreement.

#### 6.2 Benefits to Employee Upon a Change of Control Termination

In the event of a Change of Control Termination, the Employee shall be entitled to all accrued and unpaid base salary and any accrued but unused vacation through the date of termination the Employee shall be eligible to receive the following separation benefits:

(a) an amount equal to the sum of (i) twelve (12) months of the Employee’s base salary as of the date of termination (which amount shall be payable in one lump sum on the next payroll date following the 30<sup>th</sup> day after the date of termination; provided, however, that if the Change in Control Date precedes the Change in Control, then such amount shall be payable in accordance with Section 5.1(a)(i) hereof), and (ii) the greater of (x) the annual discretionary target bonus established by the Board (or any other person or persons having authority with respect thereto) for the Employee for the fiscal year in which the date of termination occurs or (y) the annual bonus paid to the Employee for the most recently completed fiscal year (which amount shall be payable in one lump sum on the next payroll date following the 30<sup>th</sup> day after the date of termination; provided, however, that if the Change in Control Date precedes the Change in Control, then such amount shall be payable in accordance with Section 5.1(a)(i) hereof);

(b) the Company shall, if the Employee is eligible for and elects to continue his/her medical and/or dental health insurance coverage pursuant to COBRA, continue to contribute during the Contribution Period defined above toward the cost of the Employee’s COBRA premiums the same amount that it pays on behalf of active and similarly situated employees receiving the same type of coverage. The remaining balance of any premium costs, and all premium costs after the Contribution Period, shall be paid by the Employee on a monthly basis. After the Contribution Period, the Employee may continue receiving coverage under COBRA at his/her own cost if and to the extent that he/she remains eligible for COBRA continuation. The Employee agrees that he/she shall notify the Company in writing immediately following the date on which he/she becomes eligible for group medical and/or dental insurance coverage through another employer; and

(c) during the Extended Benefits Period defined above, the Company shall continue to provide benefits to the Employee in accordance with any applicable life insurance, accident and/or disability plans under

which the Employee was eligible as of the date of termination consistent with such benefits as may be provided to active and similarly situated employees covered by such plans; provided, however, that if such plans do not permit continued coverage of the Employee following the date of termination, the Company shall instead reimburse the Employee for the reasonable cost of purchasing substantially comparable coverage during the Extended Benefits Period. The Employee agrees that she shall notify the Company in writing immediately following the date on which she becomes eligible for life insurance, accident and/or disability coverage through another employer. The benefits provided and/or payments made under this subsection shall be in installments in accordance with the Company's regular payroll practices, beginning with the payroll date following the 30<sup>th</sup> day after the date of termination; provided, however, that if the Change in Control Date precedes the Change in Control, then such amounts shall be payable in accordance with Section 5.1(c) hereof; and

(d) the Employee shall be entitled to immediate vesting of any unvested option shares, restricted shares and any future grants awarded to the Employee. All such equity awards (whether stock options or restricted stock grants) will remain exercisable in accordance with the applicable stock option plan or grant agreement.

6.3 Injunctive Relief. The Company and the Employee agree that any breach of Section 6 of this Agreement by the Company is likely to cause the Employee substantial and irrevocable damage and therefore, in the event of any such breach, in addition to such other remedies which may be available, the Employee shall have the right to specific performance and injunctive relief.

7. Mitigation. The Employee shall not be required to mitigate the amount of any payment or benefits provided for in Sections 5 or 6 by seeking other employment or otherwise except with regard to medical and dental coverage if new employment is obtained.

8. Survival. The provisions of Sections 5, 6, 9, 10 and 11 shall survive the termination of this Agreement for any reason.

9. Non-Competition and Non-Solicitation.

9.1 During employment with the Company and for a period of twelve (12) months after the termination of employment with the Company for any reason, the Employee shall not, either on the Employee's own behalf, or as owner, manager, stockholder, consultant, director, officer, or employee of any business entity (except as a holder of not more than one (1%) percent of the stock of a publicly held company) participate, directly or indirectly, in any capacity, in any business that is competitive with the Company's business, including, but not limited to any business or enterprise that develops, manufactures, markets or sells any product or service that competes with any product or service developed, manufactured, marketed or sold by the Company or any of its subsidiaries while the Employee was employed by the Company.

9.2 During employment with the Company and for a period of twelve (12) months after the termination of employment with the Company for any reason, the Employee shall not, either alone or in association with others, solicit, induce, recruit, or hire, or attempt to solicit, induce, recruit or hire for employment or as an independent contractor any employee of the Company.

9.3 During employment with the Company and for a period of twelve (12) months after the termination of employment for any reason, the Employee shall not solicit, divert or take away, or attempt to solicit, divert or take away, directly or indirectly, the business or patronage of any of the clients, customers or accounts, or prospective clients, customers or accounts, of the Company, which were contacted, solicited or served by the Company at any time during the term of the Employee's employment with the Company.

9.4 The restrictions contained in this Section 9 are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach of this Section 9 is likely to cause the Company substantial and irrevocable damage that is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies that may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach and the right to specific performance of the provisions of this Section 9 without posting a bond and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief. The Employee agrees that any change or changes in his/her duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Section 9.

10. Confidential Information and Developments.

10.1 Confidential Information.

(a) The term "Confidential Information" shall mean all scientific, technical, trade or business information developed for or possessed by the Company which is treated by the Company as confidential or proprietary, including, without limitation, information pertaining to sugars, heparinases, enzymes, reagents, glycoproteins, proteins, peptide mixtures, plasmas, vectors, expression systems, cells, cell lines, antibodies, organisms, chemical compounds, products, formulations, methodologies, algorithms, notation systems, computer programs, computer security systems and processes, assay systems, procedures, tests, data, documentation, reports, sources of supply, know-how, patent positioning, business plans, research, manufacturing, commercialization, marketing and any other confidential information about or belonging to Company's affiliates, suppliers, licensors, licensees, partners, collaborators, customers and any other technical or business information, whether prepared, conceived or developed by the Company or received by the Company from an outside source, which is maintained in confidence by the Company, or which might permit the Company or its customers to obtain a competitive advantage over competitors. Notwithstanding the foregoing, the term Confidential Information shall not apply to information which the Company has voluntarily disclosed to the public without restriction, or which has otherwise lawfully entered the public domain.

(b) Employee shall not, directly or indirectly, use or disclose any Confidential Information, except as may be required by Company in the ordinary course of performance of the Employee's duties as an employee of the Company. This nondisclosure obligation shall survive termination of my employment with the Company. Notwithstanding anything to the contrary herein, nothing in this Agreement is intended to or will be used by the Company in any way to limit an employee's right to communicate with a government agency, as provided for or protected under, applicable law.

10.2 Developments.

(a) Employee agrees that all discoveries, inventions, ideas, specifications, designs, concepts, know-how, trade secrets, software, works of authorship, biological substances, data, documentation, reports, research processes, products, methods and improvements, or parts thereof that the Employee may solely or jointly conceive, develop, reduce to practice, or otherwise create, or cause to be conceived, developed, reduced to practice or otherwise created, in any way relating to the Company's present or proposed products, during the period of employment with the Company, whether or not made during regular working hours, and whether or not made on the Company's premises (hereinafter referred to as "Developments"), together with all products or services which embody or emulate any such Developments, shall be the sole and exclusive property of the Company. The Employee shall make and maintain adequate and current written records of all Developments, including notebooks and invention disclosures, which records shall be available to and remain the property of the Company at all times. The Employee shall disclose all Developments promptly, fully and in writing to the Company immediately upon production or development of the same and at any time upon request.

(b) Employee hereby assigns to the Company all right, title and interest throughout the world in and to all Developments and to anything tangible which evidences, incorporates, constitutes, represents or records any Developments. Employee agrees that all Developments shall constitute works made for hire under the copyright laws of the United States and hereby assign and, to the extent any such assignment cannot be made at present, Employee hereby agrees to assign, to the Company all copyrights, patents and other proprietary rights Employee may have in any Developments, together with the right to file for and/or own wholly without restriction any and all patents, trademarks, and copyrights throughout the world. Employee agrees to waive, and hereby waives, all moral rights or proprietary rights in or to any Developments and, to the extent that such rights may not be waived, agree not to assert such rights against the Company or its licensees, successors or assigns.

(c) Employee agrees to cooperate fully, both during and after employment, to assist the Company in obtaining, maintaining, perfecting, enforcing and defending any and all trade secret, patent, copyright, mask work, know-how, and other intellectual property rights, proprietary information or confidential information protectable under the laws of any country in the world. Employee will take all necessary steps, execute all documents and perform all other acts which the Company considers necessary or advisable to secure its rights hereunder and to carry out the intent of this Agreement. Employee further agrees that if the Company is unable, after reasonable effort, to secure my signature on any such papers, any executive officer of the Company shall be entitled to execute any such papers as my agent and attorney-in-fact, and the Employee hereby irrevocably designates and appoints each executive officer of the Company as the Employee's agent and attorney-in-fact to execute any such papers on the Employee's behalf, and to take any and all actions as the

Company may deem necessary or desirable in order to protect its rights and interests in any Development. Employee acknowledges that the Company, from time to time, may have agreements with other persons, including the government of the United States or other countries and agencies thereof, which impose obligations or restrictions on the Company regarding Developments made during the course of work thereunder or regarding the confidential nature of such work. Employee agrees to be bound by all such obligations and restrictions and to take all action necessary to discharge the obligations of the Company thereunder.

10.3 United States Government Obligations. The Employee acknowledges that the Company from time to time may have agreements with other parties or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Employee agrees to be bound by all such obligations and restrictions that are made known to the Employee and to take all action necessary to discharge the obligations of the Company under such agreements.

10.4 Equitable Remedies. The restrictions contained in this Section 10 are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach of this Section 10 is likely to cause the Company substantial and irrevocable damage that is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies that may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach and the right to specific performance of the provisions of this Section 10 without posting a bond and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief. The Employee agrees that any change or changes in his/her duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Section 10.

10.5 Other Agreements. The Employee hereby represents and warrants that, except as previously disclosed in writing to the Company (which disclosure shall include the delivery to the Company of relevant written excerpts from any agreement to which the Employee is a party describing any obligations that continue, after the Commencement Date, with respect to nondisclosure, non-competition or non-solicitation of employees, customers or suppliers), he/she is not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of his/her employment with the Company, to refrain from competing, directly or indirectly, with the business of such previous employer or any other party or to refrain from soliciting employees, customers or suppliers of such previous employer or other party. The Employee further represents and warrants that his/her performance of all the terms of this Agreement and the performance of his/her duties as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by him/her in confidence or in trust prior to his/her employment with the Company and that the Employee will not disclose to the Company or induce the Company to use any confidential or proprietary information, knowledge or material belonging to any previous employer or others.

11. Notices. Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, or one (1) business day after it is sent for next-business day delivery signature required via a reputable nationwide overnight courier service, in each case to the address of the recipient set forth in the introductory paragraph hereto. Either party may change the address to which notices are to be delivered by giving notice of such change to the other party in the manner set forth in this Section 11.

12. Entire Agreement. This Agreement and any exhibits hereto constitute the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

13. Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Employee.

14. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court. The Company and the Employee each



hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

15. Successors and Assigns. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company as expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no such succession had taken place. Failure of the Company to obtain an assumption of this Agreement upon the effectiveness of any succession shall be a breach of this Agreement and shall constitute Good Reason if the Employee elects to terminate employment, except that for purposes of implementing the foregoing, the date on which any such succession becomes effective shall be deemed the Date of Termination. As used in this Agreement, "Company" shall mean the Company as defined above and any successor to its business or assets as aforesaid which assumes and agrees to perform this Agreement, by operation of law or otherwise. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns; provided, however, that the obligations of the Employee are personal and shall not be assigned by the Employee.

16. Acknowledgment. The Employee states and represents that he/she has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Employee further states and represents that he/she has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs his/her name of his/her own free act. The Employee further acknowledges that the law firm of WilmerHale is acting as counsel to the Company in connection with the transactions contemplated by this Agreement, and is not acting as counsel for the Employee.

17. Section 409A.

17.1 Distributions. Subject to this Section 17.1, any payments or benefits under Sections 5 and 6 shall begin only upon the date of a "separation from service" as defined below which occurs on or after the date of termination under Section 5.1 or a Change of Control Termination under Section 6.1(c). The following rules shall apply with respect to distribution of the payments and benefits, if any, to be provided to the Employee under Sections 5 and 6:

(a) It is intended that each installment of the payments and benefits provided under sections 5 and 6 shall be treated as a separate "payment" for purposes of Section 409A of the U.S. Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A"). Neither the Company nor the Employee shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A;

(b) If, as of the date of the "separation from service" of the Employee from the Company (as defined below), the Employee is not a "specified employee" (within the meaning of Section 409A), then each installment of the payments and benefits shall be made on the dates and terms set forth in sections 5 and 6; and

(c) If, as of the date of the "separation from service" of the Employee from the Company, the Employee is a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the payments and benefits due under Sections 5 and 6 that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the separation from service occurs, be paid within the Short-Term Deferral Period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time and in the manner set forth in the Agreement; and

(ii) Each installment of the payments and benefits due under Sections 5 and 6 that is not described in Section 17.1(c)(i) and that would, absent this subsection, be paid within the six-month period following the "separation from service" of the Employee from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Employee's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Employee's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments

that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Employee's second taxable year following the Employee's taxable year in which the separation from service occurs.

17.2 The determination of whether and when a separation from service has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h).

17.3 All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A.

17.4 The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, such section.

18. Miscellaneous.

18.1 No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

18.2 The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

18.3 In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Jo-Ann Beltranello

Title: SVP, Human Resources

EMPLOYEE

/s/ Scott M. Storer

Scott M. Storer

## INDUSTRY CONSULTING AGREEMENT

THIS INDUSTRY CONSULTING AGREEMENT (“Agreement”) is made and entered into as of the 30th day of December, 2016 (the “Effective Date”) by and between MOMENTA PHARMACEUTICALS, INC., a Delaware corporation, having a place of business at 675 West Kendall Street, Cambridge, MA 02142 (“Company”) and Richard P. Shea, having a place of business at XXX (“Consultant”).

1. DEFINITIONS

“Confidential Information” means any scientific, technical, trade or business information developed for or possessed by Company (including that developed by Consultant under the terms of this Agreement) which is treated by Company as confidential or proprietary, including, without limitation, information pertaining to sugars, polysaccharides, heparinases, enzymes, reagents, glycoproteins, proteins, peptide mixtures, peptides, glycoconjugates, primers, plasmids, vectors, expression systems, cells, cell lines, antibodies, organisms, chemical compounds, products, formulations, technologies, techniques, methodologies, algorithms, notation systems, computer programs, computer security systems and processes, assay systems, procedures, tests, data, documentation, reports, sources of supply, know-how, patent positioning, relationships with employees and consultants, business plans, business developments, research, development, process development, manufacturing, commercialization, marketing, and any other confidential information about or belonging to Company’s affiliates, suppliers, licensors, licensees, partners, collaborators, customers or others. For the purpose of clarity, the identity of any of Company’s programs or drug development candidates shall be considered Company’s Confidential Information.

Confidential Information shall not include any information which (a) was known to Consultant at the time it was disclosed, other than by previous disclosure by Company, as evidenced by Consultant’s written records at the time of disclosure, (b) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement, or (c) is lawfully and in good faith made available to Consultant by a third party who did not derive it, directly or indirectly, from Company.

“Development” means ideas, concepts, discoveries, inventions, developments, improvements, know-how, trade secrets, methodologies, biological substances, materials, devices, equipment, algorithms, notation systems, computer software and hardware, data, documentation and reports (whether or not protectable under state, federal or foreign patent, trademark, copyright or similar laws) that are developed or conceived or reduced to practice by Consultant (a) during the term of this Agreement and (b) (i) in performance of the consulting services rendered under this Agreement, (ii) by use of Company’s intellectual property, equipment or facilities or (iii) otherwise at Company’s expense.

2. SERVICES

2.1 For the term listed on Attachment A, Company hereby retains Consultant and Consultant hereby agrees to perform the consulting services listed on Attachment A in exchange for the compensation listed on Attachment A. On the last day of each calendar month, Consultant shall invoice Company for the consulting services rendered and any expenses incurred during such calendar month in respect of this Agreement. Payments shall be due within thirty (30) days from Company’s receipt of each invoice from Consultant. In addition, Consultant agrees that Company may disclose information related to this Agreement (including, without limitation, information regarding any compensation or other benefits provided to Consultant under this Agreement) to the extent required by, and in compliance with, applicable local, state, and/or federal law.

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2.2 Consultant represents that it is under no contractual or other obligation or restriction which is inconsistent with Consultant's execution of this Agreement or the performance of the consulting services contemplated by this Agreement. During the term of this Agreement, Consultant will not enter into any agreement, either written or oral, in conflict with Consultant's obligations under this Agreement. Consultant will arrange to provide the consulting services contemplated by this Agreement in such manner and at such times that the rendering of the consulting services under this Agreement will not conflict with Consultant's responsibilities under any other agreement, arrangement or understanding or pursuant to any employment relationship Consultant has at any time with any third party.

2.3 Consultant represents that the performance of the consulting services contemplated by this Agreement does not and will not breach any agreement which obligates Consultant to keep in confidence any confidential or proprietary information of any third party or to refrain from competing with the business of any third party.

2.4 In performing the consulting services contemplated by this Agreement, Consultant agrees to comply with all business conduct, regulatory and health and safety guidelines or regulations established by Company or any governmental authority with respect to the business of the Company.

2.5 Consultant represents that Consultant has not been suspended, debarred or subject to temporary denial of approval, and to the best of Consultant's knowledge, is not under consideration to be suspended, debarred or subject to temporary denial of approval, by the Food and Drug Administration from working in or providing services, directly or indirectly, to any applicant for approval of a drug product or any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992.

### 3. DEVELOPMENTS

3.1 All Developments shall be "works made for hire" and the exclusive property of Company. Consultant shall promptly and fully disclose to Company all Developments. Consultant shall keep and maintain complete records of all Developments and of all work carried out by Consultant under the terms of this Agreement. These records shall also be "works made for hire" and the exclusive property of Company. Consultant may keep one copy of these records in Consultant's files solely for reference purposes. Consultant hereby assigns to Company all of Consultant's right, title and interest in and to any and all Developments. During and after the term of this Agreement, Consultant will cooperate fully in obtaining patent and other proprietary protection for any and all Developments, all in the name of the Company and at Company's cost and expense, and, without limitation, shall execute and deliver all requested applications, assignments and other documents, and take such other measures as Company shall reasonably request, in order to perfect and enforce Company's rights in any and all Developments. Consultant hereby appoints Company its attorney-in-fact to execute and deliver any such documents on behalf of Consultant in the event Consultant shall fail to do so.

3.2 Consultant shall not use any third party intellectual property or facilities in performing the consulting services contemplated by this Agreement or engage in any other activities that would result in a third party having an ownership interest in any Developments.

### 4. CONFIDENTIALITY

During the term of this Agreement and thereafter, Consultant shall not directly or indirectly publish, disseminate or otherwise disclose, use for Consultant's own benefit or for the benefit of a third party, or deliver or make available to any third party any Confidential Information, other than in furtherance of the purposes of this Agreement and only then with the prior written consent of Company. Notwithstanding the foregoing, if required, Consultant may disclose Confidential Information to a governmental authority or by order of a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and reasonable advance notice is given to

Company. During the term of this Agreement and thereafter, Consultant shall exercise all commercially reasonable precautions to physically protect the integrity and confidentiality of the Confidential Information and shall not remove any Confidential Information from the premises of the Company, except to the extent necessary to fulfill the consulting services contemplated by this Agreement and then only with the prior oral or written consent of the Company.

## 5. EXPIRATION AND TERMINATION

5.1 This Agreement shall continue for the term listed on Attachment A unless sooner terminated by written agreement of both parties or pursuant to the terms of this Section 5.

5.2 Company may terminate this Agreement at any time without cause upon not less than twenty (20) days prior written notice to the Consultant.

5.3 Company may immediately terminate this Agreement at any time upon written notice to Consultant in the event of a breach of this Agreement by Consultant which cannot be cured (e.g., a breach of Section 4) or in the event that Consultant is accused of a felony or materially unethical conduct. In addition, Company may terminate this Agreement for cause at any time upon ten (10) days prior written notice to Consultant. Cause shall mean (a) a material breach by Consultant of this Agreement where such breach can be cured and is not remedied within such ten (10) day period, (b) the physical or mental inability of Consultant to perform the consulting services contemplated under this Agreement or (c) the unsatisfactory performance of the consulting services contemplated under this Agreement which unsatisfactory performance is not remedied within such ten (10) day period.

5.4 Upon termination, neither Company nor Consultant shall have any further obligations under this Agreement except that the liabilities accrued through the date of termination and the obligations which by their terms survive termination including, without limitation, the applicable confidentiality provisions of this Agreement, shall survive termination. Notwithstanding the foregoing, the Company's obligation to pay Consultant the Bonus Payment as provided in Schedule A shall survive the Company's termination of this Agreement on or before March 31, 2017, except in the case of a termination pursuant to Section 5.3. Upon termination, Consultant shall return to Company all Confidential Information.

## 6. MISCELLANEOUS

6.1 All consulting services contemplated under this Agreement shall be rendered by Consultant as an independent contractor. Consultant shall have no right to receive any employee benefits, such as health and accident insurance, sick leave or vacation which are accorded to employees of Company. Consultant shall not in any way represent Consultant to be an employee, partner, joint venturer, agent or officer of Company.

6.2 Consultant shall pay all required taxes on Consultant's income under this Agreement. Consultant shall provide all required tax information, including without limitation, the IRS Form W-9 "Request for Taxpayer Identification Number and Certification." Failure to provide such information may result in withholding of payments to Consultant.

6.3 All formal notices from one party to the other shall be in writing and shall be given by addressing the same to the other at the address or facsimile number set forth in this Agreement or at such other address or facsimile number as either may specify in writing to the other. Such notices to Company shall be marked "Attention: Chief Executive Officer", with a copy to "Attention: General Counsel". Such notices shall become effective when (a) deposited in the mail with proper postage for first class certified mail, return receipt requested, (b) deposited with a commercial courier, (c) hand delivered or (d) promptly confirmed by mail, commercial courier or hand delivery when dispatched by facsimile.

6.4 This Agreement is a personal services agreement. The rights and obligations under this Agreement may not be assigned or transferred by either party without the prior written consent of the other party, except that Company may assign this Agreement to an affiliated company or in connection with the merger, consolidation, sale or transfer of all or substantially all of the business to which this Agreement relates.

6.5 This Agreement constitutes the entire agreement of the parties with regard to its subject matter and supersedes all previous oral or written representations, agreements and understandings between Company and Consultant. This Agreement may be changed only by a writing signed by both parties.

6.6 In the event that any one or more provisions of this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, and all other provisions shall remain in full force and effect. If any of the provisions are held to be excessively broad, any such provision shall be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.

6.7 This Agreement shall in all events and for all purposes be governed by and construed in accordance with the law of the Commonwealth of Massachusetts, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

6.8 By signing and delivering this Agreement or any exhibit, appendix, amendment, addendum, or any legally binding document thereto, each Party will be deemed to represent to the other that the signing Party has not made any changes to

such document from the final draft provided to the other Party for signature unless the signing Party has expressly called such changes to the other Party's attention in writing (e.g., by "redlining" the document or by a comment memo or email).

IN WITNESS WHEREOF, the parties hereto have set their hand as of the Effective Date.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Scott Storer

Print Name: Scott Storer

Title: Chief Financial Officer

Facsimile: XXX

CONSULTANT:

/s/ Richard P. Shea

Print name: Richard P. Shea

## ATTACHMENT A

### 1. Services:

Consultant will provide consulting services in support of a range of Company's business objectives.

The scope of services may include, but are not limited to:

- Consult with the Chief Financial Officer (the "CFO") regarding investor relations, financial reporting, facilities and/or information technology matters.
- At the CFO's direction, consult with other Momenta employees regarding investor relations, financial reporting, facilities and/or information technology matters.
- Upon request, review and provide written comments to various documents, including, but not limited to, investor presentations, public disclosures and internal reports.
- Upon request, attend and participate in investor conferences, investor calls or other investor-related activities with the CFO and other Momenta employees.

Consultant will be available for consultation on a schedule and at such places as are determined by mutual arrangement between Scott Storer, the Company's Chief Financial Officer, to whom Consultant will report during the term of the Agreement, and Consultant. In addition, Consultant will be available for a reasonable number of telephone and/or written consultations.

### 2. Compensation and Expenses:

As compensation for the consulting services rendered under this Agreement, Company shall pay Consultant Two Hundred Dollars (\$200) per hour for such services actually rendered, not to exceed One Hundred Thousand Dollars (\$100,000) without Company's prior written consent. The parties agree that the compensation reflects the fair market value of the services rendered hereunder.

Company will reimburse Consultant for all reasonable travel and other expenses incurred by Consultant in rendering the consulting services, provided that such expenses are agreed upon in writing in advance and when confirmed by appropriate written expense statements and other supporting documentation.

In accordance with Section 2.1 of the Agreement, invoices should be sent to Momenta Pharmaceuticals, Inc., 675 West Kendall Street, Cambridge, MA 02142, Attention: Accounts Payable.

In addition, Company will pay Consultant One Hundred Fifty-Nine Thousand Eight Hundred Thirty Dollars (\$159,830), equal to 40% of Consultant's 2016 employee base salary (the "Bonus Payment"). Subject to Section 5.4 of the Agreement, the Bonus Payment will be paid on March 31, 2017.

### 3. Term:

The term of this Agreement will be for six (6) months, unless terminated earlier pursuant to Section 5 of the Agreement. The term shall begin on December 30, 2016.



**SUBSIDIARIES OF MOMENTA PHARMACEUTICALS, INC.**

**Name of Subsidiary**

Momenta Pharmaceuticals Securities Corporation

**Jurisdiction of  
Organization**

Massachusetts

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-209813, 333-188227, 333-163615, 333-161414, 333-140251, 333-126798 and 333-126356 and Form S-8 Nos. 333-212991, 333-206112, 333-197582, 333-190394, 333-179760, 333-172155, 333-164892, 333-157275, 333-149253, 333-140760 and 333-117173) of Momenta Pharmaceuticals, Inc. of our reports dated February 24, 2017, with respect to the consolidated financial statements of Momenta Pharmaceuticals, Inc., and the effectiveness of internal control over financial reporting of Momenta Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 24, 2017

## CERTIFICATIONS

I, Craig A. Wheeler, certify that:

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

Dated: February 24, 2017

/s/ CRAIG A. WHEELER

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Craig A. Wheeler  
President and Chief Executive Officer

## CERTIFICATIONS

I, Scott M. Storer, certify that:

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

/s/ SCOTT M. STORER

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Scott M. Storer

Senior Vice President and Chief Financial Officer

Dated: February 24, 2017

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

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Scott M. Storer, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

/s/ CRAIG A. WHEELER

Craig A. Wheeler  
President and Chief Executive Officer

Dated: February 24, 2017

/s/ SCOTT M. STORER

Scott M. Storer  
Senior Vice President and Chief Financial Officer

Dated: February 24, 2017